Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program

Human Research Protection Program Final Report
June 30, 2016
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EXECUTIVE SUMMARY

The University of Minnesota’s Human Research Protection Program (HRPP) was charged with the implementation of several significant and innovative changes to policies, practices, and procedures to enhance the protections of human participants in research. The HRPP was responsible for the following key components of the implementation work plan:

- Institutional Review Board (IRB) membership
- IRB review process
- Scientific review
- Monitoring of studies
- Research participants who have impaired or fluctuating capacity to consent

Sections 2 through 6 of this final report provide a summary of the activities completed or progress made to the adoption of the implementation work plan recommendations associated the key components listed above. Included in this report are relevant documents related to the recommendations.

Of note, throughout sections 2 through 6, there is reference to the HRPP Toolkit and implementation of an electronic submission system, Click. The Human Research Protection Program continues to make progress on the adoption of the HRPP Toolkit, a suite of IRB forms, policies, worksheets and review guides. The HRPP Toolkit has allowed the HRPP to create an infrastructure that supports the durable application of commitments and program enhancements related to the AHRP Implementation Workplan.
IRB Membership Final Report
June 30, 2016

Background and Purpose

Section 4 of the implementation plan addresses recommended changes to the structure and composition of the University's Institutional Review Board (IRB), promotion of the value of IRB service to departments and the institution, and facilitation of the use of central IRBs to review some types of research.

The IRB includes separate committees for Medical and Social/Behavioral Sciences. As the implementation plan and External Review report focused solely on recommended changes to the Medical committee, the information below is similarly limited in scope.

The following outlines the changes made by the Human Research Protection Program (HRPP) and IRB in response to the recommendations.

* The recommendations in the implementation plan reflect concerns in the following sections in the following External Review report sections: 3.2.1, 3.2.2, 3.2.3.

**Recommendation:** The U of M must promote measures to increase the value of service on the IRB.

**Response:** As part of the implementation plan, the University President, the Provost, the Vice President for Research, the academic deans and department chairs were charged with undertaking efforts to promote the value of IRB service in the contexts of tenure and promotion, commensurate with that recognized for service on a National Institutes of Health (NIH) study section.

HRPP staff provided OVPR and Academic Health Center (AHC) leadership with recommended strategies for recognition of service.

**Recommendation:** Increase the number of full IRB committees and limit the number of items on each agenda. Increase number of IRB members.

**Response:** As of early 2015, the University's IRB consisted of 4 separate committees: medical, faculty social/behavioral sciences, student social/behavioral sciences, and executive. In order to address stated concerns, steps were taken in March 2015 to limit the number of items for review on any given medical agenda to 20 items. In order to balance the impact of that cap, an additional monthly meeting was added as of July 2015, bringing the total number of monthly medical meetings to seven.

Initially, a new membership strategy was drafted and launched in early 2016 based on the specific recommendations made in the implementation plan. That plan provided for:

- 4 specialty-focused medical committees;
  - Vulnerable adult populations
  - Pediatrics
  - Adult hematology, oncology, transplant / cardiology / radiology
  - Genetics / Pharmacy / Surgery / Neurology / Endocrinology
- Each committee meeting weekly for a total of 16 meetings/month;
- 13 members per committee, with a quorum of 7;
- 52 total IRB members;
- compensation for all faculty and community members; and
- an expectation that each member attend 1 meeting per week (4/month).

The HRPP received substantial negative feedback regarding the proposed model. Both continuing and potential new members (internal and external to the organization) could not commit to attending four meetings per month and could not allocate the necessary time for preparation or conducting of expedited reviews. In addition, concern was expressed that...
bottlenecks in review turnaround times could occur if submission volumes exceeded agenda size for a particular specialty committee meeting. As such, a revised plan was developed to address these concerns while still being responsive to the recommendations outlined in the implementation plan.

The new model establishes eight distinct medical panels. Specialty representation is distributed across all eight panels and was determined based on relative submission volumes. Additional representation from other disciplines, nursing, vulnerable population work, and robust community representation round out the available expertise. Consultants will be utilized as needed to supplement member expertise.

The table, below, indicates required representation from specific departments/divisions (based on submission volume):

<table>
<thead>
<tr>
<th>Department/Division</th>
<th>Members</th>
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<tbody>
<tr>
<td>Hematology, Oncology and Transplantation (Hem Onc)</td>
<td>8</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>4</td>
</tr>
<tr>
<td>Pediatric Hematology/Oncology (Peds Hem)</td>
<td>4</td>
</tr>
<tr>
<td>Surgery</td>
<td>2</td>
</tr>
<tr>
<td>Cardiology</td>
<td>2</td>
</tr>
<tr>
<td>Pediatric Endocrinology (Peds Endo)</td>
<td>2</td>
</tr>
<tr>
<td>Neurology</td>
<td>2</td>
</tr>
<tr>
<td>Pediatric Blood and Marrow Transplantation (Peds BMT)</td>
<td>2</td>
</tr>
<tr>
<td>Pulmonology</td>
<td>2</td>
</tr>
<tr>
<td>Endocrinology (Endo)</td>
<td>2</td>
</tr>
<tr>
<td>MRI</td>
<td>2</td>
</tr>
<tr>
<td>Family Medicine (Fam Med)</td>
<td>2</td>
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Each of the eight panels will meet every other week, ensuring generally that sufficient expertise for review is available on no less than a weekly basis. Because meetings are scheduled on a rolling, every-other-week schedule, the average number of meetings per month will exceed the originally planned 16.

Each panel has eight members, bringing the total number of members to 64; meetings will have a quorum of 5.

Each meeting is scheduled for two hours and the number of items assigned per meeting will be closely monitored to maintain this commitment. It is anticipated agenda size will range between 8 and 12 items.

The first four panels will, after having completed training, begin meeting in July. The remaining four panels are being established and will begin meeting by September 2016.

Chairs of all eight panels will meet quarterly to discuss meeting management, committee education needs, and decision/discussion consistency.
Recommendation: Compensate IRB members.

Response: The University has committed to a generous compensation plan to promote and support faculty, staff and community member service on the IRB. The plan is streamlined to eliminate unnecessary complexity and reduce administrative burden. The upper limit for faculty compensation amounts will be based on the annual salary cap established by the National Institutes of Health (NIH).

All amounts paid are flat fees (i.e. not per meeting or review) and receipt is dependent upon satisfaction of the minimum meeting attendance requirements noted below.

For all members affiliated with the University, Fairview or Gillette (except employees of the IRB):

- Faculty members receive a 6% salary offset, up to the NIH cap, for a maximum payment of $11,106;
- Faculty chairs receive a 15% salary offset, up to the NIH cap, for a maximum payment of $27,765;
- Non-faculty members receive payment of $11,106;
- Non-faculty chairs receive payment of $27,765;
- Members designated as scientific reviewers receive an additional $1,000;
- Members designated as expedited reviewers receive an additional $1,000; and
- For University, Fairview and Gillette employees, all funds go to the department, not the individual.

For all members unaffiliated with the University, Fairview or Gillette:

- Members receive payment of $6,000; and
- Members designated as expedited reviewers receive an additional $1,000.

Recommendation: Establish requirements for attendance.

Response: All members will be required to attend 85% of scheduled meetings, or roughly 22 meetings per year. HRPP staff are responsible for tracking member attendance, providing real-time feedback and assisting members in resolving scheduling concerns.

Recommendation: Facilitate the use of central IRBs (CIRB) for human participant research.

Response: The University currently participates in a number of both single-study and multi-study reliance arrangements, including the National Cancer Institute Central IRB, StrokeNet and the Greater Plains Collaborative (GPC), supporting review of over 80 active research studies as of June 2016. Requests to cede review to another IRB are considered on a case by case basis.

The NIH released its Policy on the Use of a Single Institutional Review Board for Multi-Site Research in June 2016. It’s expected that final revisions to the Common Rule, anticipated in September 2016, will also include requirements for use of a single IRB under certain circumstances. In addition, there has been growing pressure for the University to facilitate the use of commercial IRBs for review of business and industry-sponsored, multi-site studies.

In January 2016, the HRPP hired a Reliance Agreements Administrator to assist with developing a robust, compliant infrastructure to process requests for the use of a central IRB and to ensure that compliance responsibilities which remain with the University are identified and managed appropriately. An agreement with Quorum IRB to facilitate review of business- and industry-sponsored, multi-site studies is being established.

Draft guidance articulating the circumstances under which use of a central IRB is acceptable is currently under discussion with OVPR and will be developed to align with published federal guidance and policy. Once finalized, HRPP staff will develop an appropriate communication and education strategy for the research community, as well as a supporting policy and other, internally facing documents consistent with the Huron Toolkit.

Relevant Documents:

- IRB Membership Revised Proposal (power point slide deck)
June 30, 2016

Background and Purpose
The Implementation team identified several issues related to the IRB protocol review process in response to the External Review and Legislative Auditor’s reports. The following outlines the changes made by the Human Research Protection Program (HRPP) and Institutional Review Board (IRB) in response to the Implementation team recommendations which covers the External Review report recommendations: 3.2.4, 3.2.5, 3.2.6, 3.2.7.

Overall comments regarding the recommendations
Committed to enhancing the IRB process, the HRPP launched the IRB Renew Project, which includes the adoption of the HRPP Toolkit and implementation of the Click electronic submission system. Adaptation and adoption of the HRPP Toolkit, a suite of IRB forms, policies, worksheets and review guides, will create an infrastructure that supports the durable application of commitments and program enhancements related to the AHRP implementation workplan. Implementation of the electronic submission system will enhance the IRB experience and reduce operational redundancies for IRB members, staff, and the research community.

The first phase of this project officially launched on January 4, 2016 and is complete. During that phase, IRB Renew Project team members worked closely with Huron Consulting and a small number of institutional stakeholders to gather and document the requirements of the U’s IRB and HRPP.

The second phase of the project launched on March 28, 2016. This phase consists of customization and implementation of the Huron Toolkit, redefining organizational structure, augmentation of staffing resources and training/mentoring of IRB staff and members on the effective utilization of new standard operating procedures, checklists, worksheets and training guides. The third and final phase, which will run concurrently with implementation of the Toolkit, will be configuration and launch of the online submission system with an anticipated launch date of March 2017.

Recommendation 1: Revise the format of the convened IRB meeting minutes to include a meaningful summary of the study, any controverted issues that are discussed, their resolution, and documentation to support the IRB’s rational for requesting modifications to a study.

Response: A new IRB meeting minutes template and meeting management process was established in September 2015. The new template and process more closely aligns practices for documenting controverted issues with regulatory requirements & accreditation standards. Adoption of the new process and template use was closely monitored and evaluated by the HRPP Post Approval Review staff. This monitoring of the process and template use continues as part of quality improvement activities. Post Approval Review developed standard operating procedures and an audit checklist for audit of IRB meeting minutes. Additional training around decision types (i.e. stipulations vs. deferral) and controverted issues was provided to the committees through the newsletter and during committee meeting discussions.

Recommendation 2: Consider whether certain actions may not warrant convened IRB review and therefore may not require discussion at the convened IRB meeting, freeing up time for the discussions of more complex and challenging protocols.

Response: A training plan was implemented to calibrate staff determinations for level of review and to identify actions that do not warrant a convened IRB review. The training plan is part of the larger initiative to adopt the Huron HRPP Toolkit and implementation of the electronic submission system for IRB review and management. The training plan involves close collaboration with the Huron Consulting Group and includes group training sessions and individual mentoring sessions.
Recommendation 3: Consider developing a system for evaluating the appropriate number of action items per convened meeting agenda with consideration of the expertise of those present and the planned length of the agendas.

Response: As of August 2015, HRPP established an additional monthly scheduled convened IRB meeting dedicated to reducing the number of items assigned for review at each meeting. Per the recommendations from the implementation work plan, the number of items on meeting agendas was capped to ensure adequate time for IRB member preparation and deliberation.

The HRPP conducted a survey of IRB members to evaluate workload and meetings. The results of the survey indicate the desired length of an IRB meeting to be no longer than 2 hours. This information was utilized in the development of the expanded medical IRB panels. As part of the transition to the expanded medical panels, the meeting management process will include an increase in convened IRB meetings to accommodate the volume. This includes an anticipated 8 to 12 review items per meeting agenda.

The HRPP conducted an evaluation of the committee’s expertise and types of submissions reviewed by the IRB in preparation for the adoption of expanded medical IRB panels and IRB membership. As a result of this evaluation, the expertise represented on the IRB has significantly expanded with the increase in membership. The increase in expertise allows the assignment of review items to correlate with the expertise represented on the panel.

Recommendation 4: Consider making arrangements for the University’s IRB staff to attend IRB meetings at peer institutions so as to better assess best practices and to determine ways in which the University’s IRB can be improved.

Response: IRB staff conducted a benchmarking visit in July 2015 visit to Penn State. Penn State was selected based on their recent adoption of the Huron Toolkit and electronic submission system. Penn State IRB leadership generously continue to provide guidance and support to the UMN IRB Renew Project.

Relevant Documents:
- Audit of IRB Meeting Minutes Standard Operating Procedures
- Audit Checklist for IRB Meeting Minutes
- IRB Minutes Template
- Description of the Huron Toolkit
Scientific Review of Studies Final Report  
June 30, 2016

Background and Purpose

The External Review raised concerns regarding departmental peer review, indicating a number of issues exists including a lack of appropriate expertise of the peer reviewers, a failure to follow appropriate conflict of interest guidelines for peer reviewers, lack of sufficient detail in the review documentation, violations of the policy requiring a minimum of two reviewers, and insufficient documentation in the IRB minutes that scientific review was adequately considered. The following outlines the changes made by the Human Research Protection Program (HRPP) in response to the Implementation team recommendations which covers the External Review report recommendations: 3.3.10, 3.3.11, 3.3.12, 3.3.13, 3.3.14, 3.3.15, 3.3.16.

Recommendation A: Eliminate Department Review

Response: In March of 2016, the option for departmental scientific review was eliminated as a satisfactory prerequisite for IRB review. A revised IRB Policy 904: Scientific Review and Resource Assessment was posted.

Recommendation B: Revise HRPP Managed Review Procedures

Response: IRB Policy 904:

Revised to remove reference to departmental review (method 3c) as an acceptable method for scientific assessment and expanded to include description of method 4 (HRPP Managed Scientific Assessment). Review by a biostatitian is a prerequisite for submission to the HRPP managed scientific review.

HRPP Managed Scientific Assessment Reviewers:

Scientific assessment is to be performed by a minimum of two independent peer reviewers. External reviewers will be solicited if appropriate expertise does not exist within the IRB membership. These experts will be reimbursed for their work on a per study basis and be asked to sign the Sheet-036 Expert Consult. Expert consultants are subject to the IRB Conflict of Interest Policy pertaining to IRB members.

Review assignments are performed by the HRPP Scientific Assessment Manager and based on reviewers’ expertise, availability, and the exclusion of conflict of interest. Reviewers must have appropriate expertise to understand the background, aims, and methods and to draw on the discipline’s standards for conducting research. Results of the review and recommendations noted by the reviewers are submitted to the HRPP Scientific Assessment Manager and forwarded anonymously to the investigator. Anonymous forwarding is intended to maintain a level of confidentiality and prevent bias in the assessment process.

HRPP scientific assessment reviewers and expert consultants, when engaged, are subject to the requirements of IRB Policy 202: Management of IRB Members and Consultant Conflict of Interest. Reviewers must have no real or perceived conflict of interest that would influence their work as a reviewer. Prior to the review, reviewers must assert they have no conflict of interest related to the study in question in accord with IRB Policy 202 policy:

A conflict of interest exists for a particular research protocol when an IRB panel member or consultant, or a family member of the IRB panel member or consultant:

1. Is an investigator or other member of the research team conducting the research;
2. Supervises an investigator on the protocol;
3. Holds a significant financial interest in the business entity sponsoring the research; and/or
4. Holds a business interest in the business entity sponsoring the research and the panel member has:
   a. A proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
   b. Any other interest the IRB member or consultant believes conflicts with the ability to objectively review the protocol.
5. Other circumstances that could pose a conflict of interest for a panel member or consultant include, but are not limited to:
   a. Holding a close personal relationship with an investigator;
   b. Participation in a potentially competing research program or study, and
   c. Personal biases that may interfere with the exercise of impartial judgment.

The above definition and procedure requiring scientific reviewers to assert that they have no conflict of interest were evaluated against work plan recommendations. The following slight deviations and resolutions are noted:

Work Plan Recommendation 6(B)(f):

Peer reviewers must have no real or perceived conflict of interest that would influence their work as reviewer. For the purpose of this review process, the definition of “conflict of interest” is, “Any situation that could cause a reasonable person with all the relevant facts to question the impartiality of the committee member or that leads a committee member to question his or her objectivity,” which is the definition used by NIH for reviewers participating in the review of NIH grant applications. Before reviewing the application, the reviewer must assert they have no conflict of interest related to the study in question.

Response: IRB Policy 202 includes a comprehensive definition and examples (noted above) of conflict of interest. This policy will be adhered to as part of the HRPP scientific review process.

Work Plan Recommendation 6(B)(g):

Subordinates may not serve as a peer reviewer for a study where their immediate superior is a named investigator. For example, faculty may not peer review a study of their department head.

Response: IRB Policy 202 identifies “supervises an investigator on the protocol” as a conflict of interest. Subordinates are not systematically excluded from the review of an immediate supervisor. However, the policy includes the statement that a conflict includes “personal biases that may interfere with the exercise of impartial judgment” and/or “holding a close personal relationship with an investigator” as examples of situations where recusal due to conflict is required. In addition, procedures for providing anonymous results of the scientific review to researchers creates an additional layer to prevent bias during the assessment process.

Work Plan Recommendation 6(B)(h):

Those who have collaborated on a study with the investigator during the previous 12 months may not serve as a peer reviewer.

Response: IRB Policy 202 identifies a conflict as “Is an investigator or other member of the research team conducting the research” and “Other circumstances that could pose a conflict of interest for a panel member or consultant include, but are not limited to: a. Holding a close personal relationship with an investigator; b. Participation in a potentially competing research program or study, and c. Personal biases that may interfere with the exercise of impartial judgment.” IRB policy does not restrict the timeframe for which a conflict would apply to 12 months.

Job Aids (Requester, Reviewer and Manager) have been revised to incorporate work plan recommendations. Clear instructions regarding how to conduct the review are included. HRPP Scientific Assessment Manager screens submissions for completeness and forwards review results submitted by the peer reviewers anonymously to the researcher. The submission process is conducted using the CTSI Portal. Investigators are provided with a job aid to facilitate their understanding of the submission, review and notification process. A goal of 10 days has been established for turnaroud times.

The Scientific Review Assessment Criteria and template was adjusted to address work plan recommendations.
Recommendation C: Revise IRB Panel Review Procedure

Response: Convened IRB review includes discussion and documentation of decisions related to the scientific assessment.

Recommendation D: Revise IRB Policy 904

Response: IRB Policy 904 was revised in accord with the above recommendations identified in sections A-C, above.

Relevant Documents:

- Scientific Review of Studies- Advancing Human Research Protections Final Report (5.2.16 version 2)
  - IRB Scientist Member: Review and Meeting Conduct Expectations (Implemented)
  - IRB Expert Consultants: Engagement and Review Expectations (Implemented)
  - Job Aid Scientific Assessment Manager (Implemented)
  - Form-Rev-Sheet-036_Expert Consult (Revision Required)
  - Scientific Assessment Template (Submitted to CTSI web developers)
  - Job Aid Scientific Assessment Requester (Submitted to CTSI web developers)
  - Job Aid Scientific Assessment Reviewer (Submitted to CTSI web developers)
  - IRB Minutes Template (Implemented)
  - IRB Policy 904: Scientific Review and Resource Assessment (Implemented)
  - HRPP Website Content (Pending*)

Cross Reference:

IRB Membership-Advancing Human Research Protections Final Report (Revisions Submitted to OVPR June 2016*)

IRB Policy 202: Management of IRB Members and Consultant Conflict of Interest (Implemented)
Monitoring of Studies Final Report
June 30, 2016

Background and Purpose
The Implementation team agreed that changes are required to increase the effectiveness of the post-approval monitoring program. The following information is a summary of the changes being made by the Human Research Protection Program (HRPP) in response to the Implementation team recommendations covering External Review report recommendations: 3.3.18, 3.3.19, 3.3.20, 3.3.21, 3.3.22, 3.3.23.

Recommendation 1: Increase and expand PAR monitoring
Response: PAR quality assurance reviews of investigator performance will include: reviews of greater than minimal risk biomedical and social and behavioral research; reviews of research that can be approved by expedited review; and reviews of exempt research. Studies will be selected for review employing a risk based strategy (including specific consideration of research conducted in Fairview patients or spaces).

CTSI clinical trial monitoring will be conducted on protocols under an IND or IDE held by a University faculty member serving as sponsor-investigator. CTSI/AHC plans to conduct quality assurance reviews at the time of study start-up and annually afterward (for studies with participants enrolled) on all greater than minimal risk biomedical research.

Office of Internal Audit evaluation of PAR QA reviews and the CTSI/AHC monitoring and QA program has been recommended to occur on no less than a bi-annual basis to apply (independent of OVPR or AHC) review of programs that evaluate the conduct of human research that is highest risk to research participants and the institution. Ideally, this review by the Office of Internal Audit would occur in approximately one year following this report.

Recommendation 2: Report PAR findings and IRB follow-up to department and school or college leadership
Response: Department heads will be copied on all correspondence to investigators undergoing on-site Post Approval Review;

Advisory groups will contribute to developing the communication plan for summary reports of findings and other activities. Principles of transparency in communicating results (negative and positive) and accountability (of recipients) in following through will be applied;

The Research Compliance Office (RCO) will receive no less than quarterly reports (for the previous quarter) at these intervals (July, October, January, April). The RCO will report to the following groups:

1. Academic leaders: department chairs, Dean of the Medical School, Counsel of Research Associate Deans (CRAD);
2. Research oversight groups: FUROC, OVPR Research Compliance Office, IRB; and

Prompt reporting to appropriate UMN authorities and research partners will occur if significant human subject protection issues are observed during completion of PAR reviews or if such issues are reported via existing confidential reporting lines.

Research deans, department chairs, center directors, and research partners will each bear responsibility for dissemination of this information to their respective communities. Fairview, UMP and Gillette should ensure that appropriate information about investigator performance is available to the clinical care community. Academic leadership will be held accountable for making sure corrective measures are instituted when investigator/research team performance is at issue.

Recommendation 3: Perform live consent monitoring
Response: PAR will perform live consent monitoring as one part of a comprehensive consent monitoring plan that will include both direct observation of the process as well as applying retrospective review strategies.

1. Direct Observation:
   a) IRB directed quality assurance review of high risk studies (e.g. subjects with diminished capacity) will be conducted in-person. A systematic process will be established and is intended to be supportive to the research team while facilitating an enhanced dialogue between the person obtaining consent and the participant and, when applicable, their legally authorized representative (LAR); and
   b) Review video-recorded consent discussions, when applicable, and provide feedback to investigators.

2. Retrospective Strategies:
   a) Conduct systematic evaluation of signed consent materials;
   b) Conduct post-consent interviews or administer questionnaires with research subjects using validated tools (e.g. Brief Informed Consent Evaluation Protocol (BICEP)); and
   c) Conduct evaluation of investigator submitted Report Form that include errors/deviations associated with the informed consent process.

Relevant Documents:
- Appendix A-Monitoring Plan
- PAR Policy 903
- PAR Website Link to Risk-Based Selection Table
- Executive Summary-Consent Auditing Pilot
- Retrospective Audit of Consent and HIPAA
- HRP-012-SOP
- Checklist for Consent Observation
- HRP-XXX-SOP: Recording Research Participants
- Permission to Record for Consent Observation
- Documentation of Consent Audit
- Report Template for Consent Auditing
- Consent Auditing - Metrics and Reporting Plan
- HRP-XXX-SOP: Post-Consent Interviews/Questionnaires
- Decision-making Matrix for Consent Auditing
Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent and Vulnerable Populations Final Report
June 30, 2016

Background and Purpose

Section 10 of the Advancing Human Research Protection implementation plan requires the following:

Policies, guidance, application and review forms, as well as the IRB review process should be reviewed and restructured for clarity and consistency to promote clear understanding and compliance with policies and procedures to assess and monitor capacity to consent. This review should align research participant screening or other protections with the degree of risk involved in a study or the level of risk of impairment in a targeted or enrolled population. This review should also promote strategies to enhance research participant decision-making, including the research participant’s ability to select a surrogate decision-maker in the event that the research participant loses decision making capacity during the course of the study.

The HRPP submitted a comprehensive suite of materials to fully address this charge and the specific recommendations listed in the implementation plan; those materials are attached to this Final Report. This document provides the linkage between those specific recommendations and the resulting Toolkit documents reflecting responsive policies and processes.

Communication to and education of the research community around these changes is underway and the Decision Making Capacity Consent Assessment Pilot has been initiated.

The implementation plan included the assertion that: “Best practices shall refer to all aspects of this policy. Essentially it refers to a ‘receptivity to considering new publications, research and peer models for amending all aspects of the use of human subjects insofar as such material is empirically validated and consonant with applicable laws and regulations.’ The HRPP has committed to reviewing and evaluating validated new information related to assessing capacity to consent and to incorporating new information, as appropriate, into policies, guidance or other tools. See HRP-060 - SOP - Annual HRPP Evaluations.

* The recommendations included in the implementation plan reflect concerns in the following External Review report sections: Capacity to Consent (3.4.1, 3.4.2, 3.4.3, 3.4.4), Vulnerability to Coercion (3.4.5, 3.4.6), Longitudinal Assessment of Capacity (3.4.7, 3.4.8), Legally Authorized Representatives (3.4.9, 3.4.10), and Use of Surrogate Consent (3.4.11, 3.4.12).

RESEARCH WITH HUMAN SUBJECTS WHO HAVE IMPAIRED OR FLUCTUATING CAPACITY TO CONSENT

Definitions: “Capacity to consent” has been defined under HRP-110 - POLICY - Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Participate in Research. Appropriate additional definitions will be included in HRP-001 - SOP - Definitions.

Recommendation:

Impaired consent capacity occurs in a wide range of conditions and disease states. The IRBs should inform investigators that impaired consent capacity is not limited to specific disorders. Consent capacity is task-specific both to the research proposal and to the complexity of decision-making required of the person considering consent to the study. Therefore, a judgment regarding an individual’s capacity to consent may not be the same for all research studies.

In many individuals, impaired consent capacity is not static. A research participant’s consent capacity may improve, deteriorate or fluctuate during the course of a research study. Study protocols and procedures should anticipated and address this phenomenon. Safeguards must in place prior to participant enrollment and, as appropriate, throughout the course of research participation.
Response: See HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research.

Recommendation:
The IRB may determine that research that includes individuals who lack consent capacity may be accepted for research under the conditions that the research is likely to benefit persons with impaired capacity who are similarly situated with regard to benefit from the medical knowledge to be gained by the research.

The IRB may accept that persons with mild impairments of decisional capacity (as defined by an instrument that has been validated for assessing the capacity to consent for research) and who assent to the research may consent to research that is minimal risk and eligible for expedited review.

The IRB may approve any instance of greater than minimal risk research that is likely to benefit persons with impaired capacity who are similarly situated with regard to benefit from the medical knowledge to be gained by the research provided such consent from persons with any decisional impairment results from the use a Legally Authorized Representative to consent and give ongoing consent for the subject.

Response: See HRP-013 SOP - Legally Authorized Representatives, Children, and Guardians; and HRP-417 Checklist - Cognitively Impaired Adults.

Recommendation:
IRB reviews should include a substantive assessment of the appropriateness of protocol-specific procedures addressing consent capacity in light of the subject population being approached.

Response: See HRP-417 Checklist - Cognitively Impaired Adults; and Appendix I - Populations with Additional Considerations.

Recommendation:
The IRB should devise means to verify decision-making capacity and to assess matters pertaining to vulnerability in all protocols.

Response: See HRP-090 SOP - Informed Consent Process for Research; HRP-417 Checklist - Cognitively Impaired Adults; and Appendix I - Populations with Additional Considerations.

Recommendation:
Adults who lack consent capacity may not be the subjects of research when the research can be performed with human subjects who possess consent capacity and the research is not directly relevant to investigating the disorder causing impaired consent capacity.

Response: See HRP-417 Checklist - Cognitively Impaired Adults.

Recommendation:
Studies involving minimal or greater than minimal risk but presenting the prospect of direct benefit to persons with impaired capacity may enroll adult subjects who lack consent capacity with at least the use of a Legally Authorized Representative and in some cases an additional consent auditor.

Response: See HRP-013 SOP - Legally Authorized Representatives, Children, and Guardians; HRP-417 Checklist - Cognitively Impaired Adults; and HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research.
Recommendation:
Investigators and research staff who obtain consent should consider every potential subject’s capacity to consent to the research. In studies where the recruitment of individuals with impaired consent capacity is not anticipated, the judgment that prospective participants have the capacity to consent to the research can ordinarily be made informally during routine interactions with the participant during the consent process.

Response: See HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research.

Recommendation:
The method used to assess capacity, and when appropriate, the documentation of this assessment, should be tailored to the study population, the level of risk, and the likelihood of the involvement of participants with impaired consent capacity.

Response: HRP-090 SOP - Informed Consent Process for Research; HRP-417 Checklist - Cognitively Impaired Adults; HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research; and Appendix I - Populations with Additional Considerations.

Recommendation:
Investigators and research staff responsible for the consent process and consent capacity determinations should be qualified and trained in the assessment of consent capacity, the difference between minimal risk and greater than minimal risk, the difference between competence and consent capacity and vulnerability, and the use of the chosen instrument used to assess consent capacity.

Response: See HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research; Decision Making Capacity Consent Assessment Pilot Proposal; and Appendix I - Populations with Additional Considerations.

Recommendation:
When it is anticipated that the research might include individuals who have impaired consent capacity, researchers should assess prospective participants’ consent capacity and determine whether it is adequate to permit informed consent. The Principal Investigator must propose the use of an instrument that has been validated for assessing the capacity to consent for research. This determination should be documented in the research proposal and its use documented in the subject’s personal research file.

Response: See HRP-090 SOP - Informed Consent Process for Research; HRP-091 SOP - Written Documentation of Consent; HRP-417 Checklist - Cognitively Impaired Adults; HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research; and Appendix I - Populations with Additional Considerations.

Recommendation:
When it is anticipated that the research might enroll persons whose capacity to consent or revoke consent during the study may become impaired, researchers should:

(a) Devise a consent capacity monitoring plan to last for the duration of the study. Re-assessment of consent capacity will be based on risk, initial consent capacity, and the likelihood that the consent capacity might change over time. The plan should describe the steps to be taken (e.g., either seeking a legally authorized representative or discontinuing the
subject from the study) if consent capacity is lost while a study is underway (Recommendation 3.4.7, 3.4.8.)

(b) If a patient with consent capacity, loses capacity during a study (and remains enrolled under the consent of an Legally Authorized Representative or a prospectively established Durable Power of Attorney for that study, then IRB policies should specify the requirement for a plan to secure that subject's re-consent (Recommendation 3.4.8.) The plan for this eventuality should be part of the original IRB proposal when fluctuations in consent capacity are expected to be common.

(c) Empower the subject to prospectively designate by a durable power of attorney a legally authorized representative to act in the event that consent capacity is lost during the study for that study only. Such delegation of authority may not be used for other research studies.

Response: See HRP-090 SOP - Informed Consent Process for Research; HRP-417 Checklist - Cognitively Impaired Adults; HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research; and Appendix I - Populations with Additional Considerations.

Recommendation:

(1) IRB will request that the consent process be witnessed and the form be completed by someone not associated with the research such as a UMP or Fairview nurse not associated with the research department or investigator.

(2) The IRB or the investigator may elect to have the consent interaction video recorded.

Response: See HRP-090 SOP - Informed Consent Process for Research; HRP-091 SOP - Written Documentation of Consent; HRP-417 Checklist - Cognitively Impaired Adults; Appendix I - Populations with Additional Considerations. The IRB will require that the consent process be witnessed and/or consent be obtained by someone not otherwise associated with the department or investigator if such additional protections are appropriate to the circumstances of the study and the population being invited to participate.

Recommendation:

When a subject is found to have possibly lost consent capacity (either by the prospective monitoring plan or as an incidental finding by the research team or the person’s treating clinician) a Legally Authorized Representative must be engaged to evaluate the study and to either consent or withdraw consent to participation

If the potential subject / participant revokes consent or assent at any time, then study participation is on hold. If the person reconsiders, there will be additional discussion with the advocate and a re-consent process

Response: See HRP-090 SOP - Informed Consent Process for Research; and Appendix I - Populations with Additional Considerations.

Recommendation:

Legally Authorized Representatives:

(1) Current policies 501, 506 and 703 should be reviewed and revised as needed.

(2) The IRB and HRPP will develop educational materials for LARs and investigators to explain the LAR role, authority, and considerations for making decisions. This might be placed on the IRB webpage includes “Guidance & FAQs” Adults Lacking Capacity or with Diminished Capacity to Consent http://www.irb.umn.edu/guidance/adults.html. This material shall also describe all relevant Federal Regulations to investigators.

(3) The investigator will be required to describe procedures that will be used to ensure the subject’s LAR understands his/her obligation to represent the prospective subjects interests or values in consenting to the study or in consenting to remain in the study while it is underway.
Response: See HRP-013 SOP - Legally Authorized Representatives, Children, and Guardians; HRP-090 SOP - Informed Consent Process for Research; HRP-091 SOP - Written Documentation of Consent; HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research; LAR Brochure.

Recommendation:
Consent Advocate.
(a) All potential subjects / participants will have access to an advocate at all times during Consent discussions. The plan for ensuring that the Advocate is made available will be identified in the IRB application review.
(b) Conflicts of interest for potential Advocates will be managed by the IRB. This may include a special panel of Advocates or possibly Ombudsmen or other options.
(c) The Consent Advocate should perform consent monitoring. When fully implemented, this might include: assisting investigators in finding and using validated instruments to assess capacity and obtain informed consent, memorializing the consent and monitoring the consent. Such a model would benefit from Continuous Quality Improvement.

Response: See HRP-417 Checklist - Cognitively Impaired Adults; and the Monitoring Plan final report included in this document. The IRB will require the presence of a consent advocate at the time of consent if such an additional protection is appropriate to the circumstances of the study and the population being invited to participate. All participants/potential participants are informed of resources available to them should they have questions or concerns regarding the study or their participation.

Relevant Documents:
- HRP-013 SOP - Legally Authorized Representatives, Children, and Guardians
- HRP-060 SOP - Annual HRPP Evaluations
- HRP-090 SOP - Informed Consent Process for Research
- HRP-091 SOP - Written Documentation of Consent
- HRP-417 Checklist - Cognitively Impaired Adults
- HRP-110 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults with Absent, Diminished or Fluctuating Capacity to Consent to Participate in Research
- HRP-111 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults Under Court Jurisdiction
- Decision Making Capacity Consent Assessment Pilot Proposal
- Appendix I - Populations with Additional Considerations
- LAR Brochure

RESEARCH WITH HUMAN SUBJECTS WHO ARE VULNERABLE TO COERCION OR EXPLOITATION
As Appendix I has been revised to focus exclusively on the previously discussed population, information about potentially vulnerable participants has been more appropriately moved into the body of the application. In addition, a policy on

Definitions: An expanded definition of vulnerability has been provided in Investigator Guidance: Research with Participants who are Vulnerable to Coercion or Exploitation Participating in Research. Appropriate additional definitions will be included in HRP-001 - SOP - Definitions.

Recommendation:
The IRB expects that principal investigators
(a) Will demonstrate awareness of the nature of the vulnerability of subjects in the trial under consideration.

(b) Will created procedures to avoid the coercion or exploitation of vulnerable persons including by: ensuring that each potential subject understands that participation is voluntary, that comparable health and social services will be available regardless of consent to participate in a clinical trial, that people in closed communities like schools, military units, prisons, or chronic care facilities for not knows who has and who has not consented to participate in research.

Response: HRP-111 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults Under Court Jurisdiction; Form-APP-009_Medical Application; and (as applicable) Appendix I – Adults Lacking Capacity to Consent or with Diminished or Fluctuating Capacity to Consent.

Recommendation:
The IRB will:

(a) Use internal reviewers (including consultants where necessary) who have the appropriate expertise to address the vulnerability of the subjects in the proposed studies.

(b) Ensure that there are safeguards to protect the rights and welfare of vulnerable potential research subjects.

(c) Record the nature of the vulnerability and any special protections required for human subjects in its minutes and in communications to the principal investigators.

Response: See HRP-314 – WORKSHEET – Criteria for Approval; and HRP-333 – WORKSHEET – Vulnerable Populations. General use of consultants is also addressed in HRP-051 - SOP - Consultation. Meeting minutes requirements are addressed in HRP-043 - SOP - Minutes.

Recommendation:
The IRB may:

(a) Recommend or require the use of “Independent Consent Monitors,” particularly when the treating physician is also the investigator, in order to minimize the possibility for undue influence or coercion.


In addition to the above work, existing policy was revised and expanded to establish appropriate restrictions, compliant with recent changes to Minnesota state law, to enrollment in research of individuals under subject to a commitment petition, temporarily confined involuntarily, or under court appointed guardianship. See: HRP-111 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults Under Court Jurisdiction

Relevant Documents:

- HRP-314 – WORKSHEET – Criteria for Approval
- HRP-333 – WORKSHEET – Vulnerable Populations
- HRP-111 - POLICY - UMN Investigator Guidance – Policy on Research Involving Adults Under Court Jurisdiction
- Appendix I – Adults Lacking Capacity to Consent or with Diminished or Fluctuating Capacity to Consent
- Form-APP-009_Medical Application
- UMN Investigator Guidance Vulnerable Populations
IRB Medical Committee Membership: Revised Proposal
Original Proposal

1. 4 specialty Medical committees
2. 13 members per committee (quorum is 7); total of 52 IRB members
3. Each committee meets once per week; total of 16 IRB meetings per month
4. Each meeting is capped at 2 hours duration
5. Each member attends 1 meeting per week; total attendance of 4 meetings per month
Challenges with Original Proposal

1. Potential and current IRB members cannot commit to attend 4 meetings per month

2. Potential and current IRB members cannot commit to participate for 8 hours of meeting time plus several hours per meeting for meeting preparation or for expedited review conduct

3. Bottlenecks could occur if submission volume exceeds agenda size for a particular specialty committee
Revised Proposal

1. 8 Medical panels
2. 8 members per panel (quorum is 5); total of 64 members
3. 4 panels meet per week; each panel meets every other week; minimum of 16 IRB meetings per month
4. Each meeting will be approximately 2 hours in duration
5. Each member attends 1 meeting every other week
6. Each member will be required to attend approximately 85% of scheduled meetings (=22 meetings/year)
### Work Proposal Considerations

<table>
<thead>
<tr>
<th>Problem Identified in Work Proposal</th>
<th>How Revised Proposal Addresses Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are insufficient numbers of medical board meetings to manage the volume of full committee reviews</td>
<td>Number of medical board meetings continues to be the same as the original proposal; also provides a scalable model to adjust the number of meetings in the future as needed</td>
</tr>
<tr>
<td>There are insufficient numbers of medical committee members present at meetings to manage the volume of reviews</td>
<td>Still increases the number of meetings and will decrease the current volume on each meeting agenda; the number of members proposed to attend each meeting is appropriate to manage the meeting volume (approximately 8-12 meetings/month)</td>
</tr>
<tr>
<td>There are insufficient numbers of medical committee members on the roster to meet the needs of meeting attendance, expertise and volumes of review</td>
<td>Still increases number of members on the roster (original proposal was 52; revised proposal increases to 64)</td>
</tr>
<tr>
<td>Problem Identified in Work Proposal</td>
<td>How Revised Proposal Addresses Problem</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>The rolling roster was criticized for lack of continuity, consistency or sustained attention to systemic issues</td>
<td>Membership is consistent across panels; each member attends the same panel meeting every other week</td>
</tr>
<tr>
<td>The general expertise of the IRB membership did not correlate with the topics and volume of research protocol submissions</td>
<td>Membership still correlates with topics and volume of research; expertise in different areas will be available at each meeting or at least once per week; the HRPP Toolkit will support IRB staff to evaluate and make appropriate assignments to meetings based on needed expertise</td>
</tr>
<tr>
<td>There should be consideration of compensation and alternate incentives (release from teaching time, reduction of other responsibilities, consideration during promotion) to foster and support qualified member participation</td>
<td>Members will receive compensation</td>
</tr>
</tbody>
</table>
# Specialty Representation

<table>
<thead>
<tr>
<th>Department/Division</th>
<th>Original</th>
<th>Revised</th>
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<tbody>
<tr>
<td>Hematology, Oncology and Transplantation (Hem Onc)</td>
<td>5</td>
<td>8</td>
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<tr>
<td>Psychiatry</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Pediatric Hematology/Oncology (Peds Hem)</td>
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<td>4</td>
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<tr>
<td>Surgery</td>
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<tr>
<td>Cardiology</td>
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</tr>
<tr>
<td>Pediatric Endocrinology (Peds Endo)</td>
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<tr>
<td>Neurology</td>
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<td>2</td>
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<tr>
<td>Pediatric Blood and Marrow Transplantation (Peds BMT)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Pulmonology</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Endocrinology (Endo)</td>
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<td>2</td>
</tr>
<tr>
<td>MRI</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Family Medicine (Fam Med)</td>
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<td>2</td>
</tr>
</tbody>
</table>
Operational Considerations

• An important factor to the success of any IRB model is adequate and appropriate support from IRB staff.
• The HRPP Toolkit will provide SOPs and other tools to guide IRB staff to enhance pre-review of submissions prior to scheduling for IRB review, assignment to panels and reviewers with appropriate expertise, and communication/documentation for consistency and transparency.
• The IRB Renew Project includes plans for substantial training and mentoring of IRB staff and members to ensure SOPs, review guides, worksheets and checklists are understood and implemented as designed.
Eliminate IRB Executive Committee

- Eliminate the monthly executive committee to reduce burden on panel chairs.
- Replace with new committee, meeting quarterly:
  - Chairs/vice chairs meeting focused on education, meeting management concerns, new/emerging issues related to review of research
Revise and streamline Compensation Plan

- Modify compensation plan to reflect reduced commitment (fewer meetings for members and chairs = less % effort)
- Streamline compensation scheme to eliminate complexity and reduce administrative burden.
Comparison of Plans by Time and Compensation

<table>
<thead>
<tr>
<th></th>
<th>Original Plan - Per Member</th>
<th>Original Plan - Per Chair</th>
<th>New Plan - Per Member</th>
<th>New Plan - Per Chair</th>
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<td>Percent time in hours</td>
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<td>510.5</td>
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<tr>
<td>Required # of meetings</td>
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<td>44</td>
<td>22</td>
<td>26</td>
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<tr>
<td>Prep + meeting time/mtg in hours</td>
<td>6</td>
<td>11.60227273</td>
<td>6</td>
<td>11.6</td>
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<tr>
<td>Scientific Assessment</td>
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<tr>
<td>Expedited Review</td>
<td></td>
<td></td>
<td>$1,000.00</td>
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</tbody>
</table>
1. BACKGROUND INFORMATION

1.1 IRB minutes are evidence of IRB performance and serve to provide a summary of what occurred during a convened meeting. Minutes also serve to document the IRB’s findings and determinations. Minutes should be documented in sufficient detail to permit verification that the IRB made determinations in compliance with applicable regulations.

1.2 Systematic audit of IRB minutes was initiated following the 2015 AAHRPP Accreditation process which resulted in a determination of “Reaccreditation Pending” due to standards not met as identified in AAHRPP’s final site visit report. As IRB minutes are a key indicator of IRB performance. Evaluation of minutes by the PAR program will permit ongoing monitoring for compliance and trends.

2. PURPOSE

2.1 This procedure establishes the process to review IRB minutes.
2.2 This procedure occurs monthly and/or at frequencies determined by HRPP leadership and/or in response to AAHRPP reaccreditation requirements (e.g. 3, 6, 9 & 12 months).
2.3 This procedure ends when evaluations are completed and corrective actions implemented.

3. POLICY

3.1 The goals of this quality improvement plan are to maintain compliance with governing regulations, IRB policy and AAHRPP reaccreditation standards. While a primary rationale for implementation of these assessments is related to corrective actions in response to AAHRPP’s findings, this effort also meets the PAR program goals related to quality improvement and will continue as part of ongoing program enhancements.

3.2 Objectives of the quality improvement plan are to:

3.2.1 Verify compliance of IRB review and minutes recording practices in accord with regulatory and AAHRPP standards.
3.2.2 Improve the quality and efficiency of HRPP processes related to the recording and finalization of minutes.

3.3. The measures used to assess the quality of minutes include verification that regulatory requirements are included and elements outlined in SOP HRP-108 SOP Minutes. These include:

3.3.1 Verification that an appropriate quorum is established (e.g. inclusion of non-scientist, member expertise, etc).
3.3.2 Content and accuracy of the minutes cover letter
3.3.3 Inclusion of required determinations and protocol specific findings
3.3.4 Documentation of IRB actions
3.3.5 Inclusion of the basis for requiring changes or disapproving research
3.3.6 Summary of the discussion of controverted issues and resolution
3.3.7 For initial and continuing review, the approval period
3.3.8 The follow up actions taken by HRPP staff.
3.3.9 Corrective actions implemented in accord with AAHRPP reaccreditation requirements and the implementation work plan: IND/IDE validation, completion of substantive review at continuing review, appropriate documentation of
controverted issues, IRB review of non-compliance, convened IRB review of substantive clarifications and modifications, and member expertise.

4. RESPONSIBILITY

4.1. PAR team members carry out these procedures.

5. PROCEDURE

5.1. Obtain final draft minutes following convened IRB review from Research Compliance Supervisor.
5.2. Systematically review each minutes sheet using Minutes Audit Checklist.
5.3. Examine results for adverse trends.
5.4. Summarize findings in cover sheet including recommended corrective actions, when applicable. Distribute cover sheet and audit sheets to key personnel (e.g. Assistant Directors) for consideration of interventions.
5.5. When applicable, attach addendum to final minutes that documents revisions/clarifications implemented as a result of the audit.
5.6. Prepare a summary of audit results for inclusion in the PAR Monthly Tasks Report (HRP-142 SOP Monthly Tasks Report). Describe significant trends (e.g. common observations) and planned interventions. When necessary, work with key personnel to document corrective actions for adverse trends.

6. MATERIALS

6.1. Minutes Audit Checklist
6.2. Minutes Template

7. REFERENCES

7.1. AAHRPP Tip Sheet 3: Documenting Discussions and Decisions on Research Studies and Activities
7.2. OHRP& FDA Draft Guidance November 2015: Minutes of IRB Meetings: Guidance for Institutions and IRBs
7.3. 45 CFR 46.115 & 21 CFR 56.115
## Minutes Audit

### Meeting Cover Sheet

<table>
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<tr>
<th><strong>Meeting date; IRB committee</strong></th>
<th>Yes</th>
<th>Missing</th>
<th>N/A</th>
<th>Comments</th>
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### Members Present

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Member Status</th>
<th>Attendance by Teleconference</th>
</tr>
</thead>
</table>

**Statement that IRB members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.**

### Others present—non-voting

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
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### Voting Members in Attendance for Specific Study(s)

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Specific research study</th>
<th>Rationale for attendance</th>
<th>Duration of attendance</th>
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### Meeting Information

<table>
<thead>
<tr>
<th>Total number of regular members on the current IRB roster</th>
<th>Number of members required for quorum</th>
<th>Time meeting called to order</th>
<th>Time meeting adjourned</th>
</tr>
</thead>
</table>

### Notes

**A summary of items unrelated to specific research**

### Voting Key

<table>
<thead>
<tr>
<th>For</th>
<th>Against</th>
<th>Abstain</th>
<th>Absent (non-COI)</th>
<th>Recused (COI)</th>
<th>Non-Voting</th>
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### Revised: December 10, 2015
### Individual Protocols

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<th>Submission Type</th>
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<tr>
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<tr>
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<td>☐ Report</td>
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<tr>
<td>☐ R2D</td>
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</tr>
</tbody>
</table>

| Title            |     |         |     |          |
| PI              |     |         |     |          |
| IRB number       |     |         |     |          |
| Reviewer         |     |         |     |          |

| Safety Monitoring or N/A |     |         |     |          |
| Funding type or N/A     |     |         |     |          |
| IND or IDE number or N/A |     |         |     |          |

### Submission Description

1. Summary of previous actions or N/A
2. Consultant report or N/A
3. Scientific assessment requirement was met by, or N/A
4. Scientific assessment committee determination
   - ☐ Accepted
   - ☐ Not accepted, justification provided
   - ☐ Pending
5. Controverted issues & resolution, or None
6. Discussion Notes or None
7. Risk assessment or N/A
8. Regulatory determinations and protocol-specific findings or N/A
9. NSR/SR determination or N/A
10. Approval interval or N/A
11. Motion
   - ☐ Apv
   - ☐ Cond Apv
   - ☐ Defer
   - Rationale
   - If deferred, disapproved, suspended, or terminated
   - Required modifications
   - Rationale for required modifications
12. Vote
   - Number Present at mtg _______
   - Number voting _______
   - For Number
   - Against Number
   - Abstain Number
   - Absent Number, Name
   - Recused Number, Name (COI)
   - Quorum maintained
Members Present at Meeting

<table>
<thead>
<tr>
<th>Name</th>
<th>Role(^1)</th>
<th>Member Status(^2)</th>
<th>Attendance by Teleconference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair</td>
<td>Choose an item.</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Choose an item.</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>Choose an item.</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

IRB members present by teleconference (when applicable) received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

Others Present or Voting Members in Attendance for Specific Study(s)\(^3\)

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
</table>

Meeting Information

<table>
<thead>
<tr>
<th>Total number of regular members on the current IRB roster:</th>
<th>Number of members required for quorum:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time meeting called to order:</td>
<td>Time meeting adjourned:</td>
</tr>
</tbody>
</table>

Notes\(^4\)

Items on this agenda were not necessarily reviewed in the order in which they appear.

A non-scientist member was in attendance during the discussion and vote of all action items on this convened IRB agenda.

Voting Key

\(^1\) For example: chair, vice-chair, non-affiliated member, regulatory specialist, member, prisoner representative

\(^2\) For example: physician scientist, other scientist, non-scientist

\(^3\) List individuals present and role of these individuals if in attendance at any time during the meeting. Indicate the role of each person listed, for example: HRPP staff support, HRPP staff observing meeting, IND/IDE expert for all new applications involving a drug or device, PI in attendance to address questions re HSC#, reviewer for HSC#.... If an individual serves as a voting member, identify the specific research study(s), rationale for and duration of attendance (e.g. “Attended meeting only for the review of HSC#... because of his/her expertise in XYZ.” Ad hoc substitutions for regular or alternate IRB members is not permitted.

\(^4\) Record here a summary of any meeting notes or discussion items unrelated to the review of specific research.
- “For”: Voting for the motion.
- “Against”: Voting against the motion
- “Abstain”: Present for the vote, but not voting “For” or “Against”
- “Absent”: Name of member not present for reasons other than a conflicting interest (members in attendance at the meeting, but absent from the room for the vote)
- “Recused”: Name of member not present for discussion and voting due to a conflicting interest
- “Non-Voting”: Present at the meeting but not in voting status
<table>
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<tr>
<th>Submission type:</th>
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<tr>
<td>Title:</td>
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<td>Principal investigator:</td>
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<td>IRB number:</td>
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<td>Reviewer:</td>
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<tr>
<td>Safety monitoring:</td>
<td>N/A for this review</td>
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<td>Funding type:</td>
<td>N/A for this review</td>
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<tr>
<td>IND or IDE number, if any:</td>
<td>N/A for this review</td>
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<tr>
<td>Submission description:</td>
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1. Summary of previous actions: N/A for this review
2. External consultant report: N/A for this review
3. Scientific Assessment Requirement Met by: N/A for this review
4. Scientific Assessment IRB Determination:
   - □ Accepted
   - □ Not Accepted, provide justification:
   - □ Pending
5. Controverted issues and their resolution, if any: "None" if none
   None
6. Discussion notes¹: "None" if none
   None
7. Risk assessment: Choose an item.
8. Regulatory determinations and protocol-specific findings: N/A for this review
9. NSR/SR determination: N/A for this review
10. Approval interval: N/A for this review
11. Motion: Choose an item.
   <delete this table if not defer, disapprove, suspend, terminate>
   Rationale defer/disapprove/suspend/terminate:
   <delete this table if no stipulations>
   Required modifications and rationale:
12. Vote:

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¹ Documentation of relevant points of discussion not captured elsewhere
Research involving children as subjects that involves no greater than minimal risk 45 CFR §46.404; 21 CFR §50.51

<table>
<thead>
<tr>
<th>No greater than minimal risk to children is presented</th>
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<tbody>
<tr>
<td>☑ Yes, because…</td>
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Adequate provisions for soliciting the permission of parents or guardian 45 CFR §46.408(b); 21 CFR §50.55(e)

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<tr>
<td>☐ Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child</td>
</tr>
<tr>
<td>☐ The permission of one parent is sufficient even if one parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child</td>
</tr>
<tr>
<td>☐ Parental permission is waived per 45 CFR §46.116(d); 21 CFR §50.55(d)</td>
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Adequate provisions for soliciting the assent of the children 45 CFR §46.408(a); 21 CFR §50.55

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<tr>
<td>☐ Assent is required of all children</td>
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<tr>
<td>☐ Assent is required of all children determined by the investigator to be capable of assent</td>
</tr>
<tr>
<td>☐ Assent is required of none of the children because the capability of the children is so limited that they cannot reasonably be consulted</td>
</tr>
<tr>
<td>☐ Assent is required of none of the children because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research</td>
</tr>
<tr>
<td>☐ Assent is required of none of the children because assent is waived per 45 CFR §46.116(d); 21 CFR §50.55(d)</td>
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<tr>
<th>Select one (if applicable):</th>
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<tr>
<td>☐ Assent will be documented using a written form for all children aged ____ years or older</td>
</tr>
<tr>
<td>☐ Assent will be documented by the investigator on the consent document</td>
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</table>

Research involving children as subjects that involves greater than minimal risk, but with a prospect of direct benefit to the individual subjects 45 CFR §46.405; 21 CFR §50.52

<table>
<thead>
<tr>
<th>The research involves procedures that present greater than minimal risk to children</th>
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<tbody>
<tr>
<td>☑ Yes, because…</td>
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</table>

The research procedures that present greater than minimal risk to children hold out the prospect of direct benefit for the individual subject or are likely to contribute to the subject’s well-being

| ☑ Yes, because… |

The risk is justified by the anticipated benefit to the subjects

| ☑ Yes, because… |

The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches
Yes, because…

Adequate provisions for soliciting the permission of parents or guardian 45 CFR §46.408(b); 21 CFR §50.55(e)

Select one:

- Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child
- The permission of one parent is sufficient even if one parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child

If the referenced study requires consideration of a waiver of parental permission, refer to the following section: “Waiver of parental permission when permission is not a reasonable requirement 45 CFR §46.408(c)”

Adequate provisions for soliciting the assent of the children 45 CFR §46.408(a); 21 CFR §50.55

Select one:

- Assent is required of all children
- Assent is required of all children determined by the investigator to be capable of assent
- Assent is required of none of the children because the capability of the children is so limited that they cannot reasonably be consulted
- Assent is required of none of the children because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research

Select one (if applicable):

- Assent will be documented using a written form for all children aged ____ years or older
- Assent will be documented by the investigator on the consent document

Research involving children as subjects that involves greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition 45 CFR §46.406; 21 CFR §50.53

The research involves procedures that present greater than minimal risk to children

Yes, because…

The research procedures that present greater than minimal risk to children do not hold out the prospect of direct benefit for the individual subject and are not likely to contribute to the subject’s well-being

Yes, because…

The intervention or procedure is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition

Yes, because…
The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations

Yes, because...

Adequate provisions for soliciting the permission of parents or guardian 45 CFR §46.408(b); 21 CFR §50.55(c)

Select one:

☐ Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child

If the referenced study requires consideration of a waiver of parental permission, refer to the following section: “Waiver of parental permission when permission is not a reasonable requirement 45 CFR §46.408(c).”

Adequate provisions for soliciting the assent of the children 45 CFR §46.408(a); 21 CFR §50.55

Select one:

☐ Assent is required of all children

☐ Assent is required of all children determined by the investigator to be capable of assent

☐ Assent is required of none of the children because the capability the children is so limited that they cannot reasonably be consulted

Select one (if applicable):

☐ Assent will be documented using a written form for all children aged ____ years or older

☐ Assent will be documented by the investigator on the consent document

Research involving children as subjects that is not otherwise approvable 45 CFR §46.407; 21 CFR §50.54

The research does not meet the requirements of 45 CFR §46.404, 46.405, 46.406; 21 CFR 50.51, 50.52, 50.53

Yes, because...

The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children

Yes, because...

An applicable official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, has determined either that the research in fact meets the conditions of 45 CFR §46.404, 46.405, 46.406, or 21 CFR 50.51, 50.52, 50.53

- The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
- The research will be conducted in accordance with sound ethical principles
- Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians
## Non-significant risk device 21 CFR §812.3(m)

- ☐ The device is NOT intended as an implant and does not present a potential for serious risk to the health, safety, or welfare of a subject
- ☐ The device is NOT purposed or represented to be for a use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject
- ☐ The device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a subject
- ☐ The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject

## Waiver of written documentation of consent for confidentiality risk 45 CFR §46.117(c)(1)

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality

- ☐ Yes, because…

Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern

- ☐ Yes, because…

- ☐ The research is not FDA-regulated

- ☐ The investigator has provided a written statement regarding the research that embodies the elements of consent per 45 CFR §46.116; 21 CFR §50.25

Select one:
- ☐ The investigator must provide subjects with that written statement
- ☐ The investigator does not have to provide subjects with that written statement

## Waiver of written documentation of consent for research involving no more than minimal risk to subjects 45 CFR §46.117(c)(2) and 21 CFR §56.109(c)(1)

The research presents no more than minimal risk to subjects and the research involves no procedures for which written consent is normally required outside of the research context

- ☐ Yes, because…

- ☐ The investigator has provided a written statement regarding the research that embodies the elements of consent per 45 CFR §46.116; 21 CFR §50.25

Select one:
- ☐ The investigator must provide subjects with that written statement
- ☐ The investigator does not have to provide subjects with that written statement

## Waiver of assent for research involving no more than minimal risk to subjects 45 CFR §46.116(d) and 45 CFR §46.408

The research involves no more than minimal risk to the subjects

- ☐
The waiver or alteration will not adversely affect the rights and welfare of the subjects

Yes, because…

The research could not practicably be carried out without the waiver or alteration

Yes, because…

Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Yes, because…

**Waiver of parental permission when permission is not a reasonable requirement 45 CFR §46.408(c)**

The research protocol involves children as subjects and is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects

Yes, because…

An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted

Yes, because…

The waiver is not inconsistent with Federal, State, or local law

Yes, because…

The following statements must also be true:

The research is not FDA-regulated

The research does not involve experimental subjects as defined by DOD, unless a waiver is obtained from the Assistant Secretary of DOD for Research and Engineering

**Waiver of consent or permission for research involving no more than minimal risk to subjects 45 CFR §46.116(d)**

The research involves no more than minimal risk to the subjects

Yes, because…

The waiver or alteration will not adversely affect the rights and welfare of the subjects

Yes, because…

The research could not practicably be carried out without the waiver or alteration

Yes, because…

Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Yes, because…

The following statements must also be true:

The research is not FDA-regulated

The research does not involve experimental subjects as defined by DOD, unless a waiver is obtained from the Assistant Secretary of DOD for Research and Engineering

The research does not involve nonviable neonates as subjects
Research involving prisoners as subjects 45 CFR §46 Subpart C

The research under review represents one of the categories:

- ☐ Study of the possible causes, effects, and processes of incarceration, and of criminal behavior that present no more than minimal risk and no more than inconvenience to the subjects
- ☐ Study of prisons as institutional structures or of prisoners as incarcerated persons that present no more than minimal risk and no more than inconvenience to the subjects
- ☐ Research on conditions particularly affecting prisoners as a class
  - ☐ If the study is subject to DHS, DOD, or VA regulation, the study will not proceed until an applicable official has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research
- ☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or wellbeing of the subject
  - ☐ If the study is subject to DHS, DOD, or VA regulation and requires the assignment of prisoners to control groups which may not benefit from the research, the study will not proceed until an applicable official has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research
- ☐ Epidemiologic studies where prisoners are not a particular focus of the research in which the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and the study presents no more than minimal risk and no more than inconvenience to prisoners who are subjects

The following statements must be true:

- ☐ Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired

- ☐ The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers

- ☐ Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners

Select one (if applicable):

- ☐ Control subjects will be selected randomly from the available prisoners who meet the characteristics needed for the research; or
☐ The principal investigator has provided written justification for following other procedures for selection of control subjects

☐ The information is presented in language which is understandable to the subject population

☐ Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole

☐ Each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole

☐ If the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing subjects of this fact

### Research involving incidental prisoners as subject that is not subject to regulation

- The research is not subject to DHS, HHS, or VA regulations
- The rights and well-being of the subject are not in jeopardy
- The subject can continue to consent to participate
- The subject is capable of meeting the research protocol requirements
- The terms of the subject’s confinement does not inhibit the ethical conduct of the research
- There are no other significant issues preventing the research from continuing as approved
- A prisoner representative or a subject matter expert having the expertise of a prisoner representative has been consulted
- Approval is limited to the individual subject and does not allow recruitment of prisoners as subjects

### Approvable research involving incidental prisoners as subjects that is subject to regulation

- The research will be subject to review and approved by a qualified IRB under 45 CFR §46 Subpart C

### Non-approvable research involving incidental prisoners as subjects that is subject to regulation

- The federal agency has been consulted and approves continuation of the subject in the research

### Research involving pregnant women as subjects that involves no more than minimal risk to subjects and is not subject to regulation

- The research presents no more than minimal risk to subjects
- The research is not subject to DHS, EPA, HHS, or VA regulation

### Research involving pregnant women or fetuses that involves greater than minimal risk or is subject to regulation 45 CFR §46.204

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Revised: May 26, 2016
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses

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<td>One of the following is true:</td>
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Select one:

- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus
- The risk to the fetus is not greater than minimal risk and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means <add for DHS, EPA, HHS, or VA research> and the important knowledge is important biomedical knowledge

- Any risk is the least possible for achieving the objectives of the research

Consent of the mother is obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR 50.27

If the research holds out the prospect of direct benefit solely to the fetus, the consent of the father (in addition to the mother) is obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR 50.27, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest

Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate

For children who are pregnant, assent and permission are obtained and documented in accord with 45 CFR §46.408, 21 CFR §50.55

No inducements, monetary or otherwise, will be offered to terminate a pregnancy

Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy

Individuals engaged in the research will have no part in determining the viability of a neonate

Research involving pregnant women or fetuses that is not otherwise approvable 45 CFR §46.207

The research does not meet the above requirements
The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.

An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required.

### Research involving neonates of uncertain viability as subjects 45 CFR §46.205

Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

Individuals engaged in the research will have no part in determining the viability of a neonate.

One of the following is true:

- [ ] The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective.
- [ ] The purpose of the research is the development of important knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.
  - [ ] For DHS, EPA, HHS, or VA research, the important knowledge is important biomedical knowledge.

Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

The consent of either parent or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s LAR is obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR 50.27, except that the consent of the father or his LAR need not be obtained if the pregnancy resulted from rape or incest.

### Research involving neonates of uncertain viability as subjects that is not otherwise approvable 45 CFR §46.207

The research does not meet the above requirements.
The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates

An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required.

### Research involving nonviable neonates as subjects 45 CFR §46.205

Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates

- Individuals engaged in the research will have no part in determining the viability of a neonate
- Vital functions of the neonate will not be artificially maintained
- The research will not terminate the heartbeat or respiration of the neonate
- There will be no added risk to the neonate resulting from the research
- The purpose of the research is the development of important knowledge that cannot be obtained by other means
  - For DHS, EPA, HHS, or VA research data, the important knowledge is important biomedical knowledge
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate
- The consent of both parents of the neonate is obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR 50.27 , unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest
- Consent will not be obtained from a LAR
- There is no waiver or alteration of the consent process
Research involving nonviable neonates as subjects that is not otherwise approvable 45 CFR §46.207

| The research does not meet the above requirements |
| The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates |
| An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or, neonates, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required. |

Research involving wards as subjects involving the first two categories of research involving children 45 CFR §46.409; 21 CFR §50.56

The research meets the criteria in Section 1 or 2 of "CHECKLIST: Children (HRP-310)"

Provisions for soliciting the assent of the children and the permission of their parents or guardians meet the criteria in Sections 4 and 5 of "CHECKLIST: Children (HRP-310)"

Research involving wards as subjects involving the last two categories of research involving children 45 CFR §46.409; 21 CFR §50.56

One of the following is true:
- The research is related to the subject's status as wards
- The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards

An advocate has been appointed for each child who is a ward

Each advocate has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research

Each advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization

Emergency research consent waiver 21 CFR §50.24; 45 CFR §46.116 and 45 CFR §46.117, Waiver of informed consent requirements in certain emergency research

The subjects are in a life-threatening situation
Available treatments are unproven or unsatisfactory

1. The collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions

2. Obtaining informed consent is not feasible because **all of the following are true:**
   - The subjects will not be able to give their informed consent as a result of their medical condition
   - The intervention must be administered before consent from the subjects’ LARs is feasible
   - There is no reasonable way to identify prospectively the individuals likely to become eligible for participation

3. Participation in the research holds out the prospect of direct benefit to the subjects because **all of the following are true:**
   - Subjects are facing a life-threatening situation that necessitates intervention
   - Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects
   - Risks are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity

4. The research could not practicably be carried out without the waiver

5. The proposed research defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact an LAR for each subject within that window of time and, if feasible, to asking the LAR contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact LARs and make this information available to the IRB at the time of continuing review

6. When feasible consent of subjects or LARs will be obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR 50.27

7. Additional protections of the rights and welfare of the subjects will be provided, including all of the following:
   - Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn
Public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits

Public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results

Establishment of an independent data monitoring committee to oversee the research

If obtaining informed consent is not feasible and an LAR is not reasonably available, the investigator has committed, if feasible, to attempt to contact within the therapeutic window the subject’s family member who is not an LAR, and asking whether he or she objects to the subject’s participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review

Procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, LAR of the subject, or if such LAR is not reasonably available, a family member, of the subject’s inclusion in the research, the details of the research and other information contained in the informed consent document

There is a procedure to inform the subject, or if the subject remains incapacitated, LAR of the subject, or if such LAR is not reasonably available, a family member, that he or she may discontinue the subject’s participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

If an LAR or family member is told about the research and the subject’s condition improves, the subject is also to be informed as soon as feasible

If a subject is entered into research with waived consent and the subject dies before an LAR or family member can be contacted, information about the research is to be provided to the subject’s LAR or family member, if feasible

A licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation concurs with the above findings

Indicate which of the following is true:

☐ The research is FDA-regulated and meets the requirements of 21 CFR §50.24

☐ The research is not FDA-regulated and meets the requirements of the 45 CFR §46 Waiver of informed consent requirements in certain emergency research

☐ The research is regulated by a federal department or agency other than HHS or FDA, and the department or agency Secretary has issued a waiver

FDA-regulated emergency research consent waiver 21 CFR §50.24
The protocol is performed under a separate IND or IDE that clearly identifies such protocols as protocols that may include subjects who are unable to consent

<table>
<thead>
<tr>
<th><strong>HHS-regulated emergency research consent waiver</strong></th>
<th><strong>45 CFR §46.101(i) Waiver of informed consent requirements in certain emergency research</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The research does not involve prisoners as subjects</td>
<td></td>
</tr>
<tr>
<td>The research does not involve fetuses, pregnant women, and human in vitro fertilization</td>
<td></td>
</tr>
</tbody>
</table>

**FDA Enforcement Discretion for Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable**

| The research is not regulated by a federal department or agency other than FDA |
| The IRB has reviewed the sponsor's written documentation regarding the collection and distribution of specimens and associated data, including the policies and procedures followed by the specimen provider to ensure that the subject cannot be identified |
| The research meets the criteria for approval per 45 CFR §46.111 and 21 CFR §56.111 |
| The research meets the IDE exemption criteria at 21 CFR 812.2(c)(3) |

- The research uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded, use specimens obtained from specimen repositories, or uses leftover specimens that were previously collected for other research purposes

- The specimens may be accompanied by clinical information as long as this information does not make the specimen source identifiable to the investigator or any other individual associated with the research, including the sponsor

- The individuals caring for the patients are different from and do not share information about the patient with those conducting the research

- The specimens are provided to the investigator(s) without identifiers

- The supplier of the specimens has established policies and procedures to prevent the release of personal information
UMN HRPP Toolkit Overview

UMN is in the process of implementing Huron’s HRPP Toolkit to support its HRPP and IRB operations. The HRPP Toolkit is a set of documents for use and reference primarily by IRB staff, IRB committee members and investigator, and to a lesser extent, by other HRPP components.

The HRPP Toolkit was designed with the following concepts in mind:
- Maximum regulatory flexibility consistent with compliant procedures;
- Easy to follow, non-redundant procedures;
- Focus on business process and IRB workflow; and
- Use of documents to support consistent IRB applications and reviews.

The basic components of the HRPP Toolkit consist of:

- **HRPP Plan**
  - Overview of HRPP components, scope, etc.
- **Investigator Manual**
  - Researcher facing
  - Since the UMN Investigator Manual is in the process of being created, the revised/new documents, HRP-110 - Policy - Capacity to Consent, HRP-111 - Policy - Involuntary Hold and UMN Investigator Guidance Vulnerable Participants, were created to address the immediate need per the “Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program” Work Plan
  - Will eventually incorporate investigator guidance documents and policies
- **Standard Operating Procedures (SOPs)**
  - Include policy statements
  - Organized by business process (e.g., pre-review, review, post-review) rather than by topic (e.g., continuing review, drugs, and protocol deviations)
  - Cross-reference worksheets and checklists to be used; does not duplicate information
- **Worksheets**
  - Regulatory decision making that does not need to be documented
  - Used in review to support decision making but does not need to be completed and kept in the regulatory file
  - Includes worksheets for topics such as payments, advertisements, vulnerable populations, etc.
  - Used by IRB staff and committee reviewers; accessible to researchers for reference
- **Checklists**
  - Regulatory decision making that must be documented
  - Need to be completed and kept in the regulatory file
  - Includes checklists for topics such as research with children (Subpart D), prisoners (Subpart C), cognitively impaired adults, etc.
  - Used by IRB staff and committee reviewers; accessible to researchers for reference
- **Template protocols and informed consent forms**
  - Researcher facing
  - Provides guidance in the templates for researchers to provide information the IRB needs to evaluate criteria for approval
- **Template letters/reminders**
  - Most are focused on researcher correspondence (e.g. approval letters)
University of Minnesota

Scientific Review of Studies

Advancing Human Research Protections

Leads: Michelle Biros, MD, MS, & Joanne Billings, MD, MPH
Work Plan Section: Scientific Review

Lead(s): Michelle Biros & Joanne Billings  
Date: 12/23/2015

Proposal

Issue

What is the issue/problem? (Define this based on the external review panel’s observations and the implementation team’s translation of the problem)

1. Independent peer review is required to ensure the scientific worthiness of a proposed study. Studies funded by most external sources (NIH, foundations) are scientifically vetted before funding. Other studies do not undergo this same degree of unbiased scrutiny.

2. While some studies submitted to the IRB are reviewed by specific scientific panels with known expertise (CTSI, Cancer Center), many investigator initiated studies often undergo departmental review.

3. Departmental review may be superficial; have no standard method; be subject to real and/or perceived conflict of interest; be done by reviewers with insufficient expertise or by department members who may be supervisors or subordinates of the investigator.

4. Conflict of interest is variably defined.

Who plays a role in the current process? (This is can be taken directly out of the implementation team actions plans.)

Investigators, departments/ divisions, IRB leadership and staff, IRB members

Who is impacted by this issue/problem? (This is can be taken directly out of the implementation team actions plans.)

Investigators, departments/divisions, IRB members and leadership, human participants

Proposed Work Scope

Describe the proposed work necessary to address the issue outlined above.
Be detailed in your description and focus on practical actions, particularly those that could feasibly be undertaken by a responsible University Unit.

1. Eliminate departmental scientific review of research studies submitted to the IRB.

2. Incorporate pre-submission scientific review into the duties of IRB members with appropriate clinical and scientific expertise.
   a) Please see the attached documents: IRB membership Work Proposal, IRB Scientist Member Review and Meeting Conduct Expectations, and Job Aid Scientific Assessment-Manager.
   b) For HRPP assisted scientific review, the review will be performed by a minimum of two independent peer reviewers prior to convened IRB review of any new biomedical application that includes greater than minimal risk. See “Assigning Reviewers” section of Job Aid Scientific Assessment-Manager.

3. If appropriate scientific expertise does not exist within the IRB membership, solicit external reviewers (who have no affiliation with the investigator) and reimburse them for their work.
   a) Please see the attached document: FORM-REV-SHEET-036_Expert Consult related to inclusion of Expert Consultants.
   b) Reimbursement will be an agreed upon fee per study, as applicable.
   c) External reviewers will provide evidence of their expertise (e.g. CV, publications, etc) prior to formal agreement to review. See Expert Consult Form.
   d) External reviewers must affirm that they have no COI with the investigator or study sponsor, using a standard check-list that defines circumstances of conflict. See Expert Consult Form.

4. Develop a standardized reviewer template to ensure adequate and consistent scientific review.
   a) Please see the attached documents: Scientific Assessment Template and Job Aid Scientific Assessment Requester.
   b) Criteria were determined in consultation with existing panels currently involved in evaluation of research studies. Additional modifications may be required during initiation of these new processes.
   c) Researchers will be prompted to submit specific materials and information to facilitate completion of the scientific assessment. These materials include, but are not limited to, the protocol, biostatistician information, and PI Information.
   d) Once the review is complete, results of the review and recommendations of the reviewers will be submitted to the HRPP Scientific Assessment Manager and forwarded anonymously to the investigator.
e) Final approval for scientific assessment, once granted, is forwarded to the IRB and the investigator.

5. Develop criteria that can be applied by the scientific reviewers to determine which studies should undergo additional statistical review prior to IRB submission.

   a) Please see the attached documents: Job Aid Scientific Assessment Reviewer.
   b) All submissions require confirmation of the name, contact information and credentials of the biostatistician. If a scientific reviewer requires additional statistical review prior to accepting the project, the Scientific Assessment Manager will obtain detailed information from the reviewer to facilitate identification of an appropriate expert.
   c) If statistical expertise does not exist among IRB members or an external reviewer, statistical consultation will be solicited and reviewers will be reimbursed for their work on a per study basis.

6. Upon reviewing the study, the IRB will document and describe the scientific review and any concerns arising from the review. This discussion will be reflected in the IRB meeting minutes.

   a) Please see the attached document: IRB Minutes Template (questions 3 & 4).

7. IRB policy 904, HRPP website content, and Clinical Translational Research Portal will be revised to reflect these changes.

   a) Please see the attached documents: IRB Policy 904 and HRPP website content.
   b) The Clinical Translational Research (CTR) Portal of the CTSI will be modified to reflect changes noted above and enhancements to facilitate reviewers’ use of the electronic tool.
   c) Ongoing dialogue with OIT and CTSI during implementation of changes to the CTR will occur to facilitate implementation of changes in the scientific review process and anticipated efforts related to metrics identified in the work plan.

What other personnel or other resources are needed to make the plan work? (include expertise)

Support from departmental and medical school leadership; consultation of experts to develop statistical and review guidelines; financial support to reimburse external and statistical scientific reviewers.

Define the estimate timeline by major deliverable:

Review the post-report activities work plan section for the proposed timeline and based on that list the major expected outcomes.

This plan requires and depends on the revision being proposed for the IRB membership since it will draw from the expertise of the membership, which will include scientific review as a membership responsibility. It is anticipated this will occur over the next 6 months.
Simultaneous to this, the requirements needed to implement the scientific review working plan will be completed.

<table>
<thead>
<tr>
<th>Does this plan require the identification of additional resources?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Resources could include money, equipment, space and personnel.</strong></td>
</tr>
<tr>
<td>☒ Yes.  ☐ No  ☐ I don’t know</td>
</tr>
<tr>
<td>If yes, describe: external reviewers and statistical consultants, as needed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Does this plan require permissions or expertise from outside the University to fully implement it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ Yes.  ☐ No  ☐ I don’t know</td>
</tr>
<tr>
<td>If yes, describe: External reviewers may be solicited form outside the University as needed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What challenges or barriers do you anticipate may be encountered during implementation? (These aren’t deal breakers, but instead help us estimate time and energy needed)</th>
</tr>
</thead>
</table>
| Departments may feel this plan is not needed and therefore resist.  
Finding appropriate scientific reviewers may take time; this may add time to the turnaround of the entire IRB study review. |
Work Proposal Section 2 Attachments

1) IRB Membership Work Proposal (See Key Documents Section of AHRP Website)
2) IRB Scientist Member: Review and Meeting Conduct Expectations
3) IRB Expert Consultants: Engagement and Review Expectations
4) Job Aid Scientific Assessment Manager
IRB Scientist¹ Committee Member: Review and Meeting Conduct Expectations

**PURPOSE:** To describe the expectations, role and qualifications of IRB Scientist members serving the University of Minnesota IRB review of Human Research. Wide ranging scientific or scholarly expertise among IRB members allows the IRB to review the broad variety of research in which UMN investigators are engaged.

**QUALIFICATIONS:** Will have the professional scientific experience and competence necessary to review the specific research activities presented for IRB review (e.g. Physician, nurses, etc). Experience in research and/or the critical assessment of research (e.g. peer reviewed journals). Training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline. High moral code and interest in research ethics. Should have effective knowledge of subject populations and other factors that can foreseeably contribute to a determination of a risk-benefit ratio. Practical and timely when given tasks.

**STATUS:** Maintain awareness of representative member capacity as Scientist¹. When necessary, serve as an alternate for any comparably qualified member (e.g. Scientist Member can alternate for a Scientist member) on any other UMN IRB panel.

Scientist members are expected to review assigned studies, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. Scientist members will be required to complete scientific reviews when assigned by the HRPP staff.

These members are able to advise the IRB when additional expertise in a scientific area is required to assess whether a research project plan will adequately protect the rights and welfare of subjects.

**AFFILIATION:** Non-affiliated² members are expected to provide input regarding their individual knowledge about the local community and be willing to discuss issues and research

Version Date: September 2015

1.) Scientist IRB Member: Members whose training, background, and occupation would include them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline. Scientist IRB members are professionally conversant with the scientific method (either by virtue of advanced training or by current occupation in scientific fields) and who might thus be included to view a research protocol primarily from the viewpoint of a scientist. *(45CFR46.107(c), 21CFR56.107(c), & SACHRP January 24, 2011 letter)*  

2.) Non-Affiliated: Members who are not otherwise affiliated with the UMN, Fairview, or Gillette and who are not part of the immediate family of a person who is affiliated with the aforementioned institutions. *(45CFR46.107(c), 21CFR56.107(c))
from that perspective. A non-affiliated member is also a scientist\textsuperscript{2} or non-scientist\textsuperscript{3} member and
would be expected to provide input on areas germane to his/her knowledge, expertise and
experience, professional and otherwise.

**CONFLICTS OF INTEREST:** All IRB members are to know the definition of Conflict of
Interest (COI). No IRB member may participate in any review (including discussion or voting)
in which he or she has a COI, except to provide information requested by the IRB.

When reviewing an item, each IRB member is to consider whether he or she has a COI, and if so,
to self-identify that COI.

**ATTENDANCE & TERM:** Attend 65\% of all scheduled meetings of the assigned committee.
Prompt notification to HRPP staff of a pending absence from assigned committee is expected.
IRB membership is set at three (3) year, renewable terms.

**TRAINING:** Complete all required training in a timely manner and report completion to HRPP
staff.

**CONFIDENTIALITY:** All IRB members are to treat all oral and written information obtained
as part of the review process as confidential. IRB members must not disclose or use confidential
information without prior authorization.

**COMPENSATION:** The UMN IRB adheres to Federal Guidance when recognizing the critical
work performed by IRB members. In order to avoid real or perceived conflicts of interest, no
IRB member may be paid more than reasonable compensation or receive more than reasonable
benefits for IRB-related activities; and no IRB member may receive compensation or benefits
under arrangements that could impede or discourage objective decision-making on behalf of
human participants.

**Committee Review Procedures**

All IRB members are to review regulatory requirements and, when acting as primary reviewer,
complete applicable checklists for each submission. The IRB must determine that federal criteria
for IRB approval are met prior to approving each research protocol/plan.

The guiding ethical principles outlined in the Belmont Report of respect for persons (autonomy),
beneficence, and justice must be considered when conducting each review

IRB members are responsible for reviewing every agenda item assigned to their allotted meeting
and for notifying HRPP staff to request additional information (e.g. entire study file) if needed.

**Primary Reviewer Responsibility:**
The primary reviewer for each submission leads the discussion for the studies on which he or she is assigned. They are expected to fill out applicable checklists with preliminary judgments as to whether each criterion for approval is met and provide preliminary study-specific findings justifying determinations.

The primary reviewer also reviews all submitted materials for consistency with the materials reviewed by all IRB members, including the following when they exist:

- The complete application including any previously approved protocol modifications
- Investigator brochure
- Current protocol
- HHS grant application, HHS approved protocol & HHS-approved template consent document interventions
- Consent materials, including recruitment materials
- HIPAA Authorization and/or request for HIPAA Waiver
- Any additional materials relevant to IRB review

During the presentation of the submission, the primary reviewer:

- Confirms an individual(s) with scientific/scholarly expertise performed a scientific/scholarly review, when applicable
- Reviews relevant findings of regulatory review and regulatory review contingencies.
- For a review related to an Unanticipated Problem Involving Risks to Participants or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, or Termination of IRB Approval, leads the IRB members through a discussion of the Report Form Review Sheet.
- Leads the IRB through a discussion of the criteria in applicable worksheets.
- When a checklist is applicable, discusses the checklist determinations and study-specific findings supporting those determinations.
- Summarize the IRB’s consensus

**Initial Review**: In advance of the meeting, all IRB members are to review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:

- Initial application form(s)
- Sections of the protocol relevant to the criteria.
- Consent document(s) and script(s), when they exist
- Recruitment materials, when they exist

**Modifications to Protocols**: In advance of the meeting, all IRB members are to review the modification, determine which criteria in applicable worksheets and checklists are affected, and
review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:

- Protocol
- Previously approved modifications not reflected in the current protocol, or a summary thereof
- Consent document(s) and script(s), when they exist
- Recruitment materials, when they exist

**Continuing Review:** In advance of the meeting, all IRB members review continuing review progress report and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:

- Protocol
- Previously approved modifications not reflected in the current protocol, or a summary thereof
- Consent document(s) and script(s), when they exist
- New consent document(s) and script(s), when they exist
- Recruitment materials, when they exist

**New Information:** In advance of the meeting, all IRB members review the new information and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the relevant sections of the following materials to a depth sufficient to determine as necessary whether affected criteria are met:

- Protocol
- Previously submitted modifications or a summary thereof
- Consent document(s) and script(s), when they exist
- Written reports of consultants, when they exist

**Special Considerations:**

- If the research involves prisoners as participants, the prisoner representative reviews the submitted information to determine whether criteria in IRB Policy 501C (Requirements for Research Involving Prisoners) are met, be present when the research is reviewed, and provide a review either orally or in writing.
- As required by federal regulations and/or UMN Policy, apply additional safeguards when reviewing research involving: pregnant women, human fetuses, or neonates; prisoners; children, and individuals with impaired consent capacity.
- All IRB members review written reports of consultants, if any.
IRB Expert Consultants: Engagement and Review Expectations

**PURPOSE:** As set forth in 45 CFR 46.107(f) and 21 CFR 56.107(f), the IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. The purpose of this document is to describe the expectations and role of expert consultants who may be called upon to assist the IRB during review of human participants research.

**QUALIFICATIONS:** Professional scientific experience and competence necessary to review the specific research activities presented. Experience in research and/or the critical assessment of research (e.g. reviewer for peer review journals). High moral code and interest in research ethics.

**IRB Scientist Member Review Expectations:**

**Role:** Provide expert review of research to facilitate the IRB’s evaluation of the Criteria for IRB Approval.

**Confidentiality:** Expert consultants are to treat all oral and written information obtained as part of the review process as confidential. Consultants must not disclose or use confidential information without prior written authorization.

**Conflicts of Interest:** Consultants are subject to the IRB Conflict of Interest Policy pertaining to IRB members.

**Availability:** Potential expert consultants are an available resource to the IRB and will be called upon on an as needed or when IRB members lack the expertise needed in the scientific area of concern.

**Review Expectations:** If the consultant agrees to review the protocol and the consultant has no conflicting interest, s/he is provided with all relevant information available to the IRB in order to perform an in-depth review of the research. The consultant will understand the background, aims and methods of the research. Consultants are asked to attend the IRB meeting to present their findings relative to the scientific merits of the study and risks and benefits to participants, and to answer questions. However, if the consultant is unavailable to attend the meeting, s/he may provide written comments for distribution to the IRB members in attendance. Consultants are not voting members of the IRB.

Version Date: September 2015
Scientific Assessment Manager

Job aid to document how to access, assign and manage projects submitted for scientific assessment.

Accessing Project Information
Click the link provided in the email -https://ctsi.ahc.umn.edu/portal/ and log in to the portal. Hover over the toolkit link and select “Review Request Services Forms”

The “Review Request Services Forms” link will take you to the reviewer dashboard. An example of the dashboard is below. Clicking the “Submitted,” “In Review” or “Completed” header (example circled below) allows you to choose to what displays below. In the example below projects “In Review” display and projects with the status “Submitted” or “Completed” are hidden.

Review each new submission to confirm that all required information has been entered. Submissions absent these items cannot be forwarded for review. Required information includes:

- Indication of whether the project involves the use of an FDA-regulated product (found on the Requested Services tab)
• Name, contact information and credentials of the biostatistician who assisted with the development of this project. The requester may provide the sponsor/agency contact who can verify biostatistician involvement if this is a business/industry sponsor. (found on the Requested Services tab)
• Upload of the required document(s) on the Documents tab. The required document type will vary dependent upon whether the project involves the use of an FDA-regulated product. The General Protocol Template is required for submission of non-FDA regulated projects (available on IRB Forms page). Research projects that include use of an FDA-regulated product will be asked to provide a GCP compliant protocol and product information (e.g. Investigator’s Brochure, packet insert, Device Manual). The IND (Drugs) Protocol Template and IDE (Devices) Protocol Template are available on the IRB Forms page as a resource for researchers.
• PI’s CV or Biosketch, or PI information to permit preliminary assessment of qualifications.

Make sure to test the uploaded documents for usability. For ease of review, you may need to download, save and reload some documents that present difficulty in downloading (e.g. PDFs with large file size may be easier to download if converted to reduced-size PDF files). If any documents cannot be downloaded, contact the researcher to correct this issue.

Once all information and documents have been confirmed as present and able to be downloaded, the submission is ready to be assigned to reviewers.
Assigning Reviewers
Each submission will be assigned to two reviewers. Assignments are based on reviewers’ expertise, availability, and exclusion of previously recorded conflict of Interest. Note: If an assigned reviewer identifies a conflict of interest after the assignment has been made or other rationale for inability to review, they will be able to indicate this through the CTR Portal and the submission will need to be re-assigned to a different reviewer.

To assign reviewers, click on the submission in the reviewer dashboard. Once open, click the “Assign Reviewers” button in the upper left.

A separate window will pop up listing all personnel who are able to perform scientific assessment. Locate the most appropriate reviewer and use the “Add as” drop down menu on the right to select “Reviewer.” Do this for both people being assigned. Then click the “Save Assignees” button at the bottom.
You will then be brought directly back to the main reviewer dashboard. You may confirm that the personnel assigned as reviewers are correct by checking through the Decision History tab on the submission.

There is one more step that needs to be performed to complete the assignment. In the submission dashboard, click the “More Actions” drop down and change the status to “In Review.” The following email will automatically be sent through hrpp@umn.edu to both reviewers, providing notification of assignment and directions on accessing the materials.

**Email Text Notification to Reviewer:**
You have been assigned a request for scientific assessment that is ready for your review.

Log-in with your X.500 credentials at https://samplelink.ahc.umn.edu/portal/app/index.cfm/requests/list and navigate to the Review Request Services Forms by following these steps:

- Hover over Toolkit link in top menu
- Click Review Request Services Forms
- Requests that have been assigned to you will be listed

As a reminder the HRPP pledges to deliver a prompt response which requires reviewers to note their response within 7 business days. We ask that you notify the HRPP within 48 hours if you are unable to complete this review.

The following scientific assessment questions must be considered during review of the project:

1) Is the scientific question reasonable?
- The question is precisely articulated.
- The research has the potential to provide new and useful knowledge.
- The rationale for the proposed research is supported by the literature/background in the protocol.

2) Will the methods described in the protocol answer that question?

- Research tests and procedures are appropriate to answer the scientific question.
- The proposed research measures are valid and reliable or there are methods proposed to establish validity and reliability.
- The proposed subject population is appropriate.
- The sample size calculation appears valid and will answer the research question.
- The principal investigator is qualified to conduct the research.

If you have any questions respond to this email or call 612-626-5654

Update Tracking
Once assignment is complete, fill in the following information on the tracking spreadsheet for tracking purposes:

- CTR Portal ID#
- Researcher/requester
- Date of submission to CTR Portal
- Date submission assigned to reviewers
- Date reviews are due (7 days after assignment)
- Assigned reviewer names

The remainder of the fields in the spreadsheet will/may be used later as the process progresses.

Monitoring Reviews
Continue to monitor the CTR Portal (and hrpp@umn.edu emails as needed) daily for changes in the submission status and for determinations made by reviewers. The reviewer determinations and status of reviews can be found on the “Decision History” tab of the project in the CTR Portal. (Note: ‘Not Initiated’ indicates that the reviewer has not begun their review process yet. If it is close to the due date, this status may indicate a problem with communication of assignment.)

Reminder to Reviewers
If a determination for a reviewer(s) has not been recorded in the CTR Portal by 5 days after assignment, send a reminder email to the reviewer in question (see template).

Communicating Outcomes
Reviewer determinations are recorded under the “Decision History” tab of the project in the CTR Portal. Projects can receive one of two determinations -
'Accepted' or 'Not Accepted'. The following actions should be taken regarding the indicated determination:

- **‘Accepted’** – This means the reviewer has stated that the project is scientifically valid as submitted. If both reviewers indicate this determination, the project is considered ‘accepted as submitted’ and the project status should be changed from "In Review" to "Complete," per the same process as listed above under directions for assignment. The Tracking spreadsheet should also be updated with the applicable information.

  This determination can now be communicated in a templated letter, sent via email, to the researcher/regulatory staff/preparer listed under the ‘Project Information’ tab on the project in CTR Portal.

- **‘Not Accepted’** – This indicates that the reviewer has stated that the project is not acceptable as submitted and requires further information or revisions to meet the standards. The notes following this determination under ‘Required Revisions?’ (circled in red below) should indicate what issues must be addressed in order to accept the project as scientifically valid. The project will therefore remain under the “In Review” status until all stipulated issues are resolved.

  This resolution of issues will require the HRPP Scientific Assessment Manager to act as facilitator for communication between the reviewer and the researcher. This is done by crafting a templated letter stipulating the
issues/requirements identified by the reviewer and emailing it directly to the researcher/regulatory staff/preparer. The Manager should also fill in the applicable information in the Tracking spreadsheet.

*Note: To maintain a level of confidentiality and prevent bias in the assessment process, the reviewers' identity should not be shared directly with the researcher, unless specifically indicated to do so by the reviewer. Reviewers are free to contact the researcher directly, however, if they so choose.*

Researchers are given 10 business days from the date of notification of stipulations to respond. If a response is not received by that time, the submission may be dismissed.

When a response to stipulations is received from the researcher, the Manager will forward it on to the reviewer who posed the stipulations. At that point, the reviewer will have 7 days to review and confirm in the CTR Portal whether the response is ‘Accepted’ or ‘Not Accepted,’ requiring further stipulations to be addressed. If the response is ‘Not Accepted,’ the Manager will repeat the cycle until all issues have been sufficiently addressed to the reviewer’s satisfaction and accepted.

Once both reviewers have indicated that the project is accepted as scientifically valid, refer to the instructions indicated above for submissions that are ‘Accepted.’

All letters should be saved in the appropriate folder under S:\HRPP\Scientific Assessment documentation\Letters to PI. All emails should be sent from the hrpp@umn.edu email address.
Work Proposal Section 3 Attachment

1) Form-Rev-Sheet-036_Expert Consult
Application information:

PI Name: 
HSC#: 
Date: 

Expert Consultation requested: 
Consultant name: 
Indication of consultant expertise: 
Please indicate any specific questions/concerns to be addressed: 

Confidentiality Statement

The University of Minnesota treats research proposals, protocols and all supporting materials confidentially. A protocol normally is considered proprietary to the principal investigator. Further, a protocol may contain data that are proprietary to the sponsor, which the University is contractually obligated to keep confidential. Information shared with you is for consultation purposes only. Please check the box below acknowledging you will keep these materials shared with you confidential.

☐ I agree to keep all IRB materials shared with me confidential.

Expert Consultation

Do you have a conflict of interest that prohibits you from providing an unbiased evaluation? Examples of conflicts include:

- Is an investigator or other member of the research team conducting the research;
- Supervises or is supervised by an investigator on the protocol;
- Holds a significant financial interest in the business entity sponsoring the research; and/or
- Holds a business interest in the business entity sponsoring the research and the panel member has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
- any other interest the IRB member or consultant believes conflicts with the ability to objectively review the protocol.

☐ I DO NOT HAVE A CONFLICT OF INTEREST TO DECLARE.
☐ I RECUSE MYSELF FROM REVIEW OF THIS PROJECT BASED ON A CONFLICT OF INTEREST.

Describe any concerns you may have with the scientific validity of research design?

A key consideration of IRB review is the appropriateness of risk in relation to expected benefit. Benefits may be individual or societal. Please provide the committee with your evaluation of the anticipated risk associated with the proposed research.
Work Proposal Section 4 Attachments

1) Scientific Assessment Template
2) Job Aid Scientific Assessment Requester
Scientific Assessment Questions

1). Is the scientific question reasonable?

   The question is precisely articulated.

   The research has the potential to provide new and useful knowledge.

   The rationale for the proposed research is supported by the literature/background provided in the protocol.

2). Will the methods described in the protocol answer that question?

   Research tests and procedures are appropriate to answer the scientific question.

   The proposed research measures are valid and reliable or there are methods proposed to establish validity and reliability.

   The proposed subject population is appropriate.

   The sample size calculation appears valid and will answer the research question.

   The principal investigator is qualified to conduct the research.
Job Aid - Request for HRPP Scientific Assessment

Public Request Form Documentation

Identify or create the project in the CTR Portal

Log in to the CTR portal at https://ctsi.ahc.umn.edu/portal/requests/hrpp/

Select the project for which you are requesting HRPP scientific assessment. Projects you are associated with will be listed automatically. If the project is not in the list you may search for the project using the name of the investigator or keywords that appear in the title.

If the project does not exist in the CTR portal, click the register the project link.

Registering a New Project

If it is necessary to register the project you will be taken to a form to collect basic information about the project. This will include a list of associated users and a description of the project. Once the project registration form is completed it will automatically route back to the scientific assessment form.

Once the desired project has been identified, click the blue Select button and confirm your choice. Clicking the Select button will initiate the request process.

An email will be sent to the requester, key contacts, and the investigators noted on the project. The email will contain a link that can be used to return to the request form should it need to be completed it later.
Required Information when Requesting HRPP Scientific Assessment

The information you are required to provide includes the following:

- Indicate if the project involves the use of an FDA-regulated product (this includes both those products that have FDA approval and those that are still considered investigational).
- Provide the name, contact information and credentials of a biostatistician who assisted with the development of this project. If the project is business/industry sponsored, you may provide the sponsor/agency contact who can verify biostatistician involvement.
- Upload of the required document(s) on the Documents tab. The required document type will vary dependent upon whether the project involves the use of an FDA-regulated product. The General Protocol Template is required for submission of non-FDA regulated projects (available on IRB Forms page). Research projects that include use of an FDA-regulated product will be asked to provide a GCP compliant protocol and product information (e.g. Investigator's Brochure, packet insert, Device Manual). The IND (Drugs) Protocol Template and IDE (Devices) Protocol Template are available on the IRB Forms page as a resource for researchers.
- Upload your CV or Biosketch or PI information to permit preliminary assessment of qualifications.

NOTE: All fields are required to proceed. Incomplete or inaccurate information will delay review of your request. Also, you may save your progress at any time by clicking Save Progress.

When all fields have been completed and documents have been uploaded, click Finalize and Submit Request. Fix any validation errors that may appear and verify that the document(s) attached meet the required type.

A confirmation window will appear to verify that you are submitting the project for scientific assessment. Once the request has been submitted it will not be available to edit. You and others listed (investigators, key contacts) on the project will receive an email confirmation that the request has been submitted successfully.
HRPP Scientific Assessment – After Submission

After submission, you may be contacted by HRPP staff to clarify any ambiguous answers or respond to incomplete submissions. If revisions or additions to the submission form are requested, your project will be unlocked for editing.

You will also be contacted via email with the outcome of the assessment once the review has been completed. If there are stipulations, please submit your response to hrpp@umn.edu. Please note that at this point you may choose to make the required revisions or withdraw the project from consideration.

Documenting HRPP Scientific Assessment Acceptance in IRB Materials

HRPP Scientific Assessment approval should be documented on the medical IRB application in section 12.5 “Scientific Assessment.” In response to question 12.5.1 indicate “Yes” and choose “Option 4 – HRPP Scientific Assessment.” You should also provide the HRPP Scientific Assessment Approval letter with your IRB application materials when submitted. If you have not yet received approval, please provide the CTR portal project number in your cover letter.

Questions?

Should any questions arise during the review process contact HRPP at hrpp@umn.edu or by phone 612-626-5654.
Work Proposal Section 5 Attachment

1) Job Aid Scientific Assessment Reviewer
Scientific Assessment Reviewer

This job aid documents how to access scientific assessment(s) to which you have been assigned and how to record your review decisions.

Notification of Review Pending
You will receive an email notification when a project is assigned to you. A sample of the email notification is below:

Log-in with your X.500 credentials at https://samplelink.ahc.umn.edu/portal/app/index.cfm/requests/list and navigate to the Review Request Services Forms by following these steps:

- Hover over Toolkit link in top menu
- Click Review Request Services Forms
- Requests that have been assigned to you will be listed

As a reminder the HRPP pledges to deliver a prompt response which requires reviewers to note their response within 7 business days. We ask that you notify the HRPP within 48 hours if you are unable to complete this review.

The following scientific assessment questions must be considered during review of the project:

1) Is the scientific question reasonable?
   - The question is precisely articulated.
   - The research has the potential to provide new and useful knowledge.
   - The rationale for the proposed research is supported by the literature/background in the protocol.

2) Will the methods described in the protocol answer that question?
   - Research tests and procedures are appropriate to answer the scientific question.
   - The proposed research measures are valid and reliable or there are methods proposed to establish validity and reliability.
   - The proposed subject population is appropriate.
   - The sample size calculation appears valid and will answer the research question.
   - The principal investigator is qualified to conduct the research.

If you have any questions respond to this email or call 612-626-5654
Accessing Project Information

Click the link provided in the email - https://ctsi.ahc.umn.edu/portal/ and log in to the portal using your University of Minnesota issued X.500 ID and password. As indicated in the email notification, hover over the toolkit link and select “Review Request Services Forms”

The “Review Request Services Forms” link will take you to the reviewer dashboard. An example of the dashboard is below. Clicking the “In Review” or “Completed” header (example circled below) allows you to choose what displays below. In the example below projects “In Review” display and projects with the status “Completed” are hidden.

Click the hyperlinks under the CTR Portal ID or Short Title columns to begin the review process.

If you have a potential conflict of interest with this request click Recuse due to conflict button. Please note that you may do this at any time during your review should you discover you have a conflict.

If you do not have a known conflict and you are available to complete this review within the time period required, use the series of tabs (highlighted below in yellow), beginning with Project Information to review the information submitted by the researcher about the project. Please keep in mind the email communication related
to this review assignment which outlines the specific questions to consider when conducting the scientific assessment. Final review of the project will require verification by the reviewer that the project conforms to these standards.

The **Project Information** provides the study title (short and full), a brief abstract or description (if applicable), and the study staff associated with the project and their roles. Please note that while contact email and telephone numbers are available on this page for all study staff, any questions or concerns should be relayed to the HRPP Scientific Assessment personnel. This effort is to protect the anonymity and confidentiality of the scientific reviewers.

The **Requested Services** tab contains information provided by the investigator regarding involvement of any FDA-regulated products, as well as the name, credentials and contact information of the project’s biostatistician. While each submission will include confirmation of review by a biostatistician, please contact the HRPP Scientific Assessment personnel if you have concerns about the validity of this response or if you require additional evaluation. If statistical expertise does not exist among other reviewers, the HRPP will solicit statistical consultation from the CTSI or other existing panels currently involved in the evaluation of studies.

The **Documents** tab will contain any file attachments the requester uploaded (e.g. Protocol, Investigator’s Brochure, FDA correspondence, consent form, IRB application, etc). If you do not see a document present that you think is necessary to complete your review, please contact the HRPP Scientific Assessment Staff personnel to request.

**Notes** are messages HRPP staff and reviewers can share with each other during the review process. Please make sure to review the note section for any questions or
special instructions from HRPP Scientific Assessment Staff personnel regarding the submission. These notes are never displayed to the investigator.

Documenting your Review Decision

After reviewing the information provided on the tabs (Project Information, Requested Services, Documents and Notes), click “Review Request” to record your decision. This will reveal the following window asking if the protocol meets scientific assessment standards. You are asked to consider two primary questions when making this judgment, “Is the scientific question reasonable?” and “Will the methods described in the protocol answer the question?” The bullet points under each question indicate issues that you need to consider when answering these questions.

If your answer to both the questions is “Yes”, you will click Accepted and then click Save Review. No further input from you is necessary.
However, if your answer to either or both questions is “No”, you will click **Not Accepted** and the following screen will appear.

![Review Request Screen](https://cti-dev.umn.edu/portal/index.cfm/requests/goto?citemid=188641&d=12242&dthemead=1&dthv=10&dtpage=1&dttstatus_tid=2&dttcomid=4)

This screen will require you to detail the revisions that the investigator must make to meet the assessment standard. Once you have indicated all revisions, click **Save Review**.

If you change your mind during your review (prior to clicking **Save Review**), you may click on the **Accepted** or **Not Accepted** buttons to change your decision path. If you change your mind after the review determination has been saved or need to update the revisions you provided, you may update your review at any future time by clicking the **“Review Request”** button from the main request page again.
Post Review Decision

Each project will be assigned two reviewers. After you save your review, you may see other reviewers’ decisions in the Decision History tab and correspond with the HRPP Staff via the Notes interface. The Decision History tab reveals other reviewer’s decisions only after you complete your review.

If you determine the protocol does not meet scientific assessment standards, HRPP Scientific Assessment Staff personnel will communicate this decision to the investigator and any changes or clarifications required. The investigator may choose to amend or withdraw the project. You will receive notification from HRPP Scientific Assessment Staff personnel when the investigator submits his/her response to the required revisions.

The process for reviewing a revised project is the same as reviewing a new submission. To enter your new decision, follow the Documenting your Review Decision directions above.

Questions?

If you have any questions not addressed by this job aid, please contact the HRPP Scientific Assessment Staff personnel at 612-626-5654 or, via email, at hrpp@umn.edu
Work Proposal Section 6 Attachment

1) IRB Minutes Template
Members Present at Meeting

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Member Status</th>
<th>Attendance by Teleconference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A</td>
<td>N/A</td>
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<td>N/A</td>
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<td>N/A</td>
<td>N/A</td>
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<tr>
<td></td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

IRB members present by teleconference (when applicable) received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

Others Present or Voting Members in Attendance for Specific Study(s)

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Meeting Information

<table>
<thead>
<tr>
<th>Total number of regular members on the current IRB roster:</th>
<th>Number of members required for quorum:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Time meeting called to order:</th>
<th>Time meeting adjourned:</th>
</tr>
</thead>
</table>

Notes

Items on this agenda were not necessarily reviewed in the order in which they appear.

A non-scientist member is in attendance during the discussion and vote of all action items on this convened IRB agenda.

Voting Key

- “For”: Voting for the motion.
- “Against”: Voting against the motion

---

1 For example: chair, vice-chair, non-affiliated member, regulatory specialist, member, prisoner representative
2 For example: physician scientist, other scientist, non-scientist
3 List individuals present and role of these individuals if in attendance at any time during the meeting. Indicate the role of each person listed, for example: HRPP staff support, IND/IDE expert for all new applications involving a drug or device, PI in attendance to address questions, reviewer for HSC#.... If an individual serves as a voting member, identify the specific research study(s), rationale for and duration of attendance. Ad hoc substitutions for regular or alternate IRB members is not permitted.
4 Record here a summary of any meeting notes or discussion items unrelated to the review of specific research.
- “Abstain”: Present for the vote, but not voting “For” or “Against”
- “Absent”: Name of member not present for reasons other than a conflicting interest (members in attendance at the meeting, but absent from the room for the vote)
- “Recused”: Name of member not present for discussion and voting due to a conflicting interest
- “Non-Voting”: Present at the meeting but not in voting status
Other business:

Protocol:

<table>
<thead>
<tr>
<th>Submission type:</th>
<th>Choose an item.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Principal investigator:</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>IRB number:</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Reviewer:</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Safety monitoring:</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Funding type:</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>IND or IDE number, if any:</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Submission description:</td>
<td>Click here to enter text.</td>
</tr>
</tbody>
</table>

1. Summary of previous actions: **N/A for this review**
2. Consultant report: **N/A for this review**
3. Scientific Assessment Requirement Met by: Choose an item.
4. Scientific Assessment IRB Determination:
   - [ ] Accepted
   - [ ] Not Accepted, provide justification:
   - [ ] Pending
5. Controverted issues and their resolution, if any: "None" if none
   - **None**
6. Discussion notes\(^1\): "None" if none
   - **None**
7. Risk assessment: Choose an item.
8. Regulatory determinations and protocol-specific findings: **N/A for this review**
9. NSR/SR determination: **N/A for this review**
10. Approval interval: **N/A for this review**
11. Motion: Choose an item.
   - **<delete this table if not defer, disapprove, suspend, terminate>**
   - **<delete this table if no stipulations>**
   - **Required modifications and rationale:**
12. Vote:
    | For  | Against | Abstain | Absent | Recused |
    |------|---------|---------|--------|---------|
    | 0    | 0       | 0       | 0(name)| 0(name) |

\(^1\) Documentation of relevant points of discussion not captured elsewhere
**Research involving children as subjects that involves no greater than minimal risk 45 CFR §46.404; 21 CFR §50.51**

<table>
<thead>
<tr>
<th>No greater than minimal risk to children is presented</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Yes, because…</td>
</tr>
</tbody>
</table>

**Adequate provisions for soliciting the permission of parents or guardian 45 CFR §46.408(b); 21 CFR §50.55(e)**

<table>
<thead>
<tr>
<th>Select one:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child</td>
</tr>
<tr>
<td>☐ The permission of one parent is sufficient even if one parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child</td>
</tr>
<tr>
<td>☐ Parental permission is waived per 45 CFR §46.116(d); 21 CFR §50.55(d)</td>
</tr>
</tbody>
</table>

**Adequate provisions for soliciting the assent of the children 45 CFR §46.408(a); 21 CFR §50.55**

<table>
<thead>
<tr>
<th>Select one:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Assent is required of all children</td>
</tr>
<tr>
<td>☐ Assent is required of all children determined by the investigator to be capable of assent</td>
</tr>
<tr>
<td>☐ Assent is required of none of the children because the capability of the children is so limited that they cannot reasonably be consulted</td>
</tr>
<tr>
<td>☐ Assent is required of none of the children because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research</td>
</tr>
<tr>
<td>☐ Assent is required of none of the children because assent is waived per 45 CFR §46.116(d); 21 CFR §50.55(d)</td>
</tr>
</tbody>
</table>

**Select one (if applicable):**

| ☐ Assent will be documented using a written form for all children aged ____ years or older |
| ☐ Assent will be documented by the investigator on the consent document |

**Research involving children as subjects that involves greater than minimal risk, but with a prospect of direct benefit to the individual subjects 45 CFR §46.405; 21 CFR §50.52**

| The research involves procedures that present greater than minimal risk to children |
| ☑ Yes, because… |

| The research procedures that present greater than minimal risk to children hold out the prospect of direct benefit for the individual subject or are likely to contribute to the subject’s well-being |
| ☑ Yes, because… |

| The risk is justified by the anticipated benefit to the subjects |
| ☑ Yes, because… |
The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches

Yes, because…

---

**Adequate provisions for soliciting the permission of parents or guardian 45 CFR §46.408(b); 21 CFR §50.55(e)**

**Select one:**

- Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child
- The permission of one parent is sufficient even if one parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child

If the referenced study requires consideration of a waiver of parental permission, refer to the following section: “Waiver of parental permission when permission is not a reasonable requirement 45 CFR §46.408(c).”

---

**Adequate provisions for soliciting the assent of the children 45 CFR §46.408(a); 21 CFR §50.55**

**Select one:**

- Assent is required of all children
- Assent is required of all children determined by the investigator to be capable of assent
- Assent is required of none of the children because the capability of the children is so limited that they cannot reasonably be consulted
- Assent is required of none of the children because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research

**Select one (if applicable):**

- Assent will be documented using a written form for all children aged ____ years or older
- Assent will be documented by the investigator on the consent document

---

**Research involving children as subjects that involves greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition 45 CFR §46.406; 21 CFR §50.53**

The research involves procedures that present greater than minimal risk to children

Yes, because…

The risk represents a minor increase over minimal risk

Yes, because…

The research procedures that present greater than minimal risk to children do not hold out the prospect of direct benefit for the individual subject and are not likely to contribute to the subject’s well-being

Yes, because…
The intervention or procedure is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition

Yes, because…

The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations

Yes, because…

Adequate provisions for soliciting the permission of parents or guardian 45 CFR §46.408(b); 21 CFR §50.55(e)

Select one:

☐ Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child

If the referenced study requires consideration of a waiver of parental permission, refer to the following section: “Waiver of parental permission when permission is not a reasonable requirement 45 CFR §46.408(c).”

Adequate provisions for soliciting the assent of the children 45 CFR §46.408(a); 21 CFR §50.55

Select one:

☐ Assent is required of all children

☐ Assent is required of all children determined by the investigator to be capable of assent

☐ Assent is required of none of the children because the capability the children is so limited that they cannot reasonably be consulted

Select one (if applicable):

☐ Assent will be documented using a written form for all children aged ____ years or older

☐ Assent will be documented by the investigator on the consent document

Research involving children as subjects that is not otherwise approvable 45 CFR §46.407; 21 CFR §50.54

The research does not meet the requirements of 45 CFR §46.404, 46.405, 46.406; 21 CFR 50.51, 50.52, 50.53

Yes, because…

The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children

Yes, because…

An applicable official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, has determined either that the research in fact meets the conditions of 45 CFR §46.404, 46.405, 46.406, or 21 CFR 50.51, 50.52, 50.53

- The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
The research will be conducted in accordance with sound ethical principles
Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians

Non-significant risk device 21 CFR §812.3(m)

☐ The device is NOT intended as an implant and does not present a potential for serious risk to the health, safety, or welfare of a subject
☐ The device is NOT purported or represented to be for a use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject
☐ The device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a subject
☐ The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject

Waiver of written documentation of consent for confidentiality risk 45 CFR §46.117(c)(1)

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality

☐ Yes, because...

Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern

☐ Yes, because...

☐ The research is not FDA-regulated

☐ The investigator has provided a written statement regarding the research that embodies the elements of consent per 45 CFR §46.116; 21 CFR §50.25

Select one:
- ☐ The investigator must provide subjects with that written statement
- ☐ The investigator does not have to provide subjects with that written statement

Waiver of written documentation of consent for research involving no more than minimal risk to subjects 45 CFR §46.117(c)(2) and 21 CFR §56.109(c)(1)

The research presents no more than minimal risk to subjects and the research involves no procedures for which written consent is normally required outside of the research context

☐ Yes, because...

☐ The investigator has provided a written statement regarding the research that embodies the elements of consent per 45 CFR §46.116; 21 CFR §50.25

Select one:
- ☐ The investigator must provide subjects with that written statement
- ☐ The investigator does not have to provide subjects with that written statement
Waiver of assent for research involving no more than minimal risk to subjects 45 CFR §46.116(d) and 45 CFR §46.408

<table>
<thead>
<tr>
<th>The research involves no more than minimal risk to the subjects</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>✐</td>
<td></td>
</tr>
<tr>
<td>The waiver or alteration will not adversely affect the rights and welfare of the subjects</td>
<td></td>
</tr>
<tr>
<td>✐</td>
<td></td>
</tr>
<tr>
<td>The research could not practicably be carried out without the waiver or alteration</td>
<td></td>
</tr>
<tr>
<td>✐</td>
<td></td>
</tr>
<tr>
<td>Whenever appropriate, the subjects will be provided with additional pertinent information after participation</td>
<td></td>
</tr>
<tr>
<td>✐</td>
<td></td>
</tr>
</tbody>
</table>

Waiver of parental permission when permission is not a reasonable requirement 45 CFR §46.408(c)

<table>
<thead>
<tr>
<th>The research protocol involves children as subjects and is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>✐ Yes, because…</td>
<td></td>
</tr>
<tr>
<td>An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted</td>
<td></td>
</tr>
<tr>
<td>✐ Yes, because…</td>
<td></td>
</tr>
<tr>
<td>The waiver is not inconsistent with Federal, State, or local law</td>
<td></td>
</tr>
<tr>
<td>✐ Yes, because…</td>
<td></td>
</tr>
<tr>
<td><strong>The following statements must also be true:</strong></td>
<td></td>
</tr>
<tr>
<td>The research is <strong>not</strong> FDA-regulated</td>
<td></td>
</tr>
<tr>
<td>The research does not involve experimental subjects as defined by DOD, unless a waiver is obtained from the Assistant Secretary of DOD for Research and Engineering</td>
<td></td>
</tr>
</tbody>
</table>

Waiver of consent or permission for research involving no more than minimal risk to subjects 45 CFR §46.116(d)

<table>
<thead>
<tr>
<th>The research involves no more than minimal risk to the subjects</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>✐ Yes, because…</td>
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<tr>
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<tr>
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<td>The research is <strong>not</strong> FDA-regulated</td>
<td></td>
</tr>
</tbody>
</table>
The research does not involve experimental subjects as defined by DOD, unless a waiver is obtained from the Assistant Secretary of DOD for Research and Engineering.

The research does not involve nonviable neonates as subjects.

### Research involving prisoners as subjects 45 CFR §46 Subpart C

The research under review represents one of the categories:

- ☐ Study of the possible causes, effects, and processes of incarceration, and of criminal behavior that present no more than minimal risk and no more than inconvenience to the subjects.
- ☐ Study of prisons as institutional structures or of prisoners as incarcerated persons that present no more than minimal risk and no more than inconvenience to the subjects.
- ☐ Research on conditions particularly affecting prisoners as a class.
  - ☐ If the study is subject to DHS, DOD, or VA regulation, the study will not proceed until an applicable official has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.
- ☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or wellbeing of the subject.
  - ☐ If the study is subject to DHS, DOD, or VA regulation and requires the assignment of prisoners to control groups which may not benefit from the research, the study will not proceed until an applicable official has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.
- ☐ Epidemiologic studies where prisoners are not a particular focus of the research in which the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and the study presents no more than minimal risk and no more than inconvenience to prisoners who are subjects.

Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.
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<td>Control subjects will be selected randomly from the available prisoners who meet the characteristics needed for the research</td>
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<td>The principal investigator has provided written justification for following other procedures</td>
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<td>The information is presented in language which is understandable to the subject population</td>
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<td>Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole</td>
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<td>Each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole</td>
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<td>If the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing subjects of this fact</td>
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**Research involving incidental prisoners as subject that is not subject to regulation**

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<th>The research is not subject to DHS, HHS, or VA regulations</th>
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<td>The rights and well-being of the subject are not in jeopardy</td>
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<td>The subject can continue to consent to participate</td>
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<td>The subject is capable of meeting the research protocol requirements</td>
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<td>The terms of the subject’s confinement does not inhibit the ethical conduct of the research</td>
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<td>There are no other significant issues preventing the research from continuing as approved</td>
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<td>A prisoner representative or a subject matter expert having the expertise of a prisoner representative has been consulted</td>
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<td>Approval is limited to the individual subject and does not allow recruitment of prisoners as subjects</td>
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<td>Approvable research involving incidental prisoners as subjects that is subject to regulation</td>
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<td>The research will be subject to review and approved by a qualified IRB under 45 CFR §46 Subpart C</td>
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**Non-approvers research involving incidental prisoners as subjects that is subject to regulation**

|   | The federal agency has been consulted and approves continuation of the subject in the research |   |

**Research involving pregnant women as subjects that involves no more than minimal risk to subjects and is not subject to regulation**

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<th>The research presents no more than minimal risk to subjects</th>
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<td>The research is not subject to DHS, EPA, HHS, or VA regulation</td>
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</table>
Research involving pregnant women or fetuses that involves greater than minimal risk or is subject to regulation 45 CFR §46.204

Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses

One of the following is true:

Select one:

- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus
- The risk to the fetus is not greater than minimal risk and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means <add for DHS, EPA, HHS, or VA research> and the important knowledge is important biomedical knowledge
- Any risk is the least possible for achieving the objectives of the research
- Consent of the mother is obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR §50.27
- If the research holds out the prospect of direct benefit solely to the fetus, the consent of the father (in addition to the mother) is obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR §50.27, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate
- For children who are pregnant, assent and permission are obtained and documented in accordance with 45 CFR §46.408, 21 CFR §50.55
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy
- Individuals engaged in the research will have no part in determining the viability of a neonate

Research involving pregnant women or fetuses that is not otherwise approvable 45 CFR §46.207
The research does not meet the above requirements

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The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates

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An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required.

### Research involving neonates of uncertain viability as subjects 45 CFR §46.205

Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates

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Individuals engaged in the research will have no part in determining the viability of a neonate

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One of the following is true:

- The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective
- The purpose of the research is the development of important knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research
  - For DHS, EPA, HHS, or VA research, the important knowledge is important biomedical knowledge

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Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate

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The consent of either parent or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s LAR is obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR 50.27, except that the consent of the father or his LAR need not be obtained if the pregnancy resulted from rape or incest

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### Research involving neonates of uncertain viability as subjects that is not otherwise approvable 45 CFR §46.207

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Revised: December 17, 2015
The research does not meet the above requirements

The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates

An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required.

### Research involving nonviable neonates as subjects 45 CFR §46.205

Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates

- Individuals engaged in the research will have no part in determining the viability of a neonate
- Vital functions of the neonate will not be artificially maintained
- The research will not terminate the heartbeat or respiration of the neonate
- There will be no added risk to the neonate resulting from the research
- The purpose of the research is the development of important knowledge that cannot be obtained by other means
  - For DHS, EPA, HHS, or VA research data, the important knowledge is important biomedical knowledge
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate

The consent of both parents of the neonate is obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR 50.27, unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest

Consent will not be obtained from a LAR

There is no waiver or alteration of the consent process
Research involving nonviable neonates as subjects that is not otherwise approvable 45 CFR §46.207

The research does not meet the above requirements

The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates

An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or, neonates, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required.

Research involving wards as subjects involving the first two categories of research involving children 45 CFR §46.409; 21 CFR §50.56

The research meets the criteria in Section 1 or 2 of "CHECKLIST: Children (HRP-310)"

Provisions for soliciting the assent of the children and the permission of their parents or guardians meet the criteria in Sections 4 and 5 of "CHECKLIST: Children (HRP-310)"

Research involving wards as subjects involving the last two categories of research involving children 45 CFR §46.409; 21 CFR §50.56

One of the following is true:

- The research is related to the subject's status as wards
- The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards

An advocate has been appointed for each child who is a ward

Each advocate has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research

Each advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization

Emergency research consent waiver 21 CFR §50.24; 45 CFR §46.116 and 45 CFR §46.117, Waiver of informed consent requirements in certain emergency research
The subjects are in a life-threatening situation

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Available treatments are unproven or unsatisfactory

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The collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions

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Obtaining informed consent is not feasible because **all of the following are true:**

- The subjects will not be able to give their informed consent as a result of their medical condition
- The intervention must be administered before consent from the subjects’ LARs is feasible
- There is no reasonable way to identify prospectively the individuals likely to become eligible for participation

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Participation in the research holds out the prospect of direct benefit to the subjects because **all of the following are true:**

- Subjects are facing a life-threatening situation that necessitates intervention
- Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects
- Risks are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity

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The research could not practically be carried out without the waiver

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The proposed research defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact an LAR for each subject within that window of time and, if feasible, to asking the LAR contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact LARs and make this information available to the IRB at the time of continuing review

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When feasible consent of subjects or LARs will be obtained and documented in accordance with 45 CFR §46.116 and 21 CFR §50.20; 45 CFR §46.117 and 21 CFR 50.27

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Additional protections of the rights and welfare of the subjects will be provided, including all of the following:
Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn

Public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits

Public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results

- Establishment of an independent data monitoring committee to oversee the research

If obtaining informed consent is not feasible and an LAR is not reasonably available, the investigator has committed, if feasible, to attempt to contact within the therapeutic window the subject’s family member who is not an LAR, and asking whether he or she objects to the subject’s participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review

- Procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, LAR of the subject, or if such LAR is not reasonably available, a family member, of the subject’s inclusion in the research, the details of the research and other information contained in the informed consent document

- There is a procedure to inform the subject, or if the subject remains incapacitated, LAR of the subject, or if such LAR is not reasonably available, a family member, that he or she may discontinue the subject’s participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

- If an LAR or family member is told about the research and the subject’s condition improves, the subject is also to be informed as soon as feasible

- If a subject is entered into research with waived consent and the subject dies before an LAR or family member can be contacted, information about the research is to be provided to the subject’s LAR or family member, if feasible

- A licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation concurs with the above findings

**Indicate which of the following is true:**

- The research is FDA-regulated and meets the requirements of 21 CFR §50.24

- The research is not FDA-regulated and meets the requirements of the 45 CFR §46 Waiver of informed consent requirements in certain emergency research
☐ The research is regulated by a federal department or agency other than HHS or FDA, and the department or agency Secretary has issued a waiver

**FDA-regulated emergency research consent waiver 21 CFR §50.24**
The protocol is performed under a separate IND or IDE that clearly identifies such protocols as protocols that may include subjects who are unable to consent

**HHS-regulated emergency research consent waiver 45 CFR §46.101(i) Waiver of informed consent requirements in certain emergency research**
The research does not involve prisoners as subjects

The research does not involve fetuses, pregnant women, and human in vitro fertilization

---

**FDA Enforcement Discretion for Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable**

The research is not regulated by a federal department or agency other than FDA

The IRB has reviewed the sponsor's written documentation regarding the collection and distribution of specimens and associated data, including the policies and procedures followed by the specimen provider to ensure that the subject cannot be identified

The research meets the criteria for approval per 45 CFR §46.111 and 21 CFR §56.111

The research meets the IDE exemption criteria at 21 CFR 812.2(c)(3)

☐ The research uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded, use specimens obtained from specimen repositories, or uses leftover specimens that were previously collected for other research purposes

☐ The specimens may be accompanied by clinical information as long as this information does not make the specimen source identifiable to the investigator or any other individual associated with the research, including the sponsor

☐ The individuals caring for the patients are different from and do not share information about the patient with those conducting the research

☐ The specimens are provided to the investigator(s) without identifiers

☐ The supplier of the specimens has established policies and procedures to prevent the release of personal information
Work Proposal Section 7 Attachments

1) IRB Policy 904
2) HRPP Website Content
1.0 Reason for Policy

Describe the procedure for ensuring that appropriate review for sound scientific design takes place prior to initial IRB review of Health and Biological/Medical applications and that all researchers have the resources necessary to protect participants.

2.0 Scope of Policy

This policy applies to the University research community and its healthcare components.

3.0 Policy Statement

In order to approve research in accord with the Criteria for IRB Approval, the IRB must determine that the level of scientific or scholarly review is sufficient to fulfill the following two requirements:

- Risks to participants are minimized by using procedures consistent with sound research design and that do not unnecessarily expose participants to risk.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may be reasonably expected to result.

For projects involving not greater than minimal risk and reviewed by expedited review, scientific review is performed by the IRB reviewer.
For projects involving greater than minimal risk, reviewed by the social and behavioral sciences IRB panels, the IRB members perform scientific review.

For projects involving greater than minimal risk in the medical areas and reviewed by the full IRB committee, scientific review is to be performed by a minimum of two independent peer reviewers. Researchers are required to provide documentation of fulfillment of the scientific review requirement as well as assurance that they have the resources necessary to protect participants prior to consideration by the convened IRB. The IRB will consider the completion of the scientific review as part of its evaluation of the Criteria for IRB Approval.

Procedures:

Independent scientific review is to be performed by one of four methods listed below. In all cases, the conduct of the scientific review requires the reviewers to have the expertise to understand the background, aims, and methods, and to draw on the discipline’s standards for conducting research.

Method 1: Nationally-based, federal funding organizations (NIH, NSF) when research projects have been subjected to full peer review (e.g., review by a study section or grant committee).

The actual protocol being submitted to the IRB must have been reviewed in its current form. Peer review of a grant that describes a clinical trial in general terms does not satisfy this criterion. Industry-sponsored clinical trials designed by the sponsor with or without external consultants do not satisfy this criterion for independent peer-review.

Method 2: Nationally based non-federal funding. Organizations such as, March of Dimes and American Academy of Pediatrics, employing peer review mechanisms as part of an award of funding

The actual protocol being submitted to the IRB must have been reviewed in its current form. Peer review of a grant that describes a clinical trial in general terms does not satisfy this criterion. Industry-sponsored clinical trials designed by the sponsor with or without external consultants do not satisfy this criterion for independent peer-review.

Method 3: Locally constituted mechanisms using peer review as part of an award of funding, or for permission to use resources. Locally constituted mechanisms include the following committees, which include links to scientific review assessments:

   Cancer Protocol Review Committee (CPRC)
   Clinical and Translational Science Institute (CTSI) pilot funding awards

Method 4: HRPP Scientific Assessment. Review method utilized for all other applicable medical research not reviewed under one of the methods noted above.

Review Requirements for Method 4
Confirmation of review by a biostatistician is a required element for all scientific assessments conducted under Method 4. This will ensure an initial foundation that will assure the scientific reviewers that the study is appropriately powered to assess the primary outcome. With that foundation, reviewers will consider two fundamental questions and take into consideration the bulleted items listed under each during their review and PI qualifications:

1). Is the scientific question reasonable?

The question is precisely articulated.

The research has the potential to provide new and useful knowledge.

The rationale for the proposed research is supported by the literature/background provided in the protocol.

2). Will the methods described in the protocol answer that question?

Research tests and procedures are appropriate to answer the scientific question.

The proposed research measures are valid and reliable or there are methods proposed to establish validity and reliability.

The proposed subject population is appropriate.

The sample size calculation appears valid and will answer the research question.

The principal investigator is qualified to conduct the research.

**Procedures to Satisfy Scientific Review Requirements:**

- Select one of the four scientific review methods; and
- Document fulfillment of the scientific review requirement and include said documentation with the IRB application.

*Note: Medical applications requiring full committee IRB review will not be assigned to a meeting until documentation of scientific review is provided.

**IRB Consideration of Resources:**

The IRB evaluates that individual research studies have the resources necessary to protect participants by asking the reviewer to determine if the researcher has provided the following information

- Is there adequate time to conduct and complete the research?
- Does the researcher have an adequate number of qualified staff?
- Does the researcher have adequate research facilities?
• Does the researcher have access to a population that will allow recruitment of the necessary number of participants?
• Are medical or psychosocial resources available if participants need them as a consequence of the research?

Further, by providing their signature as principal investigator on an IRB application, researchers explicitly assure the IRB that they have the resources necessary to protect participants, such as adequate funding, appropriately trained staff and necessary facilities and equipment. By his/her signature on the initial IRB application, the principal investigator assures the IRB of the following:

As Principal Investigator of this study, I assure the IRB that the following statements are true:

- The information provided in this form is correct.
- I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment.
- I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc.
- I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.
- I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation.
- I will not begin my research until I have received written notification of final IRB approval.
- I will comply with all IRB requests to report on the status of the study.
- I will maintain records of this research according to IRB guidelines.
- The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application.
- If these conditions are not met, I understand that approval of this research could be suspended or terminated.

4.0 Required approvals for this document

| Title | Executive Director, HRPP |

5.0 Revision History

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<th>Revision</th>
<th>Reason for change</th>
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<td>Revisions Prompted by the Work Plan</td>
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<tr>
<td>06/01/14</td>
<td>Update options and reformat PI attestation</td>
<td>09/02/14</td>
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<tr>
<td>01/05/11</td>
<td>Update cross references</td>
<td>01/05/11</td>
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<td>02/01/10</td>
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<tr>
<td>10/15/09</td>
<td>Update AAHRPP references</td>
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<td>05/16/07</td>
<td>Policy Development</td>
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To obtain a copy of a historical policy, e-mail the IRB at irb@umn.edu or call 612-626-5654.
Scientific Assessment of Proposals Submitted to the IRB

Since July 1, 2007, evidence of scientific review for medical research involving human subjects deemed by the Institutional Review Board (IRB) to be greater than minimal risk has been required at the time of submitting an application to the IRB.

The purpose of scientific assessment is to encourage the development of scientifically sound medical research. To justify the inclusion of human subjects in research, and to assess the balance between any risks that may be imposed upon human subjects with the utility of the outcomes of the investigation, an assessment is required to evaluate the scientific question and appropriateness of the methods planned to answer the scientific question.

After receiving documented acceptance of the protocol via an approved scientific assessment process, the IRB will determine, among other requirements and ethical standards, that the following requirements are satisfied:

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought from each subject or the subject’s legally authorized representative
- Informed consent will be appropriately documented
  - Adequate provisions to protect privacy and maintain confidentiality are in place

Applicability

Submission of documentation supporting scientific assessment is required for greater than minimal risks medical and biological sciences research that is not exempt under CFR 45 §46.101 (b) or does not qualify for expedited review under CFR 45 §46.110.

The IRB performs scientific assessment for all minimal risk research and greater than minimal risk social and behavioral sciences research.

Acceptable Methods for Scientific Assessment

Independent scientific review is to be performed by one of four methods listed below. In all cases, the conduct of the scientific review requires the reviewers to have the expertise to understand the background, aims, and methods, and to draw on the discipline’s standards for conducting research.

Method 1: Nationally-based, federal funding organizations (NIH, NSF) when research projects have been subjected to full peer review (e.g., review by a study section or grant committee).

The actual protocol being submitted to the IRB must have been reviewed in its current form. Peer review of a grant that describes a clinical trial in general terms does not satisfy this criterion.
Industry-sponsored clinical trials designed by the sponsor with or without external consultants do not satisfy this criterion for independent peer-review.

**Method 2:** Nationally based non-federal funding. Organizations such as, March of Dimes and American Academy of Pediatrics, employing peer review mechanisms as part of an award of funding

The actual protocol being submitted to the IRB must have been reviewed in its current form. Peer review of a grant that describes a clinical trial in general terms does not satisfy this criterion. Industry-sponsored clinical trials designed by the sponsor with or without external consultants do not satisfy this criterion for independent peer-review.

**Method 3:** Locally constituted mechanisms using peer review as part of an award of funding, or for permission to use resources. Locally constituted mechanisms include the following committees, which include links to scientific review assessments:

- **Cancer Protocol Review Committee (CPRC)**
- **Clinical and Translational Science Institute (CTSI) pilot funding awards**

**Method 4:** HRPP Scientific Assessment. Review method utilized for all other applicable medical research not reviewed under one of the methods noted above.

**Review Requirements for Method 4**

Confirmation of review by a biostatistician is a required element for all scientific assessments conducted under Method 4. This will ensure an initial foundation that will assure the scientific reviewers that the study is appropriately powered to assess the primary outcome. With that foundation, reviewers will consider two fundamental questions and take into consideration the bulleted items listed under each during its review and PI qualifications:

1) **Is the scientific question reasonable?**
   - The question is precisely articulated.
   - The research has the potential to provide new and useful knowledge.
   - The rationale for the proposed research is supported by the literature/background in the protocol.

2) **Will the methods described in the protocol answer that question?**
   - Research tests and procedures are appropriate to answer the scientific question.
   - The proposed research measures are valid and reliable or there are methods proposed to establish validity and reliability.
   - The proposed subject population is appropriate.
   - The sample size calculation appears valid and will answer the research question.
   - The principal investigator is qualified to conduct the research.
Procedures to Satisfy Scientific Review Requirements

1. Select one of the four scientific review methods; and
2. Document fulfillment of the scientific review requirement and include with the IRB application submission.

*Note: Medical applications requiring full committee IRB review will not be assigned to a meeting until documentation of scientific review is provided.
Human Research Protection Program (HRPP) Proposal to Address the Advancing Human Research Protections Implementation Plan:

Section 8 Monitoring of Studies

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HRP-012-SOP
CHECKLIST FOR CONSENT OBSERVATION
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| Instructions and Guidance for completing the Proposal: |

Who Completes?

Work Plan Section Leads

Review Process:

Proposals should be submitted to the Vice President for Research for review and approval. If necessary, the VPR will ask the Research Compliance Advisory Committee for their review as well. This review process should occur within the first two weeks of the work being started.

Issue section:

This section should fully incorporate the implementation team’s understanding of the current state. To accomplish this step, review implementation team’s action plans and final report. Include enough detail that demonstrates both an understanding of the issue and the context back to the external review panel’s recommendations.

Action section:

Actions need not be limited to resources that are available right now. However, when crafting your proposal focus on practical and feasible solutions, providing as much logistical detail as possible. A well-thought out proposal that addresses critical aspects of the issue and offers reasonable actions that can be taken is much more likely to succeed.

Consider the potential resources available across the University, what aspects might be used to measure the progress and success of your proposed action, and what a possible timeline for full implementation of your proposal might look like. If your proposed action is larger in scale, could it be broken down into multiple phases for easier implementation? Anticipate challenges/barriers that might be encountered during implementation and incorporate strategies into your proposal for addressing these, should they arise.
Work Plan Section: Monitoring of Studies

| Lead(s): Debra Dykhuis (assisted by Felicia Mroczkowski) | Date: 5/31/2016 |

Proposal

Issue

What is the issue/problem? (Define this based on the external review panel’s observations and the implementation team’s translation of the problem)

The external review panel described PAR policies, procedures, review tools, and a sample of reports of findings as “impressive and a potentially valuable tool to promote compliance with human subject protection priorities, including those related to the inclusion of subjects with impaired consent capacity and the use of legally authorized representatives”. The work described to make improvements to the program will build on this solid foundation.

The external review panel identified issues and problems with the monitoring of studies and recommended the following improvements:

1. Efforts to expand monitoring conducted through the PAR program and/or via the application of its methods to other HRPP monitoring efforts should be considered. Specific emphasis should be placed on increasing PAR monitoring efforts for research conducted at Fairview with an active dialogue with the Fairview staff so that they can be actively engaged in the process;

2. PAR should track and measure IRB follow-through on its findings and recommendations and report these to research leadership including department chairs and the Dean of the Medical School;

3. PAR should regularly share summary reports of its findings with department chairs and other institutional leaders charged with research oversight responsibilities to ensure that key areas of investigator and programmatic noncompliance can be readily identified and addressed.

4. Deficiencies in IRB review processes/functioning should also be addressed through existing reporting and supervisory hierarchies, and not be addressed solely within the more limited authority of the IRB and Office of the Vice President of Research;

5. In the context of ongoing concerns about problems related to subject recruitment and consent in psychiatric studies, PAR should include live consent monitoring of such studies in its repertoire of
subject safeguards;

6. Separate reporting chains for IRB review and Post-Approval Review should be considered.

The implementation team identified additional issues and problems and added recommendations, and refinements to external panel recommendations, as follows:

1. Results of PAR monitoring should be reported to the FUROC, the OVPR Research Compliance Office and to the IRB. Once accomplished, institutions represented on the FUROC (Fairview and the University specifically called out) would each bear responsibility for dissemination of this information to their respective communities. Fairview and UMP (and Gillette) should insure that information about research monitoring activities is available to the clinical care community.

2. PAR policies and procedures should be posted and available to the public. Information about the risk-based selection of protocols for review should be included in these policies and procedures.

3. The IRB should make a risk-based determination, at the time of initial approval, whether a study should undergo a PAR review during the first year.

4. PAR should evaluate “a sufficient number of other studies, as determined by statistical methods” to insure appropriate oversight of institutional research.

5. The OVPR Research Compliance Office should establish a process for monitoring follow-through on PAR findings and should provide information about findings (negative or positive) to academic leadership. Implicit in this communication is an expectation that academic leadership will be held accountable for making sure corrective measures are instituted.

6. Live consent monitoring should include video recording the consent process and a dialogue between the investigator and the consent monitor to contribute to the assessment of capacity to consent.

Who plays a role in the current process? (This is can be taken directly out of the implementation team actions plans.)

PAR personnel, IRB, investigators and research staff, clinical care community, academic leadership

Who is impacted by this issue/problem? (This is can be taken directly out of the implementation team actions plans.)

Public, University, Fairview and UMP clinical care staff, research subjects, investigators, academic leadership, University oversight and monitoring/auditing functions
Proposed Work Scope

Describe the proposed work necessary to address the issue outlined above.

*Be detailed in your description and focus on practical actions, particularly those that could feasibly be undertaken by a responsible University Unit.*

General PAR Program Development and Structure:

Resources for two to three additional FTEs for the PAR program will support efforts to expand evaluation conducted by the PAR program and/or via the application of its methods to other HRPP evaluation efforts. Preparing job descriptions and recruiting for these positions will occur after the monitoring proposal is accepted.

The external review panel recommended separate reporting chains for IRB review and Post-Approval Review. Implementation team recommendations to create a FUROC and a Research Compliance Office (RCO) will create opportunities for transparency and, in the case of FUROC, an independence from OVPR in evaluating the results and follow-through on both branches of the PAR program – investigator/research team performance and IRB performance. In addition to these beyond IRB reporting and oversight plans, an effort will be made to engage and interface with internal and/or external auditors during the ongoing review and development of both branches of the PAR program. In particular, PAR program staff interfaced with Compass Point Research monitors so that the PAR program benefited from techniques and practices of this external group. Through this and other communication efforts intended to create transparency, the community can be assured that issues uncovered by PAR will not be addressed solely within the more limited authority of the IRB and Office of the Vice President of Research.

(See attached Monitoring Proposal for detailed information regarding monitoring plans)

Evaluating Investigator/Research Team Performance:

This branch of the PAR program is reasonably well established but will require enhancement to address specific recommendations of the external panel and the implementation team. Evaluation of IRB submission volumes, consultation with experts, and consideration of the Compass Point Report recommendations associated with PAR have resulted in the following proposal to further enhance the PAR compliance evaluation processes:

1. Implement a risk-based selection process to conduct quality assurance review on greater than minimal risk research;
   - 10% of all active studies approved by the U of M IRB that are enrolling or following subjects (approximately 85 biomedical studies, if QA for these studies remains with PAR, otherwise only at the direction of the IRB for studies that involve vulnerable populations, consent capacity issues, LARs, etc; approximately 30 social and behavioral);
2. Implement a risk-based selection process to conduct quality assurance reviews on not greater than minimal risk research:
   - 5% of active studies approved by the U of M IRB via expedited review that are enrolling or following subjects (approximately 150 studies);
3. Conduct quality assurance review on 2.5% of active exempt studies (approximately 175 studies);
4. Implement risk-based selection process to conduct quality assurance reviews on research studies enrolling or following subjects where review has been ceded to another institution;
5. Hire two QA staff with Association of Clinical Research Professionals Clinical Research Associate certification and at least five years of experience evaluating investigator performance on drug and device trials, or if QA for biomedical studies will be transferred to the AHC, hire one additional FTE for PAR – an FTE that has prior IRB experience;
6. Conduct review, as appropriate, to verify investigator execution of corrective actions and to ensure no re-occurrence of non-compliance or research concerns;
7. Review, evaluate and respond to incoming communication from research participants or others related to the conduct of research. Escalate concerns, at the direction of the IRB, to the Research Compliance Office (RCO) or other responsible entity; and
8. Implement a risk-based selection process to conduct quality assurance review of informed consent via two primary mechanisms (3.3.22): Direct Observation and Retrospective Strategies

HRPP & IRB leadership will engage representatives from the following groups, as appropriate, as advisors in the annual review of PAR compliance evaluation activities associated with investigator performance:

1) Office of Internal Audit
2) Fairview University Research Oversight Committee (FUROC)
3) University Research Staff
4) CTSI
5) Community Oversight Board (COB)
6) Research Compliance Office (RCO)

Topics planned for review during the annual evaluation will include (but are not limited to):

- PAR compliance evaluation efforts for research conducted at Fairview with an active dialogue with the Fairview staff so that they can be actively engaged in the process;
- Refining and developing the risk-based determination process, that is applied at the time of initial approval, to decide whether a study should undergo a PAR review during the first year;
- Defining “a sufficient number of other studies, as determined by statistical methods” to insure appropriate PAR oversight of institutional research;
- Live consent observation procedures including video recording the consent process and a dialogue between the investigator and the consent monitor to contribute to the assessment of capacity to consent; and
- Compliance review of research that involves subjects with diminished or fluctuating capacity to consent including use of surrogate decision-makers.

Evaluating IRB Performance:
This branch of the PAR program has benefited from additional resources and development. Resources and attention to this branch have more recently been made available and applied. Examples of activities evaluated by the PAR Program include:

1. Consistency and appropriateness of IRB determinations;
2. IRB meeting documentation/minutes;
3. General IRB documentation; and
4. IRB membership.

HRPP & IRB leadership will engage representatives from the following groups, as appropriate, as advisors in the annual review of PAR review activities associated with IRB performance:

1) Department of Audits
2) Fairview Research Administration
3) Gillette Research Administration
4) Research Compliance Office
5) Community Oversight Board
6) Research Compliance Advisory Committee

Topics planned for review during the annual evaluation of PAR activities will include (but are not limited to):

- Identifying IRB review processes that need review (i.e. human subjects research determinations, exempt research, research eligible for expedited review, research requiring review by a convened IRB);
- Identifying other IRB functions that require review (i.e. minutes and other documentation, conduct of convened IRB meetings, review of protocols that involve subjects with diminished or fluctuating capacity to consent, review of protocols that involve surrogate decision-makers); and
- Defining a sufficient number of reviews to insure appropriate oversight of IRB review processes and function.

**Quality Improvement (QI) Activities Associated with IRB and Investigator Performance**

This branch of the PAR program will be enhanced to address recommendations of the external panel, implementation work plan, and to conform to accreditation standards. Quality improvement activities will be conducted to assess the quality, efficiency and effectiveness of research. Examples of QI activities include:

- Evaluation of IRB turnaround times;
- Evaluation of investigator surveys to assess efficiency and effectiveness of IRB;
- Creation of self-assessment tools for investigators to facilitate execution of high quality documentation; and
• Providing support to investigators during the creation of corrective action plans.

Results of QI activities will be reported to IRB leadership and advisory groups as appropriate.

**Communicating PAR Findings:**

Advisory groups previously defined will assist IRB leadership in developing the communication plan for PAR findings. Principles of transparency in communicating results (negative and positive) and accountability (of recipients) in following through will be applied.

The following stakeholders were identified by the external panel and/or the implementation team:

1)  Academic leaders: department chairs, Dean of the Medical School, Counsel of Research Associate Deans (CRAD)
2)  Research oversight groups: FUROC, OVPR Research Compliance Office, IRB
3)  Research partners: Fairview, Gillette

PAR will regularly share summary reports of its findings with IRB executive committee, department chairs and other institutional leaders charged with research oversight responsibilities to ensure that key areas of investigator and programmatic noncompliance can be readily identified and addressed. Research partners will each bear responsibility for dissemination of this information to their respective communities. Fairview and UMP (and Gillette) should insure that information about research review activities is available to the clinical care community. Academic leadership will be held accountable for making sure corrective measures are instituted when investigator/research team performance is at issue.

Additionally, PAR findings and trends will be used by HRPP for training and education of IRB members and staff as it may inform risk analysis of individual submissions.

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**What other personnel or other resources are needed to make the plan work? (include expertise)**

Representatives from stakeholder groups will be needed to advise HRPP & IRB leadership in the review and development of branches of the PAR program.

**Define the estimate time line by major deliverable:**

Review the post-report activities work plan section for the proposed timeline and based on that list the major expected outcomes.
The review and development of both branches of the PAR program will be completed within one month of final acceptance of the plan. Recruitment of additional positions will commence after final acceptance of the plan. Revised policies and procedures will be posted and available to the public within one month of final acceptance of the plan.

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<th>Does this plan require the identification of additional resources?</th>
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<td><strong>Resources could include money, equipment, space and personnel.</strong></td>
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<tr>
<td>☒ Yes. ☐ No</td>
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<tr>
<td>☐ I don’t know</td>
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<tr>
<td>If yes, describe: Need for more space to house additional staff.</td>
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<th>Does this plan require permissions or expertise from outside the University to fully implement it?</th>
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<tr>
<td>☒ Yes. ☐ No</td>
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<tr>
<td>☐ I don’t know</td>
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<tr>
<td>If yes, describe: We will work with our research partners, Fairview and Gillette, to fully implement this plan.</td>
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<th>What challenges or barriers do you anticipate may be encountered during implementation? <em>(These aren’t deal breakers, but instead help us estimate time and energy needed)</em></th>
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| None, except the volume and pace of change.  
As the IRB toolkit (revised IRB tools and policies) is launched, additional time may be needed to adjust PAR tools, as needed, to facilitate QA and QI efforts. |
Human Research Protection Program (HRPP) Proposal to Address the Advancing Human Research Protections Implementation Plan:

Section 8 Monitoring of Studies

Background and Rationale

Creating a culture of compliance for meeting human research protection rules, regulations and laws requires a plan for evaluation of investigator performance as well as a plan for evaluation of IRB performance. These plans and the information gathered must be transparent to the HRPP community and integrated into education, training, and quality improvement activities throughout the enterprise. This plan covers both evaluation of investigator performance and evaluation of IRB performance.

The AHRP plan dedicates $300,000 in recurring funds to support additional PAR staff. The following plan assumes funding will remain for these new PAR positions. The AHC/CTSI has indicated a potential need for resources. AHC/CTSI intentions for use of those resources have been incorporated in the following plan for consideration by leadership reviewing AHRP final reports.

Program Review – Monitoring, Quality Assurance, Quality Improvement

University programs and review units play a key role in ensuring the protections of human research participants. Many of the activities that each program and review unit undertakes related to quality assurance (Figure 1) and quality improvement (Figure 2) intersect and require collaboration and transparent communication to ensure a cohesive HRPP.

![Figure 1. Investigator Performance (Quality Assurance)](image1)

![Figure 2. Organizational/Staff Performance (Quality Improvement)](image2)
Evaluation of investigator performance of research serves an important function in the protection of human subjects by ensuring investigator compliance with IRB requirements, regulatory requirements and institutional policy. As described in the Implementation Work Plan, the most effective way to determine whether clinical research studies are being performed in accord with requirements is to evaluate them after IRB approval.

Evaluation of investigator performance is best accomplished in a program that includes these activities:

- Quality Assurance (QA) is defined as “all those planned and systemic actions that are established to ensure that the trial is performed and data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s)” [ICH1.46];
- Monitoring is defined as “the act of overseeing the progress of a clinical trial, and ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s)” [ICH 1.38]; and
- Audit is defined as “a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor’s standard operating procedures (SOPs), GCP and the applicable regulatory requirement(s)” [ICH 1.6].

At the University of Minnesota, there are two primary mechanisms for conducting evaluation of investigator performance in the conduct of human subjects research: 1) The Post-Approval Review (PAR) quality assurance function that reports to the HRPP and Office of the Vice President for Research (OVPR); and 2) The Clinical Trial Monitoring Service that reports to the Clinical and Translational Science Institute (CTSI) and the Academic Health Center (AHC). Current human subjects compliance oversight programs at the University of Minnesota, including those noted above, are summarized in Appendix A.

PAR

The PAR function (under the auspices of OVPR) conducts quality assurance (QA) activities associated with investigator performance. The PAR function is an important component of the HRPP that evaluates regulatory compliance of investigators and improves investigator performance through a systematic and independent examination of trial related activities and documents.

PAR quality assurance efforts associated with investigator performance are guided by implementing a risk-based strategy, typically occur once during the life of a study and involve an independent,

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1 Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program-Work Plan, June 2015
systematic evaluation of study process and assessment of compliance at a moment in time. Information about findings of PAR quality assurance efforts associated with investigator performance are provided to a convened IRB for evaluation and determinations, if applicable, and to HRPP education and training staff for integration into workforce educational plans.

**CLINICAL TRIAL MONITORING SERVICE**

The Clinical Trial Monitoring Service (under the auspices of the AHC) performs clinical trial monitoring, defined in E6 GCP Consolidated Guidance, as the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s) and is an ongoing assessment through the life of the study.

Currently, the CTSI maintains a regulatory group in its Research Services division that provides monitoring services over the life of the study where it is required by the FDA and requested by the study sponsor. Consistent with 5.18.1 of E6 GCP Consolidated Guidance, the main purpose of monitoring activities performed by the Clinical Trial Monitoring Service is to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete and verifiable from source documents, and that the conduct of the trial is in compliance with the currently approved protocol as well as with GCP and other applicable regulatory requirements.

Investigators are required to submit monitoring reports, within 5 days of receipt, to the IRB for administrative review and, if required, review by a convened IRB.

In addition to the aforementioned and with sufficient institutional financial resourcing, the CTSI monitoring group will initiate a process where every biomedical study that is identified as greater than minimal risk will undergo a review with the investigator to provide a resource to the study team to ensure that they are aware of all regulatory activities that must occur throughout the study. In addition, these studies will have an annual review for assessment of adherence to regulatory requirements.

**QUALITY ASSURANCE – CLINICAL TRIAL MONITORING SERVICE**

Also in addition to providing ongoing monitoring activities the CTSI proposes to initiate a quality assurance (QA) initiative for the AHC with accountability directly to the VP for Health Sciences/Dean of the Medical School to ensure that monitoring services maintain the highest possible level of effectiveness and quality of service.

With sufficient institutional financial resourcing, the CTSI will be able to initiate a process where 10% of every individual monitor’s work will be reviewed to provide feedback and formulate a corrective action plan should that be required.

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2 Good Clinical Practice: Consolidated Guidance (ICH-E6): April 1996
While the functions of quality assurance review and clinical monitoring are separate and distinct; these functions can complement each other and create additive benefit to the overall quality and integrity of research at the University; thereby, encouraging a culture of compliance with the highest ethical standards for the conduct of research and promoting the protection of human research subjects.

To assure PAR and CTSI compliance, it is recommended that the Office of Internal Audits perform, on no less than an annual or bi-annual basis, a systematic and independent examination of a sample of PAR investigator performance evaluations as well as a sample of CTSI monitoring and quality assurance activities to insure each program is being carried out in compliance with stated plans and procedures.

This regular independent examination is essential for research that is highest risk to the institution. To ameliorate concerns about independence of quality assurance review, this plan suggests that PAR continue to select a sample of greater than minimal risk biomedical research studies for review under the PAR investigator performance review plan.

**IRB PERFORMANCE - QUALITY IMPROVEMENT**

In addition to evaluating investigator performance of research, evaluation of IRB performance is required to meet the Association for the Accreditation of Human Research Protection Programs standard 1-5:

**STANDARD I-5: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.**

Element I.5.A. The Organization conducts audits or surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization makes improvements to increase compliance, when necessary.

Element I.5.B. The Organization conducts audits or surveys or uses other methods to assess the quality, efficiency, and effectiveness of the Human Research Protection Program. The Organization identifies strengths and weaknesses of the Human Research Protection Program and makes improvements, when necessary, to increase the quality, efficiency, and effectiveness of the program.

PAR quality improvement efforts dedicated to the performance of the IRB will include evaluation activities required to meet AAHRPP requirements. New evaluation activities are underway and are documented in HRPP toolkit documents that will guide the transformation of all IRB processes.

The PAR quality improvement program will apply feedback received from the evaluations defined under the Accountability Metrics portion of the implementation plan. Information about PAR program quality improvement efforts will be reported to the Research Compliance Office. Information about the quality assurance activities performed by the Research Compliance Office will be shared with the IRB and will be integrated into IRB member and staff training initiatives. New resources defined in the implementation plan will allow the PAR quality improvement program to be implemented as described

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3 **Auditing vs Monitoring in Clinical Research Studies** (IMARC Research Group, 2015)
To address recommendations detailed in the External Panel’s Final Report and the Implementation Work Plan related to the PAR function, implementation of the following strategies is either underway or is recommended. For strategies that address a specific recommendation, the source of the recommendation has been identified within the section heading.

In addition to addressing recommendations in the External Panel’s Final Report and the Implementation Work Plan, this proposal goes beyond and recommends global changes to create an environment that will permit more effective evaluation of research by both the PAR program and the Clinical Trial Monitoring Service. The responsible authority(ies) for making a decision to implement these global changes is/are indicated in parentheses after each item.

**Recommendations for Global Changes:**

**a. Revise HRPP Requirements for Human Subjects Research**

i. Set selected sections of the International Council on Harmonisation Good Clinical Practice (ICH GCP) guidelines as the performance standard for researchers conducting greater than minimal risk biomedical research that meets the National Institutes of Health (NIH) definition of “clinical trial”;

(VPs for Research and Health Sciences)

ii. For device trials meeting the NIH definition of a clinical trial, apply, to the extent applicable and in addition to the ICH GCP guidelines referenced above, investigator performance expectations based on ISO 14155:2011 and/or 21 CFR 812;

(VP for Health Sciences, Clinical Trial Monitoring Service)

iii. Require CITI ICH GCP training for all research personnel listed on greater than minimal risk biomedical applications to the IRB;

(VP for Research, IRB)

iv. Require that investigators (or their designee) for all greater than minimal risk biomedical research that meets the NIH definition of “clinical trial”, enter study information, participant consent, and visits completed information in OnCore (whether the research requires Fairview or UMP services or not);

(VPs for Research and Health Sciences)

v. Eliminate the “register only” Investigational Drug Services (IDS) option for greater than minimal risk biomedical research involving one or more drugs, and require that IDS manage drug accountability and dispensing for research conducted on University or Fairview premises; and

(VPs for Research and Health Sciences)

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5 NIH Clinical Trial Definition: “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”

6 ISO 14155:2011 addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

7 21 CFR 812 Medical Device section of FDA regulations that addresses Investigational Device Exemptions.

8 Fairview Investigational Drug Service (IDS) is the pharmacy service responsible for managing and dispensing investigational drugs for Fairview Health Services and the Academic Health Center (AHC). When a Principal Investigator chooses to utilize IDS in the “Registration Only” capacity, it is her/his responsibility to ensure that all guidelines are met.
vi. Require that investigators present to the IRB a data and safety monitoring plan that includes independent (defined as independent of the research study team) clinical trial monitoring of all greater than minimal risk biomedical research that meets the NIH definition of “clinical trial”. Such research will not be approved by the IRB without an adequate plan for independent monitoring. *(VP for Research, IRB)*

**Recommendations for Clinical Trial Monitoring and Quality Assurance:**

a. **CTSI Clinical Trial Monitoring of Investigators to Evaluate Research Team Compliance**
   
i. Evaluate and update, as needed to conform to recommendations i-vi above, the current CTSI Monitoring Plan, SOP 212.1, to reflect the regulatory/guidance foundation for monitoring each item in the plan and indicate applicability of each item to interventional drug, interventional device, or other interventional or observational research. To include:
   
   1. Primary study endpoints;
   2. Protocol required safety assessments;
   3. Adherence to protocol eligibility criteria;
   4. Reporting events;
   5. Recruitment;
   6. Consent process; and
   7. Essential documents recordkeeping – including communication with the IRB.

   The extent and nature of actual CTSI clinical monitoring practices must also comply with guidance at E6 GCP 5.18.3. Monitoring frequency determinations should take into consideration the objective, purpose, design, complexity, blinding, size, and endpoints of the clinical trial. In general, there is a need for site monitoring before, during and after (meaning after all study assessments have been performed but prior to closure with the regulatory authority(ies) a clinical trial;

   ii. Based on FDA guidance, apply a risk-based selection approach to clinical trial monitoring of greater than minimal risk biomedical research that meets the NIH definition of “clinical trial”. Based on FDA guidance⁹, apply a risk-based selection approach to clinical trial monitoring of greater than minimal risk biomedical research that meets the NIH.

   iii. Clinical trial monitors will meet with every investigator conducting a greater than minimal risk biomedical study. The purpose is to ensure that they are aware of all regulatory activities that must occur throughout the study. In addition, these same studies that have enrolled subjects will have an annual review for assessment of adherence to regulatory requirements.

b. **CTSI Reporting of Clinical Trial Monitoring Activity**
   
i. Provide monitoring reports to investigators promptly after each visit

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(Investigators are required to promptly submit (within 5 business days) all monitoring reports to the IRB);

ii. Ensure immediate reporting of significant monitoring issues to appropriate entities or individuals with authority for oversight of human subjects research.

iii. CTSI will report clinical trial documentation concerns to the AHC VP; and

iv. CTSI will evaluate and update, as applicable, section 8 of the Clinical Monitoring SOP to ensure it accurately reflects current reporting responsibilities to entities or individuals with authority for oversight of human subjects research, to include the HRPP-IRB, OVPR-VP (to include the Research Compliance Office), AHC VP, and Fairview.

c. CTSI Reporting of Quality Assurance Activity

i. Evaluate 10% of every individual monitor’s work to provide feedback and to formulate a corrective action plan for the monitor should that be required. CTSI will provide quarterly reports of quality assurance activities to entities or individuals with authority for oversight of human subjects research, to include the HRPP-IRB, OVPR-VP (to include the Research Compliance Office), AHC VP, and Fairview.

2) Recommendations for Post Approval Review of Investigator Performance and Quality Assurance

(External Panel Report 3.3.18, 3.3.19, 3.3.20, & 3.3.22; Work Plan pages 28 & 29)

a. Evaluating Investigator Performance:

i. Implement a risk-based selection process (see Table 1) to conduct quality assurance review on greater than minimal risk research:

• 10% of all active studies approved by the U of M IRB that are enrolling or following subjects that will not otherwise be QA reviewed by another institutional group (approximately 85 biomedical studies; approximately 30 social and behavioral). PAR will also perform QA review of investigator performance at the request and direction of a convened IRB for protocols that include vulnerable populations or participants who may lack capacity to consent or research that involves LARs or any other research a convened IRB requests PAR to review;

ii. Implement a risk-based selection process to conduct quality assurance reviews on not greater than minimal risk research:

• 5% of active studies approved by the U of M IRB via expedited review that are enrolling or following subjects (approximately 150 studies);

iii. Conduct quality assurance review on 2.5% of active exempt studies (approximately 175 studies);

iv. Implement risk-based selection process to conduct quality assurance reviews on research studies enrolling or following subjects where review has been ceded to another institution

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v. Hire two QA staff with Association of Clinical Research Professionals Clinical Research Associate certification\(^{11}\) and at least five years of experience evaluating investigator performance on drug and device trials if QA review of greater than minimal risk biomedical research remains with PAR; hire one QA staff person with previous IRB experience if QA function for greater than minimal risk biomedical research will reside with CTSI/AHC;

vi. Conduct review, as appropriate, to verify investigator execution of corrective actions and to ensure no re-occurrence of non-compliance or research concerns;

vii. Review, evaluate and respond to incoming communication from research participants or others related to the conduct of research. Escalate concerns, at the direction of the IRB, to the Research Compliance Office (RCO) or other responsible entity; and

viii. Implement a risk-based selection process to conduct quality assurance review of informed consent via two primary mechanisms\(^{12}\):

1. **Direct Observation:**
   a. IRB directed quality assurance review of high risk studies (e.g. subjects with diminished capacity) will be conducted in-person. A systematic process will be established and is intended to be supportive to the research team while facilitating an enhanced dialogue between the person obtaining consent and the participant and, when applicable, their legally authorized representative (LAR); and
   b. Review video-recorded consent discussions, when applicable, and provide feedback to investigators.

2. **Retrospective Strategies:**
   a. Conduct systematic evaluation of signed consent materials;
   b. Conduct post-consent interviews or administer questionnaires with research subjects using, whenever possible, validated tools (e.g. Brief Informed Consent Evaluation Protocol (BICEP)); and
   c. Conduct evaluation of investigator submitted Report Form that include errors/deviations associated with the informed consent process.

---

\(^{11}\) A clinical research associate (CRA), regardless of job title, supervises, monitors, and supports the administration and progress of a clinical trial.

\(^{12}\) A Pilot associated with consent auditing was initiated in May of 2016 to prepare for execution of QA efforts associated evaluating informed consent via the identified mechanisms. An executive summary of these efforts is attached.
Table 1. GUIDE TO RISK BASED SELECTION

<table>
<thead>
<tr>
<th>PROTOCOL ATTRIBUTES</th>
<th>POTENTIALLY HIGH RISK</th>
<th>POTENTIALLY MODERATE RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator initiated trials</td>
<td>X</td>
<td></td>
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<tr>
<td>Vulnerable populations targeted</td>
<td>X</td>
<td></td>
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<tr>
<td>IND or IDE</td>
<td>X</td>
<td></td>
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<tr>
<td>Phase I Studies</td>
<td>X</td>
<td></td>
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<tr>
<td>Complex requirements/design</td>
<td>X</td>
<td></td>
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<tr>
<td>Phase II, III studies</td>
<td></td>
<td>X</td>
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<tr>
<td>Research conducted in Fairview patients or space</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Device NSR studies</td>
<td>X</td>
<td></td>
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<tr>
<td>Federal Funding</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Relative Safety of the Investigational Product</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

PI ATTRIBUTES

| IRB found serious or continuing non-compliance in the last 3 years | X |
| High number of greater than minimal risk studies actively enrolling/following subjects | X |
| No assistance from trained research coordinator                  | X |
| High number of active studies                                    | X |
| High number of protocol deviations submitted                    | X |

b. Encouraging Investigator Performance

i. Create additional self-assessment tools and processes to help investigators evaluate their own performance (3.3.22)

1. Investigator Self-Assessments:
   a. Create voluntary self-assessment tools for Investigators to use to assess their compliance with federal and institutional requirements regarding research with human subjects;
   b. Create voluntary self-assessment tools specific to the informed consent process and the inclusion of vulnerable subjects to facilitate investigator compliance with institutional and regulatory requirements;
   c. Create tools/checklists to assist Investigators in preparation for inspections by federal entity(s); and
   d. Develop templates for investigators to voluntarily use during completion of a study to facilitate systematic collection/documentation of required elements (e.g. protocol template).

2. Direct Investigator Support:
   a. At the direction of the IRB, PAR staff will meet directly with researchers to provide guidance navigating IRB requirements
and IRB submission expectations; and

b. PAR staff will work directly with appropriate units to create comprehensive corrective and preventive strategies when problems or concerns related to non-compliance have been identified by the PAR program.

c. **Reporting Post-Approval Evaluation of Investigator Performance (3.3.19 and 3.3.20)**
   i. Department heads will be copied on all correspondence to investigators undergoing on-site Post Approval Review;
   ii. Advisory groups previously defined will contribute to developing the communication plan for summary reports of findings and other activities. Principles of transparency in communicating results (negative and positive) and accountability (of recipients) in following through will be applied;
   iii. The Research Compliance Office (RCO) will receive no less than quarterly reports (for the previous quarter) at these intervals (July, October, January, April). The RCO will share these reports with the following groups:
      1. Academic leaders: department chairs, Dean of the Medical School, Counsel of Research Associate Deans (CRAD);
      2. Research oversight groups: FUROC, OVPR Research Compliance Office, IRB; and
   iv. Prompt reporting to appropriate UMN authorities and research partners will occur if significant human subject protection issues are observed during completion of PAR reviews or if such issues are reported via existing confidential reporting lines.
   v. Research deans, department chairs, center directors, and research partners will each bear responsibility for dissemination of this information to their respective communities. Fairview, UMP and Gillette should ensure that appropriate information about investigator performance is available to the clinical care community. Academic leadership will be held accountable for making sure corrective measures are instituted when investigator/research team performance is at issue.

3) **Recommendations for PAR Contributions to IRB Quality Improvement:**
   (External Panel Report 3.3.21; Work Plan pgs. 28 & 29)

   a. **Evaluating IRB Performance [need to append the SOPs from the toolkit]**
      i. Review activities will be conducted to assess compliance with organizational policies and procedures and applicable laws, regulations, codes and guidance. Examples of quality assurance activities include review of:
         1. Consistency and appropriateness of IRB determinations;
         2. IRB meeting documentation/minutes;
         3. General IRB documentation; and
         4. IRB membership
      ii. Routine evaluation of IRB metrics (e.g. turnaround times, volume metrics,
etc.) will be conducted to identify strengths and weaknesses.

b. Encouraging IRB Performance:
   i. Quality improvement activities will be conducted to assess the quality, efficiency and effectiveness of the IRB. When necessary, improvements will be implemented to increase the quality, efficiency and effectiveness of the IRB. Examples of quality improvement activities include:
      1. Work with IRB leadership to connect turnaround times to staff performance and conduct re-training when necessary;
      2. Conduct surveys, such as the investigator final approval survey or other survey, to identify and recommend improvements to IRB policies, procedures or guidelines; and
      3. Work with leadership to implement improvements, when necessary, to provide support to IRB membership.

c. Reporting Post Approval Review of IRB Performance
   i. The following stakeholders will receive no less than quarterly reports (for the previous quarter) at these intervals (July, October, January, April):
      1. Research oversight groups: Office of Internal Audits, Research Compliance Office; and
      2. Institutional Official
   ii. In addition, PAR findings and trends will be used for training and education of IRB members and staff as it may inform risk analysis of individual submissions.
   iii. Monthly reports of selected PAR activities will be reported to membership and OVPR leadership in accord with HRPP Monthly Reporting Policy.
## Appendix A – Key Programs Overview

### Overview of Key Programs within the University that Gather Information About Compliance of Human Subjects Research

<table>
<thead>
<tr>
<th>Program</th>
<th>Scope of Reviews</th>
<th>Regulatory</th>
<th>Other</th>
</tr>
</thead>
</table>
| **Post Approval Review:** Provides internal oversight on compliance issues associated human subjects research and provides a mechanism for assuring the quality of human studies | - IRB Approved Research with Human Subjects  
  - Evaluation of IRB Performance  
  - QA/QI Activities related to IRB and investigators’ performance | - 45 CFR 46   
  - 21 CFR Parts 50 and 56   
  - 32 CFR 219   
  - Terms of the Federalwide Assurance (FWA)   
  - Belmont Report   
  - ICH GCP Guidance (E6) for applicable studies | - AAHRPP Accreditation Standards 1-5 (A-D)   
  - OHRP QA Self-Assessment   
  - IRB Guidebook 1993   
  - FDA Information Sheets: Self-Evaluation Checklist for IRBs |
| **CTSI Quality Assurance and Clinical Trials Monitoring:** Evaluates quality and effectiveness of clinical trial monitoring service and assists | - Sponsor Investigator Research subject to FDA regulations  
  - Clinical Research in Department of Psychiatry Research | - ICH Good Clinical Practice Guidelines (E6) (5.18- Good Clinical Practice: Consolidated Guidance; Monitoring  
  - FDA Guidelines & Regulations | - CTSA Grant   
  - VP Health Sciences Requirements |
| **Research Compliance Office:** Responsible for conducting for-cause investigations related to research compliance concerns and for monitoring follow through on any concerns | - For-cause investigations associated with research compliance concerns  
  - Complaints  
  - Defining accountability metrics and performing quality assurance oversight of regulatory offices reporting to OVPR | | | |
| **Office of Internal Audits:** The mission of the Office of Internal Audit is to provide independent, objective assurance and advisory services designed to add value and improve the quality of the University | - Includes within its scope all activity posing financial, operational, technological, regulatory or reputational risk to the University | - State and Federal Law | - Board of Regents Policy   
  - President   
  - University Policy |
<table>
<thead>
<tr>
<th>Office of Institutional Compliance: The University Compliance Program was established to serve, safeguard and promote</th>
<th>-Provides independent and centralized oversight over the University’s compliance risk areas</th>
<th>-Board of Regents Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Protocol Review Committee: The Cancer Protocol Review Committee's (CPRC) mission is to evaluate, approve or reject, monitor, and re-review on an annual basis all</td>
<td>-Responsibility for scientific review and prioritization of cancer related research.</td>
<td>-NCI Grant</td>
</tr>
<tr>
<td>Research Misconduct:</td>
<td>-The Research Integrity Officer for the University pursuant to federal regulations will coordinate the review of the allegation of research misconduct in stages defined in UMN Policy.</td>
<td>-UMN Policy</td>
</tr>
</tbody>
</table>
1.0 Reason for Policy

This policy describes the regulatory requirements and accreditations standards requiring post approval review (PAR) and procedures associated with this program.

2.0 Scope of Policy
This policy applies to the University community and its research partners.

3.1 Policy Statement

Program Rationale:

The purpose of the PAR program is to provide internal oversight on compliance issues associated with the performance of human subjects research conducted at the University. The PAR program is also intended to provide a mechanism for assuring the quality of human subjects’ research. Regulatory guidance and Accreditation standards guiding these efforts include the following:

- Continuing review responsibilities: The IRB is appointed with the authority to determine which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

- Provisions of the Federalwide Assurance: The Institution and the designated IRB(s) must establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that researchers, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with relevant federal regulations; written IRB procedures; OHRP guidance; other applicable guidance, state and local laws; and institutional policies for the protection of human subjects.

- Accreditation standards: The IRB must measure and improve, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance and measure and improve, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.

HRPP Post Approval Review (PAR) Activities:

Evaluating Investigator Performance:

A risk-based selection process is implemented to conduct quality assurance reviews of investigator performance in an appropriate proportion of studies from the following key areas:

- Active greater than minimal risk studies approved by the U of M IRB that are enrolling or following subjects;
- Active not greater than minimal risk research studies approved by the U of M IRB via expedited review that are enrolling or following subjects;
- Active exempt studies;
- Research studies enrolling or following subjects where review has been ceded to another institution; and
- Informed consent practices via direct observation or, for not greater than minimal risk studies via retrospective strategies.

At the time of initial approval, the IRB shall determine if a greater than minimal risk research protocol should be evaluated by PAR during the first year of activity. In addition, when appropriate, PAR will
also conduct reviews to validate corrective actions implemented by investigators when problems have occurred.

**Encouraging Investigator Performance**

PAR creates self-assessment tools and processes to help investigators evaluate their own performance during the preparation for and conduct of research. Examples of PAR efforts to encourage investigator performance include:

- Creation of voluntary self-assessment tools for Investigators to use to assess their compliance with federal and institutional requirements regarding research with human subjects;
- Creation of tools/checklists to assist Investigators in preparation for inspections by federal entity(s); and
- Develop templates for investigators to voluntarily use during completion of a study to facilitate systematic collection/documentation of required elements (e.g. protocol template).

In addition, PAR works directly with investigators during the creation of comprehensive corrective and preventive strategies when problems or concerns related to non-compliance have been identified.

**Evaluating IRB Performance**

Quality assurance activities are conducted to assess compliance with organizational policies and procedures and applicable laws, regulations, codes and guidance. Examples of quality assurance activities associated with IRB performance:

- Consistency and appropriateness of IRB determinations;
- IRB meeting documentation/minutes;
- General IRB documentation; and
- IRB membership

In addition, PAR routinely evaluates IRB metrics (e.g. turnaround times, volume metrics, etc) to identify strengths and weaknesses.

**Encouraging IRB Performance:**

Quality improvement activities are conducted to assess the quality, efficiency and effectiveness of the IRB. When necessary, improvements are implemented to increase the quality, efficiency and effectiveness of the IRB. Examples of quality improvement activities include:

- Work with IRB leadership to connect turnaround times to staff performance and conduct re-training when necessary;
- Conduct surveys, such as the investigator final approval survey or IRB RAT survey, to identify and recommend improvements to IRB policies, procedures or guidelines; and
- Work with leadership to implement improvements, when necessary, to provide support to IRB membership.

**Additional PAR activities**

In addition to the QA/QI activities noted above, PAR performs the following:

- Manages, monitors, and promptly responds to inquiries made to the Research Subject Advocate
Telephone Line or via the online Feedback Form.

- Provides support to the IRB or other oversight committee (e.g. Research Compliance Office) during the conduct of for-cause reviews.

**Reporting Post Approval Review of IRB Performance**

Department heads will be copied on all correspondence to investigators undergoing on-site Post Approval Review. PAR reports associated with evaluation of investigator performance are forwarded to the IRB for assessment and determination. The IRB follows respective policies if PAR reports include findings of serious and/or continuing non-compliance.

Reports identifying compliance concerns require prompt corrective action by the PI. Prompt reporting to appropriate UMN authorities and research partners (e.g. Fairview) will occur in accord with reporting policies if significant human subject protection issues are observed during completion of PAR reviews or if such issues are reported via existing confidential reporting lines.

The following stakeholders will receive no less than quarterly reports of PAR activities:

- Academic leaders: department chairs, Dean of the Medical School, Counsel of Research Associate Deans (CRAD);
- Research oversight groups: FUROC, OVPR Research Compliance Office (RCO), IRB; and
- Research partners: Fairview, Gillette.

In addition, the PAR team will work closely with RCO to provide accountability metrics to facilitate reporting by that oversight function to key stakeholders.

Research deans, department chairs, center directors, and research partners will each bear responsibility for dissemination of information to their respective communities.

Monthly reports of selected PAR activities will be reported to membership and OVPR leadership in accord with HRPP Monthly Reporting Policy. In addition, PAR findings and trends will be used for training and education of IRB members and staff as it may inform risk analysis of individual submissions.

### 4.0 Required approvals for this document

<table>
<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>Executive Director, HRPP</td>
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</table>

### 5.1 Revision History

<table>
<thead>
<tr>
<th>Revision</th>
<th>Reason for change</th>
<th>Date of release</th>
</tr>
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<tbody>
<tr>
<td>05/29/16</td>
<td>Revisions to implement recommendations detailed the UMN work plan</td>
<td>06/30/16</td>
</tr>
<tr>
<td>06/04/14</td>
<td>Slight revision in prep for AAHRPP</td>
<td>09/02/14</td>
</tr>
<tr>
<td>05/20/13</td>
<td>Revisions</td>
<td>07/25/13</td>
</tr>
<tr>
<td>Date</td>
<td>Change Description</td>
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<tr>
<td>11/11/10</td>
<td>Reorganization of functions</td>
<td>11/19/10</td>
</tr>
<tr>
<td>11/02/09</td>
<td>Update AAHRPP reference</td>
<td>11/02/09</td>
</tr>
<tr>
<td>08/26/09</td>
<td>Revisions</td>
<td>08/26/09</td>
</tr>
<tr>
<td>07/10/09</td>
<td>Revisions, reformat</td>
<td></td>
</tr>
<tr>
<td>09/29/06</td>
<td>Policy development</td>
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</tbody>
</table>

To obtain a copy of a historical policy, e-mail IRB at irb@umn.edu or call 612-626-5654
Post Approval Review

Under the direction of the Vice President for Research and the IRB Executive Committee, the continuing review procedures of the IRB have been expanded to include a Post Approval Review (PAR) function. This function is housed within the Human Research Protection Program (HRPP) office, the administrative home of the IRB. The PAR component of HRPP is designed to enhance the oversight of approved research involving human subjects and provide a mechanism for assuring the quality of our human subjects research. HRPP will utilize post approval reviews to direct its quality improvement and educational initiatives.

Continuous Improvement

IRB staff members are developing mechanisms and methods to assist researchers in meeting the continuous review requirements set by the IRB. These will include researcher self-assessment tools, on-site interviews, research records review, and other collaborative activities to measure and improve the quality, effectiveness, and efficiency of human subjects research approved by the IRB. The reviews are IRB-focused and will not duplicate the reviews conducted by internal or external monitors, auditors, or regulatory personnel. Results of the reviews are shared with the convened IRB and the IRB determines whether action is needed on any observations or areas of concern identified through the PAR process. Researchers can expect to receive written notice from the IRB following a review. Researchers are encouraged to contact staff with any concerns or suggestions regarding the HRPP processes or IRB reviews.

Background

For more on the regulations, guidance, and accreditation requirements for this program, download Post Approval Review Background.

For information regarding the risk-based selection of studies, download the following table:

To ask a question or to request a self-assessment guide or an onsite review, contact irb@umn.edu.

<table>
<thead>
<tr>
<th>Table 1.</th>
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PI ATTRIBUTES
| IRB found serious or continuing non-compliance in the last 3 years | X |
| High number of greater than minimal risk studies actively enrolling-following subjects | X |
| No assistance from trained research coordinator | X |
| High number of active studies | X |
| High number of protocol deviations submitted | X |
HRPP Actions to Address the
Advancing Human Research Protections Implementation Plan:
Section 8 Monitoring of Studies - Consent Auditing Pilot Phase

Executive Summary
May 31, 2016
(Note progress updates in green as of 06.27.2016)

Context
The need for enhanced auditing of the consent process is addressed in the Advancing Human Research Protection Implementation Work Plan (Work Plan)¹ and in the PAR Monitoring Proposal Draft (submitted with this document), which has been revised in response to recommendations detailed in both the External Panel’s Final Report² and the Work Plan.

Section 8 of the Work Plan states:

*Live consent monitoring should be a part of this [PAR monitoring] model with patient consent. The process would include: memorializing the interaction by recording, preferably by video; monitoring the process; and contributing to capacity assessment and consent via dialogue between the investigator and the consent monitor.*

The PAR Monitoring Proposal Draft calls for:

-Implementing a risk-based selection process to conduct quality assurance review of informed consent via two primary mechanisms:
  1. Direct Observation (either in-person or video-recorded) at the direction of the IRB, based on risk.
  2. Retrospective Strategies including records review, post-consent interviews/questionnaires, and evaluation of investigator-submitted Report Forms related to consent.

-Creating voluntary self-assessment tools specific to the informed consent process and the inclusion of vulnerable subjects to facilitate investigator compliance with institutional and regulatory requirements.

In response to the above, PAR is developing a comprehensive plan for consent auditing. In order to ensure that this plan is informed, robust, and viable, PAR team members conducted the following activities:

- Online research regarding how other institutions are addressing these issues.
- Literary review of articles examining a variety of approaches to informed consent evaluation.
- Benchmarking with members of the Committee on Institutional Cooperation and the Compliance Network Group (a group of post-approval compliance professionals from CIC member institutions and others) regarding consent auditing practices, including direct observation of the consent discussion.
- Consultation with key stakeholders, including IRB members.
- Participation on the Engaging Research Participants Work Group, including work on consent and community engagement.

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Pilot Phase

On May 11th, the PAR team began a pilot phase for auditing consent, which will continue through the end of June. The primary objectives of this phase are: 1) test out a number of approaches, including both direct observation strategies and retrospective strategies, and 2) refine and develop related tools (such as the Checklist for Consent Observation). Insights gained during the pilot phase will help to guide the development of robust and viable processes, procedures, and tools for auditing consent at the University of Minnesota.

Key Activities to Date:
- Communicated with all current IRB members with active, enrolling studies requesting their assistance in providing opportunities for PAR staff to practice consent auditing activities, particularly live observation of the consent discussion.
- Initiated live consent observation
- Observed online videos to test the use of the Checklist for Consent Observation with recorded consent discussions. (Due to participant confidentiality concerns, the PAR team does not plan to conduct observation of video-recorded consent discussions during the pilot phase.)
- Disseminated information about consent auditing to approximately 150 members of the UMN research community via HRPP Newsletter.
- Developed talking points for study team members to use in conversations with participants regarding consent auditing activities (for example, requesting permission from a participant for their consent discussion to be observed).
- Developed documentation of consent-auditing activities to be provided to study teams for addition to regulatory binders.
- Created template for PAR reporting of consent auditing findings to the IRB.
- Initiated data collection on investigator-submitted Report Forms involving informed consent process errors/deviations.

Upcoming Activities: (updates in green as of 6/27/2016)
- Conduct additional consent observations Four live consent observations have been conducted to date.
- Work with Huron Consulting Group as applicable to ensure seamless integration of consent auditing plans with IRB Toolkit
- Conduct consent-focused site visits, including evaluation of signed consent materials (see attached: Retrospective Audit of Consent and HIPAA DRAFT)
- Practice utilizing validated post-consent questionnaire/interview tools (e.g. BICEP)
- Refine process and tool/s for consent auditing The following have been drafted (see attached):
  - SOP for Observation of Consent, along with related tool:
    - Checklist for Consent Observation
  - SOP for Recording Research Participants, along with related form:
    - Permission to Record for Consent Observation - to be signed by prospective participants in advance of the consent meeting
  - Materials related to reporting consent audit observations:
    - Documentation of Consent Audit - to serve as documentation of audit for study files and to provide summary feedback & determination to PI/consenter
    - Report Template for Consent Auditing - to be used for reporting back to the IRB
    - Consent Auditing Metrics and Reporting Plan
  - SOP for Post-Consent Interviews/Questionnaires
- Develop consent-focused self-assessment
- Create plan for providing feedback to investigators / consenters As noted above, a Documentation of Consent
Audit sheet has been developed. This could be used to provide feedback to PIs/consenters. The specific process for this feedback loop is still being determined.

- Develop recommendations to address participant confidentiality concerns related to video-recording consent discussions. As noted above, an SOP for Recording Research Participants and a Permission to Record for Consent Observation form have been drafted. Both the SOP and the form address confidentiality issues, however there are a number of specifics still being ironed out.
- Develop decision-making matrix to identify studies that require direct observation of consent in alignment with IRB Policy: Adults with Potentially Absent, Potentially Diminished, or Potentially Fluctuating Capacity to Consent to Participation in Research. A decision-making matrix tool has been drafted (see attached).

Deliverables

At the completion of the Pilot Phase, a plan for ongoing consent auditing will be delivered, as a section of the PAR Monitoring SOP. This will include:

- Procedures for all consent auditing activities. As noted above, SOPs for Observation of Consent, for Recording Research Participants, and for Post-Consent Interviews/Questionnaires have been drafted. Additional consent auditing approaches (site visits/records review and self-assessments) will be covered by the general SOPS for those activities.
- A decision-making matrix for determining the level/method of consent auditing required for a given study or consent process. Key factors will be level of risk, anticipated capacity of participants, and history of PI non-compliance. As noted above, a decision-making matrix has been drafted.
- A plan for collecting and utilizing consent auditing data. As noted above, a Consent Auditing Metrics and Reporting Plan has been drafted. Work on a spreadsheet for gathering consent observation data has begun.

Attachments

The following documents are attached:

- Retrospective Audit of Consent and HIPAA 05.31.16 (DRAFT)
- HRP-012 – SOP: Observation of Consent (DRAFT)
- Checklist for Consent Observation (DRAFT)
- HRP-XXX – SOP: Recording Research Participants (DRAFT)
- Permission to Record for Consent Observation form (DRAFT)
- Documentation of Consent Audit form (DRAFT)
- Report Template for Consent Auditing (DRAFT)
- Consent Auditing Metrics and Reporting Plan (DRAFT)
- HRP-XXX – SOP: Post-Consent Interviews/Questionnaires (DRAFT)
- Decision-Making Matrix for Consent Auditing (DRAFT)
<table>
<thead>
<tr>
<th><strong>IRB #</strong></th>
<th><strong>Auditor Name(s)</strong></th>
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<tr>
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<td><strong>PI Name</strong></td>
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<td><strong>Number of participants reviewed</strong></td>
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<td><strong>Percentage of total participants reviewed</strong></td>
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<td><strong>Reason for audit</strong></td>
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<td><strong>Name(s) of research staff involved in review</strong></td>
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<td><strong>Role in study</strong></td>
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<td><strong>Documents reviewed</strong></td>
<td>Consent Plan</td>
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<tr>
<td>List of study team members</td>
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<tr>
<td>List of all consented participants</td>
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<tr>
<td>Participant consent documents</td>
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</tbody>
</table>
2. Study Overview

Study Overview & Consent Plan Summary
### 3. Versions of consent

<table>
<thead>
<tr>
<th>Type of form</th>
<th>Signed by</th>
<th>Version number or date</th>
<th>IRB approval letter date</th>
<th>Includes all applicable elements - See Required consent elements</th>
<th>Comments</th>
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</table>
4. Required elements Consent

<table>
<thead>
<tr>
<th>CONSENT ELEMENTS</th>
<th>Version date or number</th>
<th>Version date or number</th>
<th>Version date or number</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Y - N - N/A</td>
<td>Y - N - N/A</td>
<td>Y - N - N/A</td>
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</table>

The PI is identified.
The affiliation with the University of Minnesota is identified.
The consent is understandable at an 8th grade level.
The study sponsor is identified.
The drug manufacturer is identified.

46 CFR 46.116. The following information shall be provided to each subject:
Study involves research.
Explanation of purposes.
Expected duration of participation.
Procedures.
Identification of procedures that are experimental.
Risks or discomforts.
Any benefits to the subject or others.
8. Alternatives (Required by UMN for treatment studies).
9. Standard language about injury/compensation (For greater than minimal risk).
10. Extent to which confidentiality will be maintained.
11. The Food and Drug Administration (FDA) may inspect your records (FDA-regulated research).
12. Participation is voluntary.
13. Subjects can withdraw at any time.
14. Refusal involves no penalty or loss of benefits.
15. Contact for research-related questions.
16. Contact for research subjects’ rights.
17. Contact in case of research-related injury.

ASSENT FORM
The assent form is no more than 1-2 pages.
The language is simple and the sentences are short.

ADDITIONAL ELEMENTS OF CONSENT (46 CFR 46.118 & 21 CFR 50.24)
The particular treatment or procedure may involve risks to the subject or to the embryo or fetus, if the subject is or may become pregnant which are currently unforeseeable.
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
Any additional costs to the subject that may result from participation in the research.
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
The approximate number of subjects involved in the study.
The amount and schedule of all payments.

OPTIONAL FOR CLINICAL TRIALS (ICH GUIDANCE FOR INDUSTRY1 E6 Good Clinical Practice)
This study was approved by the Institutional Review Board (IRB) at the University of Minnesota.
A description of the probability for random assignment to each treatment.
The subject's responsibilities.
Risks or inconveniences to an embryo, fetus, or nursing infant.

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<tr>
<th></th>
<th>NA</th>
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<tbody>
<tr>
<td>There is no intended clinical benefit to you as a result of participating in this research study.</td>
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<tr>
<td>Monitors, auditors, IRB, and regulatory authorities will be granted direct access to your original medical records in order to verify clinical trial procedures and data, to the extent permitted by applicable laws and regulations. This will not violate your confidentiality. By signing the consent document, you are authorizing such access.</td>
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<td>If the results of the trial are published, your identity will remain confidential.</td>
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</table>
### 5. Required elements HIPAA

<table>
<thead>
<tr>
<th>HIPAA ELEMENTS</th>
<th>Version date or number</th>
<th>Version date or number</th>
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<tbody>
<tr>
<td>1. The PI is identified.</td>
<td>Y - N - N/A</td>
<td>Y - N - N/A</td>
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<td>1. Title of the study</td>
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<td>1. IRB number</td>
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<td>2. Individual health information</td>
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<td>4. Name of the researcher</td>
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<td>6. Researcher's name and address</td>
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### 6. Documentation of Consent

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<th>Capacity to consent documented</th>
<th>Type of form</th>
<th>Signed by Correct signature present</th>
<th>Date signed</th>
<th>Consenter signature</th>
<th>Date consenter signed</th>
<th>Signed &amp; consenter signed same day</th>
<th>Date screening/study procedures began</th>
<th>Study procedures began after signed</th>
<th>The version currently approved at time of consent</th>
<th>The version that was signed</th>
<th>Correct version was signed</th>
<th>Comments</th>
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7. Documentation of HIPAA

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<th>Participant ID</th>
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<tr>
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<th>Category</th>
<th>Issues identified</th>
<th>Corrective actions</th>
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8. Results
### 9. Summary

<p>| General description of the scope of the review |  |
| Summary statement to put the number of issues found in the context of the scope of the review |  |
| Unresolved items from prior reports, whether and how they have been resolved, there are no unresolved items from prior reports, or there are no prior reports. |  |
| Summary and conclusions |  |
| Recommendations for committee discussion |  |</p>
<table>
<thead>
<tr>
<th>Type of form</th>
<th>Type of form</th>
<th>Subject</th>
<th>Notes</th>
<th>Reason for audit</th>
<th>Current Study Status</th>
<th>Original level of review</th>
<th>Role in study</th>
<th>Additional Info needed</th>
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<td>Yes</td>
<td>Screening only</td>
<td>Adult</td>
<td>Enrollment Subjects</td>
<td>Principal Investigator</td>
<td>PI retained original signed form</td>
<td>Consent process is one page, not just signature page</td>
</tr>
<tr>
<td>Consent - Current</td>
<td>Minor</td>
<td>No</td>
<td>Unknown</td>
<td>Minor</td>
<td>Enrollment Subjects</td>
<td>Principal Investigator</td>
<td>PI retained original signed form</td>
<td>Consent process is one page, not just signature page</td>
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<tr>
<td>HIPAA - Current</td>
<td>Parent/Guardian</td>
<td>No</td>
<td>Unknown</td>
<td>Adult</td>
<td>Enrollment Subjects</td>
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<td>PI retained original signed form</td>
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<td>Permission - Current</td>
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<tr>
<td>Short form - Current</td>
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<td>Yes</td>
<td>Discontinued</td>
<td>Complete</td>
<td>Discontinued</td>
<td>Principal Investigator</td>
<td>PI retained original signed form</td>
<td>Consent process is one page, not just signature page</td>
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</table>

Consent - Past:
- Evaluation of capacity to consent
- Witness re-consented as required
- Consent forms used free of any changes or handwritten corrections
- Issues were not pre-dated or pre-signed
- Signatories are on staff list
- There is a consent form for each participant
- Evaluation of capacity to consent
1 PURPOSE and SCOPE
1.1 This procedure establishes the process to observe the meeting at which the Informed Consent Document is signed (consent meeting).
1.2 The process begins when the IRB determines that a consent meeting should be observed.
1.3 The process ends when the consent meeting has been observed, related follow-up and documentation has been completed, and the IRB determines that the matter is closed.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Not applicable.

3 POLICY
3.1 Observation of the consent meeting may be conducted when:
   3.1.1 The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB review (quality assurance).
   3.1.2 There are allegations or findings of non-compliance (for-cause).
   3.1.3 The nature of the research indicates that consent observation is warranted (risk-based).
3.2 The IRB, Institutional Official, or designee determines who conducts the observation. The observation may be conducted by:
   3.2.1 Post Approval Review team members
   3.2.2 IRB members
   3.2.3 Independent individuals hired by the IRB, but paid for by the investigator’s funds.

4 RESPONSIBILITIES
4.1 The individual designated to conduct the consent observation (observer) carries out these procedures.

5 PROCEDURE
5.1 Send notification to the Principal Investigator (PI).
5.2 Provide the person obtaining consent (consenter) with communication points for discussing consent observation with the prospective participant or their Legally Authorized Representative (participant/LAR).
5.3 Live observation is preferable. However, the observation may also be completed using a recording of the consent meeting. For live observation, the participant/LAR must give verbal permission. For observation of a recorded consent meeting, the participant/LAR must give written permission prior to recording. Follow HRP – XXX – SOP: Recording Research Participants (in addition to this policy).
   5.3.1 If the participant/LAR declines to give permission for live or recorded observation, the following alternatives may be presented:
      5.3.1.1 Post-consent meeting questionnaire to be filled out by the participant/LAR, using a standardized tool (see HRP – XXX – SOP: Post-Consent Interviews / Questionnaires).
      5.3.1.2 Post-consent meeting phone interview of participant/LAR conducted by observer, using a standardized tool see HRP – XXX – SOP: Post Consent Interviews / Questionnaires).
   5.3.2 If the participant/LAR declines participation in any of the above, or if the PI feels strongly that any of the above options would negatively affect the consent process, the PI may submit an alternate plan to ensure a robust consent process. This plan should include a rationale
for not using the above options. This alternate plan will be presented to the IRB for review and approval.

5.4 Work with the consenter to prepare for the observation. In advance of the consent meeting, provide the consenter with a copy of the evaluation tool (Checklist for Consent Observation), and confirm the following:

5.4.1 Who is being consented (participant, legal Guardian, LAR)
5.4.2 That the participant meets the inclusion criteria for the study.
5.4.3 The version date/s of the Consent Form and any other forms to be used.
5.4.4 Whether any special circumstances apply, including: capacity to consent, LAR, assent, participant does not speak English, participant is not able to read/write/talk.

5.5 Observe the consent process and determine whether the information in the Consent Form and any other written information was accurately explained to, and apparently understood by, the Participant/LAR, and that informed consent was freely given by the Participant/LAR.

5.5.1 If yes, document in writing that the consent meeting was observed and that informed consent was properly obtained.
5.5.2 If no, document in writing that consent is not legally effective and the prospective participant may not be entered into the research study.

5.6 Provide documentation of consent observation and determination to the PI (Documentation of Consent Audit).

5.7 If consent was not properly obtained, promptly submit a written report to the IRB for review and corrective action. Follow up as directed by the IRB until the matter is determined by the IRB to be closed.

5.8 Record consent observation data for metrics and reporting purposes. Written reports of consent observation activities will be submitted to the IRB on a regular basis.

6 MATERIALS
6.1 Checklist for Consent Observation
6.2 Documentation of Consent Audit

7 REFERENCES
7.1 HRP – XXX – SOP: PAR Monitoring
7.2 HRP – XXX – SOP: Recording Research Participants
7.3 HRP – XXX – SOP: Post-Consent Interviews/Questionnaires
7.4 HRP – XXX – SOP: Self-assessments
Checklist for Consent Observation\(^1\)

(Live or Recorded)

Study Name:

IRB Study Number:

Unique ID Number:

GENERAL INFORMATION

1. Date:
2. Name of Principal Investigator:
3. Name of Consenter:
4. Title of Consenter:
5. Name of Observer:
6. Reason for observation: \(^2\) For-cause / Risk-based / Quality Assurance / Other
   Comment:
7. Type of observation: Live / Recorded
8. Person being consented (circle one): Participant / Legal Guardian(s) / LAR
9. Participant category (circle all that apply):
   a. Adult capable of providing consent
   b. Adult not capable of providing consent, able to provide assent
   c. Adult not capable of providing consent or assent
   d. Child capable of providing assent
   e. Child not capable of providing assent
   f. Does not speak English
   g. Not able to read/write/talk
10. Type of consent discussion: Initial / Re-consent
11. Comment/s on General Information:

---


\(^2\) For-cause: there are allegations or findings of non-compliance; Risk-based: the nature of the research indicates that consent observation is warranted; Quality Assurance: the IRB wants verification that no material changes have taken place since prior IRB review.
COMPLIANCE – to be confirmed prior to consent meeting

12. Y / N  The Consenter is on the IRB-approved list of people who will obtain consent for this study.
Comment:

13. Y / N  The Participant meets the inclusion parameters of the study, per the Consenter.
Comment:

14. Y / N  Form/s being used are the most current IRB-approved version/s.
Comment:

BASIC ELEMENTS3 – The Consenter explained:

15. Y / N  That the study involves “research”.
Comment:

16. Y / N  The purpose of the study.
Comment:

17. Y / N  The study procedures / design.
Comment:

18. Y / N / NA  Which, if any, procedures are experimental.
Comment:

19. Y / N  The duration / time commitment of participation.
Comment:

20. Y / N  The possible risks of participation.
Comment:

21. Y / N  The possible benefits of participation.
Comment:

22. Y / N / NA  If applicable, alternative procedures / treatments.
Comment:

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23. Y / N  Measures taken to protect confidentiality and limits to confidentiality.
Comment:

24. Y / N / NA  If applicable, compensation.
Comment:

25. Y / N / NA  If applicable, what would happen if injury/harm to the participant during the study.
Comment:

26. Y / N  Contact information for questions and concerns.
Comment:

27. Y / N  The voluntary nature of participation. The participant’s right to withdraw at any time.
Comment:

28. Y / N / NA  If applicable, that the study involves a non-FDA approved agent.
Comment:

ADDITIONAL ELEMENTS4 – The Consenter explained:

29. Y / N / NA  The research may involve risks that are currently unforeseeable.
Comment:

30. Y / N / NA  Circumstances under which the researcher might decide that the participant cannot continue to be in the study and/or that the entire study might end before it is complete.
Comment:

31. Y / N / NA  Any additional costs to the participant.
Comment:

32. Y / N / NA  Consequences of withdrawal and procedures for orderly termination of participation.
Comment:

33. Y / N / NA  Significant new findings will be shared with participant during course of the study.
Comment:

34. Y / N / NA  The approximate number of participants in the study.
Comment:

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PROCESS

35. Y / N  The Participant was provided with a copy of the Consent Form in advance of the consent discussion, per the Consenter.
Comment:

36. Y / N  The consenting environment was suitable (e.g., private, reasonably comfortable).
Comment:

37. Y / N  The Consenter used understandable language and avoided medical terms/scientific jargon.
Comment:

38. Y / N  The Consenter encouraged the participant to ask questions.
Comment:

39. Y / N  The Consenter sufficiently answered questions asked by the participant.
Comment:

40. Y / N  The Consenter spent sufficient time obtaining consent.
Comment:

41. Y / N  The participant seemed to understand the information being presented.
Comment:

42. Y / N / NA  The Consenter checked for understanding and assessed comprehension (e.g., utilized the “teach back” method).
Comment:

DECISION/DETERMINATION

43. Y / N  The participant (or parent/guardian or LAR) agreed to enroll in the study.
Comment:

If “no”, this form is complete. If “yes”, answer questions 44-51.

44. Y / N  Was the information in the Consent Form (and any other written information) accurately explained to, and apparently understood by, the Participant/LAR, and was informed consent freely given by the Participant/LAR? IF NO: the consent is not valid. The prospective Participant may not be entered in research unless and until:

If “no”, this form is complete. If “yes”, answer questions 45-51.
45. Y / N   The **Consent Form** was properly signed and dated.
Comment:

46. Y / N / NA   If the **Short Form** was utilized, it was properly signed and dated.
Comment:

47. Y / N / NA   If an **Assent Form** was utilized, it was properly signed and dated.
Comment:

48. Y / N / NA   If HIPAA authorization is required, the **HIPAA Form** was properly signed and dated.
Comment:

49. Y / N   The **participant was given signed copies** of the Consent Form and, if applicable, additional forms (HIPAA, Assent, Short Form)
Comment:

50. Y / N/ NA   If applicable, the **witness was given signed copies** of appropriate forms.
Comment:

51. Additional Comments:

__________________________________________________________________________________________

SPECIAL CIRCUMSTANCES:
Capacity to Consent, Child, Participant Non-English Speaking, Participant Unable to Read/Write/Talk

__________________________________________________________________________________________

CAPACITY TO CONSENT

* Determination of Capacity

52. Y / N / NA   The participant completed the appropriate validated tool to assess capacity.
Comment:

53. Y / N / NA   An independent assessor was utilized.
Comment:

54. Y / N / NA   The participant was determined to have the capacity to consent.
Comment:
If it was determined that participant did not have the capacity to consent:

**Legally Authorized Representative (LAR)**

55. Y / N  LAR was present.
   Comment:

56. Y / N  The Consenter explained the role of the LAR using understandable language.
   Comment:

57. Y / N  The LAR appeared to understand their role.
   Comment:

58. Y / N  The LAR received a copy of the LAR brochure.
   Comment:

**Assent/Dissent**

59. Y / N  The Participant was able to provide assent.
   Comment:

60. Y / N / NA  If the Participant was able to provide assent, an assent form was used.
   Comment:

61. Y / N / NA  If the Participant was not able to provide assent, an information sheet was provided.
   Comment:

**CHILD / LEGAL GUARDIAN**

62. Y / N  The child was able to provide assent.
   Comment:

63. Y / N / NA  If the child was able to provide assent, an assent form was used.
   Comment:

64. Y / N / NA  If the child was not able to provide assent, an information sheet was provided.
   Comment:

**PARTICIPANT DOES NOT SPEAK ENGLISH**

65. Y / N  A short form in language understandable to the Participant was used.
   Comment:
66. Y / N  An interpreter was used.
   Comment:

67. Y / N  A witness who speaks both English and a language understandable to the Participant was present.
   Comment:

Note: If enrolled using short form:
   a. Short form should be signed by participant and witness.
   b. Summary (usually English consent form) should be signed by witness and consenter.
   c. Copies of short form and summary should be provided to participant.

PARTICIPANT NOT ABLE TO READ / WRITE / TALK

68. Y / N  An impartial third party was present.
   Comment:

69. Y / N  The consent form documented the method used for communication.
   Comment:

70. Y / N / NA  If enrolled, the consent form documented the specific means by which the Participant communicated agreement to participate.
   Comment:

Note: If enrolled, consent form should be signed by the impartial third party.
1 PURPOSE and SCOPE

1.1 This policy applies to the recording of current or prospective research participants and/or their legally authorized representatives (participants/LARs) during the meeting at which the informed consent form is signed (consent meeting).

1.2 The process begins when a consent observation is requested, and it is determined that observation of a recorded consent meeting is the preferred approach (vs. live observation).

1.3 The process ends when the recorded consent meeting has been evaluated and reported on, and:

   1.3.1 If the recording was created solely for consent observation, the recording has been destroyed.

   1.3.2 If the recording was created as part of systematic recording of consent for the study, the recording has been returned to the PI.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Not applicable.

3 POLICY

3.1 Recording of the consent meeting takes place if the IRB determines that the consent meeting should be observed, and the participant or the PI would prefer that this be conducted using a recording of the meeting (vs. live). See HRP – 012 – SOP: Observation of Consent.

3.2 Recording the voice and/or image of an individual creates a type of record that requires unique handling and storage, particularly if the content may be considered sensitive. As with all research-related procedures, the dignity of participants should be respected. Therefore, only what is necessary for the purpose of consent observation should be recorded.

3.3 Participants must provide permission prospectively for such recording to occur, and must be provided with information about the storage, use, confidentiality, and destruction of the resulting recorded materials.

4 RESPONSIBILITIES

4.1 The individual designated to conduct the consent observation (observer) carries out these procedures.

5 PROCEDURE

5.1 Provide the person obtaining consent (consenter) with the permission to record for consent observation document. This document must contain the following elements:

   5.1.1 Type of recording that will be utilized;

   5.1.2 Specific identifiers that will be recorded, e.g., partial facial features, full facial features, subject’s name;

   5.1.3 Who will have access to the recording(s);

   5.1.4 Mechanisms in place to protect the confidentiality of the person(s) being recorded;

   5.1.5 Clear plan for when the recording(s) will be destroyed;

   5.1.6 Specific and defined use(s) of the recording(s) by HRPP staff;

   5.1.7 Statement that participation in the research study is not contingent upon agreeing to be recorded for consent observation;

   5.1.8 Signature block including lines for printed name, signature, and date.

5.2 If the participant/LAR does not provide written permission, recording cannot take place.

5.3 If the participant/LAR provides written permission:

   5.3.1 The consenter ensures that the consent meeting is recorded.
5.3.2 Secure the signed Permission to Record form and the recording from the consenter.
5.3.3 After evaluation utilizing the Checklist for Consent Observation, destroy the recording or return it to the PI, as described in the Permission to Record form.
5.3.4 Complete documentation and reporting per HRP – 012 - SOP: Observation of Consent.

6 MATERIALS
6.1 Permission to Record Document
6.2 Checklist for Consent Observation

7 REFERENCES
7.1 HRP – XXX - SOP: PAR Monitoring
7.2 HRP – 012 - SOP: Observation of Consent
UNIVERSITY OF MINNESOTA IRB
PERMISSION TO RECORD THE INFORMED CONSENT MEETING

Observing the consent discussion is one way that the University of Minnesota makes sure that the rights of potential or current research participants are protected. We are asking for your permission to allow us to record the informed consent meeting so that it may be observed by a staff member of the University of Minnesota’s Human Research Protection Program (HRPP).

- The staff member will not be evaluating you or any information that you share.
- The staff member will keep all information about you confidential and will not write down any personal information about you.
- If you don’t want to have your consent discussion recorded, it is ok to say so. The discussion will not be recorded unless you give your permission.
- If you have questions about consent observation or the Human Research Protection Program, please contact Bethany Hansen at 612.624.4490 or hans1142@umn.edu.

The recording will be watched only by HRPP staff for the purpose of evaluating the consent meeting.

The recording will include [indicate whether the subjects name or any other identifier will be recorded. If videotaping will be utilized, indicate the extent to which subject’s identity would be masked (e.g., Facial features partially blocked out; recording will not include facial pictures; recording will include full facial pictures)].

The recording will be transferred by a study team member to the HRPP staff.

The recording will be stored [include measures taken to protect subjects privacy. For example: in a locked file cabinet with no link to subjects’ identity; in a locked file cabinet and linked with a code to subjects’ identity; in a locked file cabinet and labeled with subjects’ name or other identifiable information].

The recording will [indicate whether, upon completion of evaluation by HRPP staff, the recording will be destroyed or returned to the PI].

The recording will not be used for any other reason than that stated in this form.

Your signature on this form grants the person obtaining consent permission to record you as described. It also grants the HRPP staff permission to watch the recording.

_________________________________                                        __________________
Signature of Prospective Participant                                                Date

Initials of Consenter: ______________                                    __________________
                                                                                       Date
UNIVERSITY OF MINNESOTA  
Human Research Protection Program  
Institutional Review Board – Post Approval Review  
Documentation of Consent Audit  
(Live or Recorded Observation, Post-Consent Interview or Questionnaire)

IRB Study Number:  
Audit Date / Time:  
Principal Investigator:  
Consenter:  
Consent Auditor:  

REASON FOR AUDIT:  
☐ Risk-based  ☐ For-cause  ☐ Quality Assurance  ☐ Other: ________________

TYPE OF AUDIT:  
☐ Observation  ☐ Live  ☐ Recorded  ☐ Participant Questionnaire  ☐ Participant Interview

Observations:  

Recommendations:  
☐ Consent meeting conducted appropriately. No recommendations.  
☐ Consent meeting conducted appropriately. Minor recommendations. Issues noted do not impact the validity of consent.  
   Comments:  

☐ Consent meeting not conducted appropriately. Consent not valid.  
   Comments:  

______________________________  ______________
Consent Auditor Signature  
Date

Bh v. 6.20.2016  
Unique ID: ___________________
Post Approval Review (PAR) Consent Audit

Report of Observations

[Audit Activity] Date/s: [ dates ]

Research Conducted by: [ name of PI ]

[Title of PI] [Department]

RE: [“Project/Study Title”]
IRB Code Number: [Number]
BACKGROUND INFORMATION

Reason for audit

Concerns being responded to

Date of IRB review / summary of discussion & decision

As part of the IRB’s determination, the Post-Approval Review (PAR) component of Human Research Protection Program (HRPP) was engaged to conduct a review of consent practices to assess compliance with IRB requirements. Specifically, the IRB requested that the PAR team conduct [direct observation of a consent discussion, records review, other]. In response to this request, the PAR team contacted [PI name] on [date of communication] to schedule an immediate, for-cause site visit.

[PI response]

During the site visit, PAR team members discussed with [PI name] questions that arose during [the consent observation, the review of study records, other] and requested clarification from the study team on specific items (e.g. xxxxxxxx). A formal summary of observations was not provided to the researcher. However, in accordance with standard practice, a synopsis of more significant observations and/or questions was discussed in an effort to clarify and understand the researcher’s practices. A summary of next steps related to the PAR report was provided as well as a reminder of the procedures for IRB vetting of the PAR report.

Preliminary details regarding each study reviewed by PAR is included below:

**Study Information**

<table>
<thead>
<tr>
<th>IRB Code Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titles:/</td>
</tr>
<tr>
<td>Population: [age, gender, other criteria]</td>
</tr>
<tr>
<td>Procedures: [brief summary]</td>
</tr>
<tr>
<td>Number of participants included to date:</td>
</tr>
<tr>
<td>Adverse Events:</td>
</tr>
</tbody>
</table>

Bh DRAFT 06/24/2016
AUDIT METHODS

If records review
PAR conducted a targeted review of [ex: signed consent materials (i.e. parent/guardian consent documentation and child assent documentation) when available, for [each participant enrolled at the UMN / random sample / other].

Detailed results were recorded in a spreadsheet for analysis.

If direct observation
PAR conducted a [live or recorded] observation of [number] consent discussions. The Checklist for Consent Observation was utilized to record observations, and this information was recorded in a spreadsheet for analysis.

If participant phone interview or questionnaire
PAR asked [number] participants to complete post-consent discussion [phone interviews / questionnaires] utilizing the [name of tool] standardized tool. Responses were recorded in a spreadsheet for analysis.

[Challenges encountered – ex: lack of version identification for consent forms]

[Any additional information related to PAR procedures/process employed]

OBSERVATIONS
At the time of this report, it is not anticipated that the final PAR report will include significant differences from results noted below.

Ratings are characterized according to the following system:

**High:** Significant area of risk or concern that relates to compliance with IRB requirements (45CFR46, 21CFR56, 21CFR50, IRB policies) and requires immediate correction to protect the rights, welfare, and safety of human participants.
Medium: Area of risk or concern that may affect compliance and/or rights, welfare, and safety of human participants.

Low: Best practice recommendation intended to facilitate compliance with IRB requirements, promote the rights, welfare and safety of participants, and provide education to the research team.

[Study number]1209M21381

Key Observations:

1) [Observation]
   a. Results:
      i. Related finding
      ii. Related finding
      iii. Related finding
   b. Rating: [High / Medium / Low]
      i. Rationale for rating (ex: percent of instances not in accord with UMN IRB approval; identify specific regulations if applicable)
   c. Recommendations [recommend corrective and preventive actions for IRB committee deliberation]

2) [Observation]
   a. Results:
      i. Related finding
      ii. Related finding
      iii. Related finding
   b. Rating: [High / Medium / Low]
      i. Rationale for rating (ex: percent of instances not in accord with UMN IRB approval, identify specific regulations if applicable)
   c. Recommendations [recommend corrective and preventive actions for IRB committee deliberation]

3) [Observation]
   a. Results:
      i. Related finding
      ii. Related finding
      iii. Related finding

Bh DRAFT 06/24/2016
b. Rating: [High / Medium / Low]
   i. Rationale for rating (ex: percent of instances not in accord with UMN IRB approval, identify specific regulations if applicable)
   c. Recommendations [recommend corrective and preventive actions for IRB committee deliberation]

*Repeat for results of additional studies if applicable.*
Consent Auditing
Metrics and Reporting Plan

Direct Observation – Live or Recorded

- Observer completes Checklist for Consent Observation
- Student worker enters data from Checklist into Consent Observation Spreadsheet – Excel

Reporting: Data gathered through direct observation will be analyzed for trends, including strengths and areas for improvement, and reported per PAR policy. This information will help to guide quality improvement and education activities.

Post-Consent Interview/Questionnaire

- Participant completes standardized tool (e.g., BICEP or QuIC).
  - If phone interview, this is conducted by PAR staff.
  - If questionnaire, the completed form is collected by study team member and sent to PAR staff.
- Student worker enters data from completed tool into appropriate spreadsheet.

Utilization: Data gathered through participant interviews and questionnaires will be analyzed for trends, including strengths and areas for improvement, and reported per PAR policy. This information will help to guide quality improvement and education activities.
1 PURPOSE and SCOPE
1.1 This procedure establishes the process to utilize standardized tools to gather information from research participants about their experience of the meeting at which the informed consent document was signed (consent meeting) for the purpose of quality assurance and/or quality improvement.
1.2 The process begins when the IRB or Post Approval Review team (PAR) determines that information about a participant’s experience of a consent meeting should be gathered.
1.3 The process ends when the research participant/s have completed one of the approved, standardized tools and the results have been recorded and reported on, as appropriate.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Not applicable.

3 POLICY
3.1 Post-consent interviews and/or questionnaires may be conducted when:
3.1.1 The IRB wants verification from sources other than the investigator that consent meetings are being conducted such that research participants have the information and autonomy to give their informed consent (quality assurance).
3.1.2 There are allegations or findings of non-compliance (for-cause).
3.1.3 The nature of the research indicates that retrospective auditing is warranted (risk-based).
3.1.4 As an alternative when the IRB requests consent observation, but the prospective participant does not give permission for the consent meeting to be observed (see HRP – 012 – SOP: Observation of Consent)
3.1.5 Other triggers?
3.2 The IRB, Institutional Official, or designee determines who conducts the observation. The observation may be conducted by:
3.2.1 Post Approval Review team members
3.2.2 IRB members
3.2.3 Independent individuals hired by the IRB, but paid for by the investigator’s funds.

4 RESPONSIBILITIES
4.1 The individual designated to conduct the retrospective audit (auditor) carries out these procedures.

5 PROCEDURE
5.1 Send notification to the Principal Investigator (PI).
5.2 Provide the person obtaining consent (consenter) with:
5.2.1 Standardized tool/s that may be used (e.g., BICEP, QuIC, DICCT).
5.2.2 Communication points for discussing retrospective consent auditing with the prospective participant or their Legally Authorized Representative (participant/LAR).
5.3 The participant/LAR must give verbal permission. If the participant/LAR declines to give permission, or if the PI feels strongly that a post-consent interview/questionnaire would not be appropriate, the PI may submit an alternate plan. This alternate plan will be presented to the IRB for review and approval.
5.4 In advance of the consent meeting, confirm the following with the consenter:
5.4.1 Who is being consented (participant, legal Guardian, LAR)
5.4.2 That the participant meets the inclusion criteria for the study.
5.4.3 The version date/s of the Consent Form and any other forms to be used.
5.4.4 Whether any special circumstances apply, including: capacity to consent, LAR, assent, participant does not speak English, participant is not able to read/write/talk.

5.5 Ensure that the standardized tool is utilized appropriately:

5.5.1 If using a written questionnaire, provide the questionnaire to the consenter, along with standardized instructions for administering the instrument. The consenter ensures that the questionnaire is completed appropriately. Arrange with the consenter to collect the completed questionnaire.

5.5.2 If conducting a phone interview, work with the consenter to determine date and time (preferably directly following the consent meeting). Conduct the phone interview with the participant per standardized instructions.

5.6 Provide documentation of interview/questionnaire completion to the PI (Documentation of Consent Audit).

5.7 If it appears that consent was not properly obtained, promptly submit a written report to the IRB for review and corrective action. Follow up as directed by the IRB until the matter is determined by the IRB to be closed.

5.8 Record collected data for metrics and reporting purposes. Written reports of consent auditing activities will be submitted to the IRB on a regular basis.

6 MATERIALS

6.1 Documentation of Consent Audit
6.2 Standardized Interviews / Questionnaires

7 REFERENCES

7.1 HRP – XXX - SOP: PAR Monitoring
7.2 HRP – 012 - SOP: Observation of Consent
Informed Consent Auditing

Decision-Making Matrix

The University of Minnesota’s Human Research Protection Program employs a range of methods for auditing informed consent. The matrix below provides guidelines regarding which method/s may be most appropriate for a given study. Decisions regarding level of consent auditing required are made on a case-by-case basis.

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>PI / Population</th>
<th>Consent Observation (live or recorded)</th>
<th>Post-consent Interview / Questionnaire</th>
<th>Site Visit / Records Review</th>
<th>Self-assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater than Minimal Risk</td>
<td>Capacity to Consent Tool Required (e.g., MacArthur)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Allegations or Findings of Investigator Noncompliance Related to Consent Process</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complaint or Concern Received</td>
<td>Depends on nature of complaint and results of initial information-gathering</td>
<td>Depends on nature of complaint and results of initial information-gathering</td>
<td>Depends on nature of complaint and results of initial information-gathering</td>
<td>Depends on nature of complaint and results of initial information-gathering</td>
</tr>
<tr>
<td>Not Greater than Minimal Risk</td>
<td>Capacity to Consent Tool Required (e.g., UBACC)</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Allegations or Findings of Investigator Noncompliance Related to Consent Process</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complaint or Concern Received</td>
<td>Depends on nature of complaint and results of initial information-gathering</td>
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<td>Depends on nature of complaint and results of initial information-gathering</td>
</tr>
</tbody>
</table>
1 PURPOSE
1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
   1.1.1 Legally authorized representative
   1.1.2 Children
   1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative. Minnesota law does not specifically address the issue of research participation by incapacitated adults.
   3.1.1 Based on legal advice, the IRB follows the Minnesota laws on surrogate consent in health care to determine surrogate consent for research participation, including specifically the law on surrogate consent for treatment of incapacitated patients undergoing in-patient mental health treatment. When research is conducted in Minnesota the following individuals meet this definition in order of priority:
      3.1.1.1 Healthcare agent previously appointed by the individual through a health care power of attorney;
      3.1.1.2 Spouse;
      3.1.1.3 Parents;
      3.1.1.4 Adult children; and
      3.1.1.5 Adult siblings.
   3.1.2 The legally authorized representative may not be a member of the clinical or research staff or an employee or beneficiary of the sponsor of the research project.
   3.1.3 Under Minnesota law, an incapacitated adult who has a court appointed guardian or conservator may not receive experimental treatment of any kind unless: 1) a court first approves the treatment through a court order; or 2) the court's guardianship order specifically authorizes the guardian to consent to research participation in addition to medical treatment generally.
   3.1.4 For research outside Minnesota, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.

3.2 DHHS and FDA’s Subpart D applies to all research involving children.
   3.2.1 When research is conducted in Minnesota all individuals under the age of 18 years are children. Exceptions exist for certain individuals as described below. Contact legal counsel for more information.
   3.2.2 A child may consent to medical, mental and dental services, and therefore to participation in medical research, if:
      3.2.2.1 The child:
         3.2.2.1.1 is living apart from his/her parents and managing his/her own financial affairs; or
         3.2.2.1.2 has been married; or
         3.2.2.1.3 has given birth; or
      3.2.2.2 The research is primarily focused on providing medical, mental or other health services for:
         3.2.2.2.1 determining the presence of, treatment of, or conditions associated with pregnancy, not including contraception; or
         3.2.2.2.2 sexually transmitted infections; or
3.2.2.2.3 alcohol or other drug abuse.

3.2.3 For research outside Minnesota, a determination of who is a child is to be made with consultation from legal counsel.

3.3 Unless the IRB has waived the requirement to obtain consent, when research involves children, consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care\(^1\). Before obtaining permission from an individual who is not a parent, contact legal counsel.

3.3.1 Under Minnesota law, a minor who has a court appointed guardian may not receive experimental treatment of any kind without a court order.

4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR §46.102, 45 CFR §46.402
7.2 21 CFR §50.3

\(^1\) This is the DHHS and FDA definition of “guardian”
SOP: Annual HRPP Evaluations

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>AUTHOR</th>
<th>APPROVED BY</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-060</td>
<td>5/25/16</td>
<td>L. Anderson</td>
<td>D. Dykhuis</td>
<td>1 of 2</td>
</tr>
</tbody>
</table>

1 PURPOSE
1.1 This procedure establishes the process to conduct annual evaluations of the human research protection program.
1.2 The process begins the first business day of each June.
1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 The human research protection program is evaluated annually.
3.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making the document "BROCHURE: Should I Take Part in Research (HRP-104)" available to the patient population.

4 RESPONSIBILITIES
4.1 IRB staff ensure completion of these procedures.

5 PROCEDURE
5.1 Have the Institutional Official or designee evaluate the following resources provided to the human research protection program and make adjustments as part of the budgeting process.
   5.1.1 Space
   5.1.2 HRPP educational program
   5.1.3 Legal counsel
   5.1.4 Conflicts of interests
   5.1.5 Quality improvement plan
5.2 Have the Institutional Official or designee evaluate validated new information related to assessing capacity to consent.
   5.2.1 Conduct a literature review of existing and any new validated instruments designed to assess capacity to consent.
   5.2.2 Incorporate new information, as appropriate, into policies, guidance, or other tools.
5.3 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
   5.3.1 Provide a copy of the evaluation to the Institutional Official or designee.
   5.3.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the Institutional Official or designee to modify the IRB structure.
5.4 Have the IRB chair or IRB manager evaluate the knowledge, skills, and performance of each regular and alternate IRB member.
   5.4.1 Provide a copy of the evaluation to the Institutional Official or designee.
   5.4.2 Provide each IRB member with a copy of his or her evaluation.
   5.4.3 Send a copy of the "TEMPLATE LETTER: IRB Member Appreciation (HRP-562)" to the IRB member's supervisor.
   5.4.4 If needed, work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.
5.5 Have the Institutional Official or designee evaluate the knowledge, skills, and performance of each IRB chair.
   5.5.1 Provide a copy of the evaluation to the Institutional Official or designee.
   5.5.2 Provide each IRB chair with a copy of his or her evaluation.
   5.5.3 If needed, work with each IRB chair to develop a plan to improve the individual’s knowledge, skills, and performance.
5.6 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.
   5.6.1 Provide a copy of the evaluation to the Institutional Official or designee.
5.6.2 Provide each IRB staff with a copy of his or her evaluation.
5.6.3 If needed, work with each IRB staff person to develop a plan to improve the individual’s knowledge, skills, and performance.

5.7 Use the “WORKSHEET: IRB Composition (HRP-304)” to evaluate whether the composition of the IRB meets regulatory and university requirements.

5.7.1 Provide a copy of the evaluation to the Institutional Official or designee.
5.7.2 If the composition of an IRB does not meet regulatory and university requirements, work with the Institutional Official or designee to modify the IRB composition.

5.8 Evaluate the subject outreach plan.

5.8.1 Provide a copy of the evaluation to the Institutional Official or designee.
5.8.2 If the subject outreach program is not meeting university goals, work with the Institutional Official or designee to modify the plan.

5.9 Check when the last time each IRB was registered. If more than 3 years, update the registration.1

5.10 Check when the last time the federalwide assurance (FWA) was updated or renewed. If more than 5 years, update/renew the federalwide assurance (FWA).2

6 MATERIALS

6.1 BROCHURE: Should I Take Part in Research (HRP-104)
6.2 TEMPLATE LETTER: IRB Member Appreciation (HRP-562)
6.3 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

7.1 None

---

1 PURPOSE
1.1 This procedure establishes the process to obtain informed consent from subjects, the legally authorized representatives of adults unable to consent, or the parents or guardians of children.
1.2 The process begins when an individual identifies a subject as a potential candidate for a research study.
1.3 The process ends when a subject or the subject’s legally authorized representative provides legally effective informed consent or declines to do so.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 In this procedure “investigator” means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.
3.2 In this procedure “subject/representative” means:
3.2.1 The subject when the subject is an adult capable of providing consent.
3.2.2 Legally authorized representative when the subject is an adult unable to give consent.
3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.
3.3 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.
3.4 If the subject is an adult unable to consent:
3.4.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
3.4.2 Permission is obtained from a legally authorized representative.
3.4.3 A legally authorized representative must be in the class or persons approved by institutional policy or the IRB. See “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”
3.4.4 If the subject regains the capacity to provide consent during the study, obtain informed consent from the subject.
3.5 If the subject could have fluctuating capacity to consent throughout the study:
3.5.1 Do not obtain consent, if feasible, during periods which prospective subjects may be likely to experience greater than normal impairment to functional abilities (for example, due to changes in participants’ medication schedules, acute intoxication or episodic increases in the severity of the symptoms associated with their conditions).
3.5.2 Ask the subject to prospectively designate an individual to serve as an LAR [per SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)] if necessary, and involve the potential LAR in the consent process.
3.5.3 Assent should be obtained and documented when appropriate.
3.6 If the subject is a child:
3.6.1 The IRB must have specifically approved the protocol to allow the enrollment of children.
3.6.2 Permission is obtained from both parents unless:
3.6.2.1 One parent is deceased, unknown, incompetent, not reasonably available;
3.6.2.2 Only one parent has legal responsibility for the care and custody of the child; or
3.6.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
3.6.3 In the absence of a parent permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.
3.7 If the subject/representative cannot speak English:
   3.7.1 The IRB must have specifically approved the protocol to allow the enrollment of
   subjects able to speak language that the subject understands.
3.8 Conduct all discussions in a private and quiet setting.
3.9 Any knowledgeable individual may:
   3.9.1 Review the study with subject/representative to determine preliminary interest.
   3.9.2 If the subject/representative is interested, notify an investigator.
   3.9.3 If the subject/representative is not interested, take no further steps regarding
   recruitment or enrollment.

4 RESPONSIBILITIES
4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE
5.1 If the consent process will be documented in writing with the long form of consent
   documentation:
   5.1.1 Obtain the current IRB approved consent form.
   5.1.2 Verify that you are using the most current IRB-approved version of the study specific
   consent form and that the consent form is in language understandable to the
   subject/representative.
   5.1.3 Provide a copy of the consent form to the subject/representative. Whenever possible
   provide the consent form to the subject/representative in advance of the consent
   discussion.
   5.1.4 If the subject/representative cannot read obtain an impartial witness to be present
   during the entire consent discussion to attest that the information in the consent form
   and any other information provided was accurately explained to, and apparently
   understood by, the subject/representative, and that consent was freely given. The
   witness may be a family member or friend. The witness may not be a person involved
   in the design, conduct, or reporting of the research study.
   5.1.5 If the subject/representative cannot speak English, obtain the services of an
   interpreter fluent in both English and the language understood by the
   subject/representative. The interpreter may be a member of the research team, a
   family member, or friend of the subject/representative.
   5.1.6 Read the consent document (or have an interpreter read the translated consent
   document) with the subject/representative. Explain the details in such a way that the
   subject/representative understands what it would be like to take part in the research
   study.
5.2 If the consent process will be documented in writing with the short form of consent
   documentation:
   5.2.1 Obtain the current IRB approved short consent form and summary (same as the
   English consent form used for long form of consent documentation).
   5.2.2 Verify that you are using the most current IRB-approved version of the study specific
   short consent form and summary that the short consent form is in language
   understandable to the subject/representative.
   5.2.3 Provide copies to the subject/representative. Whenever possible provide the short
   consent form and summary to the subject/representative in advance of the consent
   discussion.
   5.2.4 Obtain the services of an interpreter fluent in both English and the language
   understood by the subject/representative. The interpreter may be a member of the
   research team, family member, or friend of the subject/representative.
   5.2.5 Obtain the services of an impartial witness who is fluent in both English and the
   language spoken by the subject/representative to be present during the entire consent
   discussion to attest that the information in the short consent form, summary, and any
other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness and the interpreter may be the same person. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.2.6 Have the interpreter translate the summary (not the short consent form) to the subject/representative.

5.2.7 Through the interpreter explain the details in such a way that the subject/representative understand what it would be like to take part in the research study. When necessary provide a different or simpler explanation to make the information understandable.

5.2.8 Have the subject/representative read the short consent form or have the interpreter read the short consent form to the subject/representative.

5.3 If the requirement for written documentation of the consent process has been waived by the IRB:

5.3.1 Obtain the current IRB approved script.

5.3.2 Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/representative.

5.3.3 When possible provide a copy of the script to the subject/representative.

5.3.4 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.

5.3.5 Read the script (or have an interpreter translated the script) with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

5.4 Invite and answer the subject/representative’s questions.

5.5 Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.

5.6 Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

5.7 Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:

5.7.1 The subject/representative understands the information provided.

5.7.2 The subject/representative does not feel pressured by time or other factors to make a decision.

5.7.3 The subject/representative understands that there is a voluntary choice to make.

5.7.4 The subject/representative is capable of making and communicating an informed choice.

5.8 If the subject is an adult that has diminished capacity and may be unable to provide consent:

5.8.1 If the research involves greater than minimal risk, administer the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) (or the alternate tool approved by the IRB for use in the study) appropriate to the context of the research. See “CHECKLIST: Cognitively Impaired Adults (HRP-417).”

5.8.2 If the research is minimal risk, administer a version of the UCSD Brief Assessment of Capacity to Consent (UBACC) (or the alternate tool approved by the IRB for use in the study) appropriate to the context of the research. See “CHECKLIST: Cognitively Impaired Adults (HRP-417).”

5.8.3 Consider if any of the following may be appropriate for the subject:
5.8.3.1 A stepwise consent process, which involves a waiting period between each phase of the process (e.g. capacity assessment, initial presentation of information, and obtaining consent).

5.8.3.2 An enhanced presentation of consent information during the initial presentation and/or immediately prior to obtaining consent, including:
   5.8.3.2.1 Repetition of information (especially misunderstood information),
   5.8.3.2.2 Both oral and written presentation of information,
   5.8.3.2.3 Multi-media presentation of information,
   5.8.3.2.4 Interactive questioning, and
   5.8.3.2.5 Written study summaries.

5.8.3.3 Where appropriate, consider video monitoring or use of a witness to the consent process.

5.9 If the subject/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

5.10 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

5.11 If the subject/representative agrees to take part in the research study:
   5.11.1 If the subject is a child:
      5.11.1.1 Whenever possible explain the research to the extent compatible with the child’s understanding.
      5.11.1.2 Request the assent (affirmative agreement) of the child unless:
         5.11.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.
         5.11.1.2.2 The IRB determined that assent was not a requirement.
      5.11.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.
   5.11.2 If the subject is an adult unable to consent:
      5.11.2.1 Whenever possible explain the research to the extent compatible with the adult’s understanding.
      5.11.2.2 Inform the LAR of his or her responsibilities and confirm and document in the study binder that they are capable and willing to execute his or her responsibilities.
      5.11.2.3 Request the assent (affirmative agreement) of the adult unless:
         5.11.2.3.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.
         5.11.2.3.2 The IRB determined that assent was not a requirement.
      5.11.2.4 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.
   5.11.3 Obtain written documentation of the consent process according to “SOP: Written Documentation of Consent (HRP-091).”

6 MATERIALS
   6.1 Long form of consent documentation:
      6.1.1 Consent form
   6.2 Short form of consent documentation:
      6.2.1 Short consent form
      6.2.2 Summary (same information as the English consent form used for long form of consent documentation)
   6.3 Requirement for written documentation of the consent process has been waived by the IRB:
6.3.1 Consent script (same as consent form used for long form of consent documentation except that signature block is optional)


6.5 SOP: Written Documentation of Consent (HRP-091)

7 REFERENCES

7.1 21 CFR §50.20, 50.25

7.2 45 CFR §46.116
1 PURPOSE
1.1 This procedure establishes the process to document the informed consent process in writing.
1.2 The process begins when a subject agrees to take part in a research study.
1.3 The process ends when the consent process is documented in writing to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 In this procedure “investigator” means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.
3.2 In this procedure “subject/representative” means:
3.2.1 The subject when the subject is an adult capable of providing consent.
3.2.2 Legally authorized representative when the subject is an adult unable to give consent.
3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child’s general medical care.

4 RESPONSIBILITIES
4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE
5.1 If the consent process will be documented in writing with the long form of consent documentation:
5.1.1 Verify that the consent form is in language understandable to the subject/representative.
5.1.2 Print the name of the following individuals on the consent document:
   5.1.2.1 Subject/Representative
   5.1.2.2 Person obtaining consent
5.1.3 Have the following individuals personally sign and date the consent document:
   5.1.3.1 Subject/Representative
   5.1.3.2 Person obtaining consent
5.1.4 If the IRB required written documentation of assent, note on the signature block one of the following:
   5.1.4.1 Assent of adults unable to consent or children was obtained.
   5.1.4.2 Assent of adults unable to consent or children was not obtained because the capability of the child or adult is so limited that the child or adult cannot reasonably be consulted.
5.1.5 Have the person obtaining consent personally sign and date the consent document.
5.1.6 If an impartial witness was part of the consent process:
   5.1.6.1 Print the name of the impartial witness on the consent document.
   5.1.6.2 Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.
5.1.7 Provided copies of the signed and dated consent document to the subject/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.
5.2 If the consent process will be documented in writing with the short form of consent documentation:
5.2.1 Verify that the short consent form is in language understandable to the subject/representative.
5.2.2 Print the name of the following individuals on the short form consent document and the summary:
5.2.2.1 Subject/Representative
5.2.2.2 Person obtaining consent
5.2.2.3 Impartial witness

5.2.3 Have the following individuals personally sign and date the short form consent document and the summary:
5.2.3.1 Subject/Representative
5.2.3.2 Person obtaining consent
5.2.3.3 Impartial witness

5.2.4 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:
5.2.4.1 Assent of adults unable to consent or children was obtained.
5.2.4.2 Assent of adults unable to consent or children was not obtained because the capability of the child or adult is so limited that the child or adult cannot reasonably be consulted.

5.2.5 Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.

5.3 If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing.
5.3.1 If the subject/representative declines, take no further action.
5.3.2 If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation

5.4 Place the signed and dated documents in the subject’s binder.
5.5 For subjects unable to consent:
5.5.1 Any formal assessments and determinations of the capacity to consent should be included in the subject’s binder.
5.5.2 Where appropriate, consider video monitoring or use a witness to the consent process.

6 MATERIALS
6.1 If the consent process will be documented in writing with the long form of consent documentation:
6.1.1 Consent document
6.2 If the consent process will be documented in writing with the short form of consent documentation:
6.2.1 Short consent document
6.2.2 Summary (same content as the long form of consent documentation)

7 REFERENCES
7.1 21 CFR §50.27
7.2 45 CFR §46.117
The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval (HRP-314) when research involves cognitively impaired adults as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to “Submit Non-Committee Review” activity. The IRB Office (HRPP/HSPO) retains this checklist in the protocol file.

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office (HRPP/HSPO) uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file.

All research must meet the criteria in Sections 1 or 2. Complete Section 3 if applicable.

<table>
<thead>
<tr>
<th>Section 1: Greater than minimal risk research involving cognitively impaired adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ There is anticipated direct benefit to the subject.</td>
</tr>
<tr>
<td>☐ Subjects have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual subject that is unavailable outside the research context.</td>
</tr>
<tr>
<td>☐ The objectives of the trial cannot be met by means of study of subjects who can give consent personally.</td>
</tr>
<tr>
<td>Provide protocol specific findings justifying this determination:</td>
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<table>
<thead>
<tr>
<th>Section 2: Risks to subjects are reasonable in relation to anticipated benefits to subjects.</th>
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<tbody>
<tr>
<td>☐ Provide protocol specific findings justifying this determination:</td>
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<table>
<thead>
<tr>
<th>Section 3: The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Provide protocol specific findings justifying this determination:</td>
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<tr>
<th>Section 4: The trial is not prohibited by law.</th>
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<tbody>
<tr>
<td>☐ Provide protocol specific findings justifying this determination:</td>
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<tr>
<th>Section 5: Subjects will be particularly closely monitored.</th>
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<tr>
<td>☐ Provide protocol specific findings justifying this determination:</td>
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<tr>
<th>Section 6: Subjects will be withdrawn if they appear to be unduly distressed.</th>
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<tbody>
<tr>
<td>☐ Provide protocol specific findings justifying this determination:</td>
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<thead>
<tr>
<th>Section 7: The proposed plan for the assessment of the capacity to consent is adequate. The MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) appropriate to the context of the research (or other validated instrument deemed more appropriate for the population participating in the study) will be utilized.</th>
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<td>☐ Provide protocol specific findings justifying this determination:</td>
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<tr>
<th>Section 8: The subject will be informed about the research to the extent compatible with the subject’s understanding.</th>
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<tr>
<td>☐ Provide protocol specific findings justifying this determination:</td>
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<thead>
<tr>
<th>Section 9: Assent will be obtained from: (One of the following must be checked)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ All subjects.</td>
</tr>
<tr>
<td>☐ Some subjects, specify:</td>
</tr>
<tr>
<td>☐ None of the subjects, provide rationale</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Section 10: If assent will be obtained, specify the process for documentation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Investigator will document assent in the consent signature block.</td>
</tr>
<tr>
<td>☐ Other (NOTE: The protocol needs to describe the process of assent documentation)</td>
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<tr>
<td>☐ N/A</td>
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<tr>
<th>Section 11: The consent document includes a signature line for a legally authorized representative.</th>
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<tbody>
<tr>
<td>☐ If capable, the subject will sign and personally date the written informed consent.</td>
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<tr>
<th>Section 12: If appropriate, one or more independent monitors will be appointed to assist with various aspects of the study, such as:</th>
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<tbody>
<tr>
<td>☐ A participant advocate, such as a member of the target population or family member thereof, or an employee of an organization that advocates for the target population;</td>
</tr>
<tr>
<td>☐ An individual with expert knowledge of the relevant psychological or physical condition who will monitor the consent of participants capable of providing it as well as the assent of participants incapable of consenting and the consent of their LARs; or</td>
</tr>
<tr>
<td>☐ A health care professional, to serve as a consultant to participants and their LARs</td>
</tr>
<tr>
<td>CHECKLIST: Cognitively Impaired Adults</td>
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<td>-----------------------------------------</td>
</tr>
<tr>
<td><strong>NUMBER</strong></td>
</tr>
<tr>
<td>HRP-417</td>
</tr>
</tbody>
</table>

- Consent auditor assigned by HRPP Post Approval Review (PAR)
- [ ] N/A

- If appropriate, one or more of the following:
  - Video monitoring of the consent process;
  - Use of a witness to the consent process and documentation in the consent signature block
- [ ] N/A

- If appropriate, other enhancements to the consent process. Specify:
- [ ] N/A
<table>
<thead>
<tr>
<th>2</th>
<th>Minimal risk research involving cognitively impaired adults (Check if “Yes”. All must be checked)</th>
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<tbody>
<tr>
<td></td>
<td>Subjects have a disease or condition for which the procedures involved in the research are intended.</td>
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<td>The proposed plan for the assessment of the capacity to consent is adequate. A version of the UCSD Brief Assessment of Capacity to Consent (UBACC) appropriate to the context of the research (or other validated instrument deemed more appropriate for the population participating in the study) will be utilized.</td>
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</tr>
<tr>
<td></td>
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<tr>
<td>3</td>
<td>Research involving cognitively impaired adults with fluctuating capacity to consent (Check if “Yes”. All must be checked)</td>
</tr>
<tr>
<td></td>
<td>Subjects' capacity to consent over the course of the study will be periodically re-evaluated.</td>
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<td></td>
<td>Subjects will be asked to prospectively designate an individual to serve as an LAR for the study, if necessary.</td>
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<td></td>
<td>Individuals identified as potential LARs will be involved in the consent process</td>
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<tr>
<td></td>
<td>Subjects will be asked to document their wishes regarding future participation in the study if their capacity changes over time.</td>
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<td></td>
<td>N/A</td>
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</table>
1.0 Reason for Policy

The University of Minnesota is committed to the ethical and responsible conduct of research and to ensuring that the rights and welfare of participants are protected. Research involving adults with potentially diminished or fluctuating capacity to consent to research participation, or adults who lack that capacity altogether, requires careful planning by investigators and special consideration by the Institutional Review Board (IRB) before approval can be granted.

2.0 Scope of Policy

This policy establishes requirement for investigators who plan to enroll adults with absent, diminished, or fluctuating capacity to consent.
3.0 Policy Statement

Impairment of the capacity to consent potentially occurs in a wide range of conditions and disease states and is not limited to specific medical or psychiatric disorders. The capacity to consent is task-specific and depends on the nature and complexity of the proposed study and study procedures, and may even be impacted by the decision-making process itself. It is not a static phenomenon and may improve, deteriorate, or fluctuate over time. Where limitations in capacity to consent are present, additional consent enhancements, safeguards, and support may be required.

If you plan to enroll adult subjects who have a condition known to cause diminished functional abilities that affect capacity to consent in a research study and/or the protocol inclusion criteria allows for consent to be provided by a legally authorized representative (LAR), this policy applies to you.

Examples of conditions known to cause diminished functional abilities may include, but are not limited to:

1. Acute medical conditions;
2. Psychiatric disorders;
3. Neurologic disorders;
4. Developmental disorders; and
5. Behavioral disorders.

See Department of Psychiatry Dual Role Consenting Policy for specific requirements for Department of Psychiatry research.

Assessing and Documenting Capacity to Consent

The study protocol should describe the plan to assess and document capacity to consent and be tailored to the likelihood of the involvement of participants with impaired consent capacity and the risks of the study.

The IRB recommends that the following validated tools be used to evaluate capacity to consent in research studies that involve adults with absent, diminished, or fluctuating capacity to consent:

- For greater than minimal risk research, the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) appropriate to the context of the research.
- For minimal risk research, a version of the UCSD Brief Assessment of Capacity to Consent (UBACC) appropriate to the context of the research.

You may propose use of a different validated instrument deemed more appropriate for the population participating in the study. If you wish to use an assessment other than the MacCAT-CR or UBACC, you must provide the rationale for use of the instrument and a description of the training plan for study staff who will administer the assessment.

Research staff seeking consent from potential participants to research should consider each potential participant’s capacity to provide that consent. Note that, in studies that do not anticipate enrolling individuals with impaired capacity to consent, and where no potential impairment of an individual is evident, assessment can usually be informally made during routine interactions with participants. No specific assessment or documentation of capacity is required under those circumstances.
Required training on use of the tools will be available in the form of an interactive, online course. In addition to completing the appropriate course(s), investigators must otherwise document any additional, applicable training and qualifications for study personnel assigned to conduct capacity assessments.

See **HRP-417- CHECKLIST: Cognitively Impaired Adults** for the IRB’s approval criteria for research that involves adults with absent, diminished, or fluctuating capacity to consent.

**Obtaining Consent from a Legally Authorized Representative**
If, based on the capacity to consent assessment, it is determined that the potential research subject cannot provide informed consent, consent must be obtained from an LAR. The LAR should be provided with the same information during the informed consent process that would be given to the research subject. The LAR should receive regular information about the research subject’s status and any new information that may affect the LAR’s willingness to permit the subject to continue in the study.

The LAR may not be a member of the clinical or research staff or an employee or beneficiary of the sponsor of the research project.


**Obtaining Assent from Adult Subjects Unable to Provide Consent**
The research protocol should address whether assent from adults unable to provide consent will be obtained. If assent will not be obtained from any of the subjects, rationale should be included in the protocol. The IRB may require that assent be obtained from none, some, or all of the subjects.

See **HRP-417- CHECKLIST: Cognitively Impaired Adults** that addresses the IRB’s determination to obtain assent.

**Subjects with Fluctuating Capacity to Consent**
Capacity to consent may improve, deteriorate, or fluctuate over the course of a study. The IRB expects that investigators include procedures to address fluctuating capacity, where applicable.

Where fluctuating capacity to consent is anticipated in a subject population, the protocol must include plans for monitoring capacity for the duration of the study.

See Section 3 of **HRP-417- CHECKLIST: Cognitively Impaired Adults** for the IRB’s approval criteria for research that involves adults fluctuating capacity to consent and **HRP-090 - SOP: Informed Consent Process for Research** for the process for obtaining informed consent from subjects with fluctuating capacity to consent.

### 4.0 Required approvals for this document

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### 5.0 Revision History
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To obtain a copy of a historical policy, e-mail at IRB@umn.edu or call 612-626-5654
1.0 Reason for Policy

The University of Minnesota is committed to the ethical and responsible conduct of research and to ensuring that the rights and welfare of participants are protected. Research involving adults under court jurisdiction may not be enrolled in human research.

2.0 Scope of Policy

This policy establishes conditions under which potential subjects may not be enrolled.

3.0 Policy Statement

Adults Under a Hold

Due to the potential for coercion or undue influence and concerns about potential lack of decisional capacity or diminished capacity to consent, researchers may not recruit or enroll the following persons in any clinical drug trial under Minnesota law (effective August 1, 2016) and/or existing IRB Policy: 1) individuals subject to a commitment petition; and/or 2) individuals temporarily confined involuntarily under: a) 72-hour emergency admission holds; b) “intent to leave” periods; or c) peace officer/health officer authority (formerly “transport hold”) or a court apprehend and hold order.
This restriction applies during the period of the emergency admission or hold. It does not prohibit a person already enrolled in a clinical drug trial at the time of the emergency admission or peace officer/court hold from continuing their participation.

Under IRB Policy, the above restrictions on recruitment and enrollment also apply to any clinical trial involving psychiatric devices or biologics (as well as all clinical drug trials).

Additionally, under Minnesota law, an individual who has had a commitment hearing, and is released by the court before a commitment order is issued, is prohibited from participating in a psychiatric clinical drug trial during the period of a stay of commitment, unless the court specifically authorizes the participation.\(^1\)

Investigators wishing to recruit such individuals must provide justification for doing so and a process compliant with the terms of the statute.

In addition, no member of a study team may participate in a decision to rescind or discontinue a patient’s involuntary status (as described above) before its expiration, provisionally discharge a committed patient, or rescind a provisional discharge, when the patient is a prospective research subject for a study conducted by the study team.

**Adults Under Court Appointed Guardianship**
Under Minnesota law, adults with court appointed guardians may not participate in “experimental treatment of any kind” unless: 1) the court first approves the treatment through a court order; 2) the court’s guardianship order specifically authorizes the guardian to consent for research participation in addition to medical treatment generally. The University interprets “experimental treatment” in this context to align with the National Institutes of Health (NIH) definition of a clinical trial as a “research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related or behavioral outcomes.” As such, any investigator who seeks to enroll or include participants who are under a legal guardianship must propose specific processes to ensure and to document that necessary judicial orders are secured for each such participant, as well as comply with the tenets of this policy as applicable.

**Adults Classified as "Incompetent"**
Competence is a legal state, not a medical state. Distinct from capacity, competence may only be determined by a court of law. Under this policy, adults who are individually adjudicated or classified by law as "incompetent" may be considered for participation in research but are automatically deemed to lack capacity to consent to participation. Investigators intending to include or recruit such individuals must include in the protocol a strong rationale for doing so and plans for use of an LAR to consent to the research.

These requirements are not intended to prevent access by individuals to potentially life-saving experimental treatment. See **HRP-023 - SOP - Emergency Use Review** and **HRP-322 - WORKSHEET - Emergency Use**.

### 4.0 Required approvals for this document

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\(^1\) Minnesota Statute 253B.095, Subd. 1(e). https://www.revisor.mn.gov/statutes/?id=253B.095

\(^2\) Minnesota Statute 524.5-313(c)(4)(i). https://www.revisor.mn.gov/statutes/?id=524.5-313
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To obtain a copy of a historical policy, e-mail at IRB@umn.edu or call 612-626-5654
Decision-Making Capacity Assessment Pilot

Executive Summary

May 10, 2016

This protocol provides a comprehensive plan for the launch of the decision-making capacity assessment pilot. It includes an overview of the pilot purpose, timeline, communication plan, and tasks that must be completed before the launch of the pilot. In addition, a cost-analysis regarding staff resources and instrument materials/resources is provided. Pilot procedures are fully described in Section 3, which includes the launch of an online course and a plan for the adoption of the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) and the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC). The plan for evaluating the online course and use of assessment tools is described in Section 4.
Decision-Making Capacity Assessment Pilot

I. Overview

Purpose
The purpose of this pilot is to gather feedback from principal investigators on the use of decision-making capacity assessment tools in research:

- **MacCAT-CR** - MacArthur Competence Assessment Tool for Clinical Research
- **UBACC** - University of California, San Diego Brief Assessment of Capacity to Consent

While formal certification is not required to use these tools, many studies have recommended the adoption of training. There is currently no standardized training for the MacCAT-CR or UBACC. As a result, the pilot will also include the development and evaluation of an online, interactive course. The purpose of including the course in the pilot is to gather feedback from principal investigators and study coordinators about the content and whether the training is sufficient or excessive. In addition, this will provide further insight into the long term sustainability of maintaining and facilitating the course.

Timeline
The pilot timeline is dependent on recruitment of research participants, which affects the frequency of tool use. As a result, there will be monthly reports developed to summarize investigator feedback on tool use. However, more immediate feedback regarding the online course will be evaluated as soon as principal investigators complete the course.

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<td>Preparatory Activities</td>
<td>Communication</td>
<td>Evaluation of Online Course</td>
<td>Evaluation of Tool Use</td>
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<td>Identification of Pilot Candidates</td>
<td>Adoption of Capacity Assessment Tools</td>
<td>Summary Report of Pilot</td>
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<td>Training (Online Course)</td>
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<td>Evaluation of Tool Use</td>
<td>Summary Report of Online Course Feedback</td>
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II. Preparatory to the Pilot

Engagement of Stakeholders

Prior to the launch of this pilot, the IRB will engage key stakeholders, including IRB, Post Approval Review, University, and Department of Psychiatry leadership (including the CTSI/Psychiatry Research Director), to discuss the purpose and goals of the pilot, review the pilot procedures, and provide an overview of the online course curriculum. In addition, IRB members and staff will be engaged to ensure transparency regarding the pilot.

The HRPP Education and Outreach Specialist will identify additional collaborators, including:

- Post Approval Review program staff (i.e. consent auditors and reporting specialists);
- University of California, San Diego authors of the UBACC;
- Dr. Paul Appelbaum, a co-author of the MacCAT-CR in vetting training curriculum related to the administration of the instrument; and
- Rush Medical Center, developer of an online decision-making capacity course.

Communication Plan

Communications will be sent to all Department of Psychiatry principal investigators regarding the pilot purpose, procedures, training opportunities and evaluation plan. The communication strategy may also include brief presentations at departmental meetings to discuss the pilot and answer questions. In addition, IRB members and staff will receive communication regarding the pilot through internal newsletters and meetings.

Cost Analysis

Staff Resources

- Preparatory work will require staff resources, as this will require the development of communications, surveys, the online course, and ongoing attendance at departmental meetings. HRPP staff will primarily resource the development of content and will collaborate with stakeholders and subject matter experts for vetting purposes (i.e. surveys and online course).
- It is anticipated that 8-10 staff hours will be required to develop, vet, and finalize the online course. It is unknown how many staff hours will be required to manage the course, but the goal is to utilize Moodle automation and reporting tools to minimize staff resource needs. Specific allocation of staff resources will be gathered as part of the pilot evaluation.

Instruments

- The MacCAT-CR must be purchased for use. The publisher does not allow a singular purchase for the use of the tool by multiple researchers.
  - To purchase a single copy, the cost is $24.95 plus $6.00 for shipping.
  - If the HRPP commits to a bulk purchase, the publisher is willing to provide a 35% discount for 11-25 copies or 40% discount for 26+ copies.
    - If purchased in bulk, it is recommended that copies of the manual would be distributed to participants enrolled in the online course at no charge.
- The UBACC does not require purchase for use. Copies with appropriate citation will be provided to principal investigators.
III. **Pilot Protocol**

*Training of Investigators and Coordinators*

Prior to the implementation of the pilot procedures, an online, interactive training course will be developed by the HRPP Education and Outreach Specialist. This course will be offered to all Department of Psychiatry principal investigators and study coordinators. To determine whether participants have met course objectives, each unit (excluding the overview and resource units) will have quizzes. In order to receive course completion, participants must achieve passing scores on the quizzes.

The curriculum will include four units:

1. Course overview
2. Administration of the UBACC
3. Administration of the MacCAT-CR, and
4. Resources

Course materials will include:

- A hard copy of the MacCAT-CR manual
- An electronic copy of the UBACC
- Literature review of MacCAT-CR adaptations
- Consent Resource Guide
- Investigator Guide

It is recommended that continuing education credits be offered for this course. A course evaluation will be administered after the completion of the course to evaluate the delivery, relevance, and applicability of the curriculum, as well as the estimated time to complete the course. This evaluation is critical to determine whether the course content, approach, and length are sufficient for preparing principal investigators and study coordinators in using the assessment tools.

*Sampling Procedures for Tool Use Determinations*

In order to evaluate the use of the MacCAT-CR and UBACC, this pilot will target a representative sample of research studies from the Department of Psychiatry submitted for IRB review. Two sampling procedures are proposed for this pilot in order to gather sufficient information about the use of the capacity assessment tools.

**Sampling Method 1** - Requires the adoption of validated assessment tools for studies meeting specific criteria related to the risk of impairment and not yet approved by the IRB.

**Sampling Method 2** – Recruits principal investigators with active, IRB approved protocols to incorporate validated assessment tools for studies meeting specific criteria related to the risk of impairment.

**Sampling Method 1**

This method allows for the adoption of capacity assessment tools for research protocols under IRB review. In order to identify studies that meet the pilot’s criterion for participation, the IRB will:

- Identify IRB submissions from the Department of Psychiatry;
- Determine the level of risk based on the information provided by the principal investigator and the IRB’s final determination; and
- Categorize studies based on the level of risk.
  - Studies posing no more than minimal risk will be placed in **Group A (UBACC)**
Studies posing greater than minimal risk will be placed in Group B (MacCAT-CR)

Studies posing no more than minimal risk will be placed in Group A (UBACC)

Studies posing greater than minimal risk will be placed in Group B (MacCAT-CR)

Sampling Method 2
This method allows for the identification of existing, active protocols that may be able to participate in the pilot. This method will:

- Identify existing, active protocols from the Department of Psychiatry;
- Communicate with principal investigators regarding the opportunity to participate in the pilot;
- Identify the IRB’s determination of risk based on IRB review documentation; and
- Categorize studies based on the level of risk.

- Studies posing no more than minimal risk will be placed in Group A (UBACC)
- Studies posing greater than minimal risk will be placed in Group B (MacCAT-CR)

IV. Pilot Evaluations
To evaluate the pilot of the course and the use of the capacity assessment tools, the HRPP will gather informal and formal feedback from principal investigators and study coordinators, including but not limited to:

Course evaluation survey – An assessment of the online course (delivery, applicability/relevance of content, and estimated time to completion);

Assessment tool survey* – An assessment of the tool (ease of use, estimated time to completion, applicability / adaptability of the tool for a participant population); and

Informal feedback – Participation in departmental meetings to gather feedback.

Consent Auditing – Independent assessment of tool use conducted by the Post Approval Review program

*It is anticipated that the surveys will be administered on an ongoing basis due to the rate of recruitment, ultimately affecting the frequency of tool use for assessing capacity to consent for research.

Summaries of evaluations and reports regarding the pilot of the training course and use of the assessment tools will be provided to HRPP leadership, the Department of Psychiatry leadership, and the CTSI/Psychiatry Research Director with a goal to further enhance training and determine if additional adaptations or clarifications are needed regarding assessment tool use in research.
Appendix I - Populations with Additional Considerations

The targeting or inclusion of potentially vulnerable populations in research requires special considerations. Complete this appendix if the proposed research includes or targets:

- Subjects who are mentally, emotionally or developmentally disabled
- Adults lacking capacity to consent and/or adults with diminished capacity to consent.
- Non-English speakers
- Economically or educationally disadvantaged populations
- Minority groups

Special protections apply and additional information is required if the research project includes children, pregnant women, or prisoners. See links below for more information and IRB forms.

Section 1 – Targeting or Including Adults Lacking Capacity to Consent and/or Adults with Diminished Capacity to Consent.

Review UMN Investigator Guidance – Capacity to Consent prior to completing this section.

1.1 Does this research include or specifically target subjects who are mentally, emotionally or developmentally disabled or may otherwise have impaired decision making ability?

☐ No – section 1 complete, go to section 2
☐ Yes
  ☐ Included, but not targeted  ☐ Targeted

1.2 Provide justification for including or targeting this population. Include a description of the importance of the knowledge to be gained for the population(s) under study.

1.3 Does the population included or targeted represent the population with the least degree of impairment compatible with the aims of the study?

1.4 Specify how risks are minimized for this population:

1.5 The IRB requires that one of the following validated tools be used to evaluate capacity to consent in research studies that involve adults with absent, diminished, or fluctuating capacity to consent. Indicate which tool will be used to evaluate capacity to consent:
the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) appropriate to the context of the research must be utilized (required for research that is greater than minimal risk)

- The UCSD Brief Assessment of Capacity to Consent (UBACC) appropriate to the context of the research must be utilized (acceptable for use only in research deemed not greater than minimal risk)

In rare circumstances the IRB will approve use of an alternate validated instrument if it is recommended for the population under study. To evaluate its use, please provide the IRB with all of the following:

- A copy of the instrument
- Documentation of training required to administer the instrument
- List of those who have completed the training/will administer the instrument
- Documentation from the PI regarding the appropriateness of its use
- Literature supporting the use of the instrument

1.6 Provide the name(s) and credentials of all those who will evaluate capacity to consent. For each individual listed, provide documentation of training on the tool indicated above for use to evaluate capacity to consent.

1.7 Will risks or discomforts be greater for the adults who lack capacity to consent than unimpaired subjects?

- No
- Yes, explain how:
- Not applicable

1.8 A research participant’s consent capacity may improve, deteriorate or fluctuate during the course of a research study. Study protocols, consent forms and procedures should anticipate and address this phenomenon. Describe the safeguards in place prior to participant enrollment and, as appropriate, throughout the course of research participation

1.9 Document plans, if any, to avoid seeking consent during periods of greater than normal impairment.

1.10 If subjects lacking capacity to consent will be enrolled, document the plan for obtaining surrogate consent from a legally authorized representative (LAR).
See HRP-013 Legally Authorized Representatives, Children and Guardians

1.11 If surrogate consent will occur, explain whether the researcher will obtain the assent of prospective participants with impaired capacity.

1.12 Is this research a clinical psychiatric drug, device or biologic trial?

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06/01/14  Update options and reformat PI attestation  09/02/14

1.13 Clinical Trials and Persons Under Involuntary Medical Holds

Due to the potential for coercion or undue influence and concerns about lack of decisional capacity or diminished capacity, the following persons may not be recruited or enrolled in an any clinical drug trial under Minnesota law (effective August 1, 2016) and/or existing IRB Policy:

- Persons subject to a commitment petition, and/or
- Persons temporarily confined involuntarily under:
  - 72-hour emergency holds;
  - “Intent to leave” periods; or
  - Detainment under a peace Officer/health Officer Authority (formerly “transport hold”) or a court apprehend and hold order.

This restriction applies during the period of the emergency admission or hold. It does not prohibit a person already enrolled in a clinical drug trial at the time of the emergency admission or peace officer/court hold from continuing their participation.

Under IRB Policy, the above restrictions on recruitment and enrollment also apply to any clinical trial involving psychiatric devices or biologics (as well as all clinical drug trials).

No member of a study team may participate in a decision to rescind or discontinue a patient’s involuntary status as described above before its expiration, provisionally discharge a committed patient, or rescind a provisional discharge, when the patient is a prospective research subject in a study conducted by the study team.

☐ I confirm that I will not recruit or enroll persons on an involuntary medical hold or those subject to a commitment petition in any clinical drug trial or psychiatric device or biologic trial during the period of the medical hold or while undergoing the commitment process.
I confirm that no member of the study team will participate in a decision to rescind or discontinue a patient’s involuntary medical hold before its expiration, provisionally discharge a committed patient, or rescind a provisional discharge, when the patient is a prospective research subject in this study.

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<th>1.14 Psychiatric Drug Trials and Persons under a Stay of Commitment</th>
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<td>Are persons who are under a stay of commitment excluded or included in the potential subject population pool?</td>
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<td>Included - requirements of Minnesota Statute 253B.095 Subdivision 1 apply</td>
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**Psychiatric Drug Trials and Inclusion of Persons under a Stay of Commitment Order (Minnesota Statute 253B.095 Subdivision 1)**

Under Minnesota Law, a person who has had a commitment hearing and is released by the court before a commitment order is issued, is prohibited from participating in a psychiatric clinical drug trial during the period of a stay of commitment unless the court specifically authorizes the participation. The statute states:

[D]uring the period of a stay of commitment, the court may allow the patient to give consent to participate in a specific psychiatric clinical drug trial if the treating psychiatrist testifies or submits an affidavit that the patient may benefit from participating in the trial because, after providing other treatment options for a reasonable period of time, those options have been ineffective. The treating psychiatrist must not be the psychiatrist conducting the psychiatric clinical drug trial. The court must determine that, under the circumstances of the case, the patient is competent to choose to participate in the trial, that the patient is freely choosing to participate in the trial, that the compulsion of the stayed commitment is not being used to coerce the person to participate in the clinical trial, and that a reasonable person may choose to participate in the clinical trial.

**1.14 Provide justification for inclusion of persons under a stay of commitment.**

**1.15 Provide plan for obtaining consent compliant with Minnesota Statute 253B.095 Subdivision 1.**

If requirements of Minnesota Statute 253B.095 Subdivision 1 apply, a copy of the court order(s) authorizing participation must be provided to the IRB.
You are what is called a “legally authorized representative” of a person who is or might become a participant in a research study.

This means that the participant you represent does not have the capacity to make an independent decision about treatment or about participating in research. Therefore, you have been asked to make decisions on behalf of the participant.

Research Risk
Basically, you are being asked to weigh the risks and benefits of participating in clinical research. “Risk” means the chance of harm that might happen. There could be risks from medication side effects or risks from certain medical procedures. Sometimes doctors will tell you that these risks are “very rare” or “common”, and sometimes they will give you information to help you understand the level of risk. For example, they might tell you that a side effect has happened to 10% of research participants in the past.

Research Benefit
Likewise, you are being asked to evaluate the benefits of participating. A benefit might be that the new experimental drug would actually help treat the person’s medical problem. Doctors call this kind of benefit a “direct” benefit to the individual. There is another kind of benefit that is indirect. In this case, the benefit might be that a lot can be learned about promising medications or procedures. Also, other people might benefit from the knowledge gained from this study.

Risk and Benefit
You have to weigh the risks against the benefits. That is, “this much risk for that much benefit.” The benefits should outweigh or offset the risks.

Two Approaches
When you are asked to make this risk/benefit decision, there are two ways to go about it: (1) the “substituted judgment” approach and (2) the “in the individual’s best interest” approach.

The substituted judgment approach means that you are being asked to make the decision based on how you think the participant would do it. In other words, you express exactly what you think the person you are representing would do if there was no impairment in decision-making. For example, a research treatment might have a small likelihood of benefit for the individual and may have serious side effects, but you know that the person would want to advance science and be of possible benefit to others. In this case, you might decide to agree to the person’s participation using the substituted judgment approach.

The individual’s best interest approach takes a different perspective. In this case, you make the decision about participation in research based on what you think is best for the person, independent of what he or she might have decided if there was no impairment in decision-making. You look out for the safety and overall well-being of the person, considering all aspects of well-being.

For example, a research treatment might hold out a promise of effectiveness, but the person is so ill that even this improvement will make no difference in quality of life. In this case you might decide to not agree to the research treatment using the individual’s best interest approach.

Being a legally authorized representative is a serious role and the research team takes it seriously as well.

If you are having difficulty in making this decision, ask the person’s doctor or the researcher for more information until you feel confident that you are making the best decision you can under the circumstances.
If you have questions about your rights as a legally authorized representative of a UMN research study participant, you may call the University of Minnesota Human Research Protection Program at 612-626-5654.
**WORKSHEET: Criteria for Approval**

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The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used. It does not need to be completed or retained. (LAR = “subject's legally authorized representative”)

### 1 General Considerations (Check if “Yes” or “N/A”. All must be checked)

- The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.
- For initial review the principal investigator is not Restricted. (“N/A” if not initial review) N/A: □
- Materials are complete.

### 2 Criteria for Approval of Research: (Check if “Yes” or “N/A”. All must be checked) (Applies to initial, continuing, modifications)

- Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
- Risks to subjects are minimized by using procedures already being performed on the subjects for other purposes. (“N/A” if none) N/A: □
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable. (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (“N/A” if < Minimal Risk) N/A: □
- There are adequate provisions to protect the privacy of subjects.
- There are adequate provisions to protect the confidentiality of data.
- Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. (Refer to HRP-333-WORKSHEET: Vulnerable Populations; “N/A” if no vulnerable subjects) N/A: □
- The informed consent process meets one of these sections or checklists
- Section 5: Consent Process   □ Waiver or alteration of consent process (HRP-410) □ Permanently closed to enrollment
- The informed consent documentation meets one of these sections, worksheets, or checklists
- Section 6: Long Form   □ Waiver of documentation (HRP-411) □ Permanently closed to enrollment
- Short Form (HRP-317) □ Waiver or alteration of consent process (HRP-410)
- Additional applicable criteria are met (“N/A” if none)

### 3 Additional Considerations (Check all that apply.)

- Does the research involve no more than Minimal Risk to subjects?
- Should review take place more often than annually? □ If so, specify period.
- Is verification needed from sources other than the investigator that no material changes have occurred since prior review? □ (“N/A” if initial) N/A: □
- Does information need to be provided to subjects because it may affect their willingness to continue participation? (“N/A” if initial) N/A: □

### 4 Primary Reviewer Criteria for Initial review (Check if “Yes” or “N/A”. All must be checked; May be determined by a primary reviewer)

- The research has the resources necessary to protect subjects. (Time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)
- There are no inconsistencies between the DHHS grant and protocol. (“N/A” if there is no DHHS grant.) N/A: □
- The plan for communication among sites is adequate to protect subjects. (“N/A” if not a multicenter trial where PI is the lead or not initial) N/A: □

**Complete remaining items when applicable**

### 5 Consent Process (Check if “Yes”. All must be checked)

- The investigator will obtain the legally effective informed consent of the subject or LAR.
- The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
- The circumstances of consent minimize the possibility of coercion or undue influence.
- Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
- There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
- Consent will disclose the elements in Section 7: Elements of Consent Disclosure

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1 Advertisements (HRP-315); Payments (HRP-316); Additional Federal Agency Criteria (HRP-318); Pregnant Women (HRP-412); Non-Viable Neonates (HRP-413); Neonates of Uncertain Viability (HRP-414); Prisoners (HRP-415); Children (HRP-416); Cognitively Impaired Adults (HRP-417); Non-Significant Risk Device (HRP-418)

2 Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB’s experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures.

3 Implement when the veracity of the information provided is questioned.
### WORKSHEET: Criteria for Approval

- **NUMBER**: HRP-314  
- **DATE**: 4/7/2016  
- **PAGE**: 2 of 2

#### 6 Long Form of Consent Documentation (Check if “Yes” or “N/A”. All must be checked)

- The written consent document is accurate, complete, and consistent with the protocol.  
- The written consent document embodies the elements in Section 7: Elements of Consent Disclosure.  
- The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.  
- The subject or LAR will sign and date the consent document.  
- The person obtaining consent will sign and date the consent document.  
- A copy of the signed and dated consent document will be given to the person signing the document.  
- If there is an LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. ("N/A" if no signature line) N/A:

- When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. ("N/A" if all subjects are able to read) N/A:

#### 7 Elements of Consent Disclosure (Check if “Yes” or “N/A”. All must be checked)

**Required:** (*Can be omitted if there are none.*)

- The study involves research.  
- The purposes of the research.  
- The expected duration of the subject’s participation.  
- The procedures to be followed.  
- Identification of any procedures, which are experimental.*  
- Any reasonably foreseeable risks or discomforts to the subject.*  
- Any benefits to the subject or to others, which may reasonably be expected from the research.*  
- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*  
- The extent, if any, to which confidentiality of records identifying the subject will be maintained.*  
- How to contact the research team for questions, concerns, or complaints about the research.  
- How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects’ rights; to obtain information; or to offer input.  
- Whom to contact in the event of a research-related injury to the subject.  
- Participation is voluntary.  
- Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.  
- The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**Required for More than Minimal Risk Research**

- Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.  
- Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

**Required for Clinical Trials that Follow ICH-GCP**

- The approval of the IRB.  
- The probability for random assignment to each treatment.  
- The subject’s responsibilities.  
- When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.  
- The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.  
- When there is no intended clinical benefit to the subject, a statement to this effect.  
- The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject’s original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.  
- If the results of the trial are published, the subject’s identity will remain confidential.

**Required for FDA-Regulated Research**

- The possibility that the Food and Drug Administration may inspect the records.  
- The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.  
- The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.  
- For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

**Additional:** (Include when appropriate.)

- The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.  
- If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.  
- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.  
- Any additional costs to the subject that may result from participation in the research.  
- The consequences of a subject’s decision to withdraw from the research.  
- Procedures for orderly termination of participation by the subject.  
- Significant new findings developed during the course of the research, which may relate to the subject’s willingness to continue participation will be provided to the subject.  
- Approximate number of subjects involved in the study.  
- Amount and schedule of all payments.
The purpose of this worksheet is to provide support for IRB members reviewing research in evaluating whether potential research subjects could be vulnerable to coercion or exploitation that might influence their consent to research or their decision to continue in research. This worksheet is to be used. This worksheet does not need to be completed or retained.

1. **Is the research likely to enroll subjects to which any of the following would apply?**
   - Difficulty understanding information about the research due to the complexity of the study (e.g. gene transfer research)
   - Non-English speakers
   - Unable to read (illiterate)
   - Approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.
   - Employees of researcher
   - Students
   - Members of the military
   - Serious health condition for which there are no satisfactory standard treatments
   - Fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior)
   - Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research:

2. **Research Review/Design/Conduct Considerations**
   - Engage consultant in IRB review of the study
   - Use of a consent monitor
   - Translation of consent form and/or use of interpreter during consent process
   - Use of short-form consent form and process
   - Modify timing of consent process if possible (before or after stressful situation)
   - Alternative to participation in research to fulfill course requirement
   - Additional information in the informed consent form
   - Exclusion of the population if not required to achieve study objectives
   - Researcher should not have any role in decisions impacting subjects' status (e.g. institutionalization, judicial determination of competence)
   - Treating physician (if member of the research team) should not participate in the consent process
   - Apply for Certificate of Confidentiality (CoC)
   - Other:
Submit this application, along with all required appendices and supplemental documents to the University of Minnesota IRB

<table>
<thead>
<tr>
<th>Electronic Submission (preferred): Submit to: <a href="mailto:irb@umn.edu">irb@umn.edu</a></th>
<th>U.S. Mail Address: Human Research Protection Program 420 Delaware St. SE Minneapolis, MN 55455-0392</th>
</tr>
</thead>
</table>

For more information please visit our website http://www.research.umn.edu/irb/index.html
Contact our office
Phone: 612-626-5654
Email: irb@umn.edu
Fax: 612-626-6061

Project Title
If the project is funded, the Sponsored Project Administration (SPA) project title must match the IRB project title. If the project is funded by multiple grants, provide all grant titles below:

Section 1  Principal Investigator

<table>
<thead>
<tr>
<th>Name</th>
<th>Highest Earned Degree:</th>
</tr>
</thead>
</table>

Preferred contact information:
Preferred email or phone number at which the PI may be contacted by IRB staff or reviewers to resolve questions or concerns.

Affiliation and contact information
- University of Minnesota (complete contact info section 1 only)
- Fairview (complete contact info section 2 only)
- Gillette (complete contact info section 2 only)

Required Contact information

<table>
<thead>
<tr>
<th>U of M Internet ID (x.500):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>U of M Employee/student ID Number:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>University Department:</th>
</tr>
</thead>
</table>

Required contact information

<table>
<thead>
<tr>
<th>Address:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Phone number:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Mobile  Pager  Office  Email address:</th>
</tr>
</thead>
</table>

Occupational Position:
- Faculty  Physician  Staff  Student - Students must complete the faculty academic advisor section below and submit Appendix J
- Other:
**Conflict of Interest:**
Does the PI have a reportable conflict as defined in Section 11 of the application?
- [ ] Yes
- [ ] No

**Required CITI Human Subjects Training**
Date (Month/Year) CITI completed (either initial or refresher course):

Note: The IRB requires researchers to complete refresher courses every three years after completion of initial course. For more information on training requirements see IRB Training

**HIPAA TRAINING**
Check box below if HIPAA training is required.
- [ ] HIPAA Required – Data contains PHI
- [ ] UMN
- [ ] Other:

**For information regarding human subjects and HIPAA training requirements please go to** [http://www.irb.umn.edu/training.html](http://www.irb.umn.edu/training.html).

As Principal Investigator of this study, I assure the IRB that the following statements are true:
- The information provided in this form is correct.
- I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment.
- I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc.
- I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.
- I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation.
- I will not begin my research until I have received written notification of final IRB approval.
- I will comply with all IRB requests to report on the status of the study.
- I will maintain records of this research according to IRB guidelines.
- The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application.
- If these conditions are not met, I understand that approval of this research could be suspended or terminated.

**Signature/Digital signature/x.500 of PI**
**Title of PI**
**Date**

**Today’s date.**

---

**Faculty Academic Advisor - Student Research**

If the PI of this research is a student, include Appendix J filled out by the advisor with this application form.

Student research requires the approval of a faculty academic advisor. As academic advisor to the student investigator, the advisor assumes responsibility for ensuring that the student complies with University policies and federal regulations regarding the use of human subjects in research.

**Faculty Academic Advisor Name (Last name, First name MI):**

**University Department:**

**U of M Employee ID:**

**U of M x.500 ID (ex. smith001):**

**Conflict of Interest:**
Does this person have a reportable conflict as defined in Section 11 of the application?
- [ ] Yes
- [ ] No
Human Subjects Training:
CITI – Date completed (either initial or refresher course):

Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training

HIPAA TRAINING
Check box below if HIPAA training is required.

☐ HIPAA Required – Data contains PHI

HIPAA Training completed through:
☐ UMN
☐ Other:

Today’s date.

Signature/Digital signature/x.500 of Advisor
Advisor must be cc’ed on emailed submission to the IRB

Person preparing this document
☐ PI prepared this application – section 1 complete
☐ The person named below prepared this application

Name: 
Preferred contact info:

Role on study: ☐ Co-Investigator ☐ Study Coordinator (Research Staff)

The person preparing the document must be listed on the application as a co-investigator or in a role that allows him/her to receive correspondence related to the application. See section 13 of the application for more information

Additional study personnel? Complete section 13 of this application.

Section 2 Summary of Activities
The following questions must be answered in lay language or language understood by a person unfamiliar with your area of research. A research plan or protocol is required with this submission. In the responses below, area-specific jargon should be avoided or explicitly explained. Do not say “see protocol” or “protocol attached”.

Protocol templates are available on the IRB forms page.

2.1 What is your research question?
State hypothesis or primary objective, and provide a brief background on subject population, treatment procedures, and the rationale for conducting the study.

2.2 Who developed the research plan/protocol?
☐ Principal Investigator ☐ Business and Industry Sponsor ☐ Other:

2.3 Explain how the study design and methods will answer the research question.
2.4 What will the subjects be asked to do solely for the purpose of this research?

2.5 Does the study involve treatment?

- No.
- Yes. List any procedure that would be performed if research was not conducted (i.e. procedures performed for diagnostic or treatment purposes).

2.6 Indicate whether your research includes any of the following to determine which supplemental forms must be submitted with your application:

<table>
<thead>
<tr>
<th>If the research includes</th>
<th>Appendices and supplemental materials required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration of approved or unapproved drugs, chemical or biological agents</td>
<td>Appendix E required with the application</td>
</tr>
<tr>
<td>Administration of approved or unapproved devices</td>
<td>Appendix F required with the application</td>
</tr>
<tr>
<td>Genetic testing (whether or not results are returned to subjects)</td>
<td>Appendix G required with the application</td>
</tr>
<tr>
<td>Use of (collecting or having access to) Protected Health Information (PHI)</td>
<td>Appendix H required with the application</td>
</tr>
<tr>
<td>Field Work</td>
<td>Appendix L required with the application</td>
</tr>
<tr>
<td>Use of a deceptive technique</td>
<td>Appendix N required with the application</td>
</tr>
<tr>
<td>Community based participatory research</td>
<td>Appendix Q required with the application</td>
</tr>
<tr>
<td>Collection or storage of biological samples (including blood draws, marrow biopsy sampling, biopsy of other tissues)</td>
<td>Appendix T required with the application</td>
</tr>
<tr>
<td>Use of Magnetic Resonance devices housed at the Center for Magnetic Resonance Research (CMRR)</td>
<td>Documentation of CMRR Safety Committee approval required. CMRR users must submit the completed CMRR Device and Safety Review form to the CMRR prior to submission of their IRB application. A draft copy of the IRB application must be included for CMRR Safety Committee</td>
</tr>
</tbody>
</table>
Section 3  Risks and Benefits

3.1 Please indicate if the proposed research will include any of the following (check all that apply). The list below is not exhaustive but represents common elements or procedures in research with associated risks that are frequently overlooked or not clearly articulated.

- [ ] Administration of physical stimuli
- [ ] Probing for personal or sensitive information in surveys or interviews
- [ ] Collection of data with identifiers
- [ ] Possible invasion of privacy of the subject or the subject’s family
- [ ] Modification or extension of a surgical process to achieve research related objectives.
- [ ] Major changes in diet, exercise, or sleep
- [ ] Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses
- [ ] Placebo Use
3.2 Describe in detail the nature and degree of the risk associated with participation. The risks must be disclosed in the consent form. Include in the response all potential risks, not just those indicated in the checklist above.

3.3 Describe the precautions that will be taken to minimize each of the risks identified in questions 3.1 and 3.2.

3.4 List any anticipated direct and societal benefits to participation in this research project. If none, state that in the space provided below and in the consent form. The benefit of receiving treatment is not necessarily a benefit to participation in the research project. **Compensation paid to subjects is not considered a benefit.**

3.5 Justify the risk in terms of the potential scientific yield and in relation to the anticipated benefits to the subjects.

---

**Section 4 Subject Profile**

4.1 How many people will need to go through the consent process (but not necessarily enroll) to get the data sets necessary? Subjects who go through the consent process are counted toward the total number of subjects approved by the IRB even if they have no further participation in the study (i.e. Drop out, are screened out, etc.)

*Note that this is the number of subjects for which IRB approval will be granted.*

<table>
<thead>
<tr>
<th>Total:</th>
<th>Of the total requested indicate</th>
<th>Percent Male</th>
<th>%</th>
<th>Percent Female</th>
<th>%</th>
</tr>
</thead>
</table>

4.1.1 Provide justification if all or more of one gender is targeted for participation

4.2. How many subjects are needed to enroll to get the data sets required to answer the research question? For multi-center trials provide the number enrolled locally.

Total: 

4.3 If this is a multi-center study, provide the total number of subjects to be enrolled from all centers:

Total:
4.4 Which of the following describe the subjects (check all that apply)

- [ ] Inpatients
- [ ] Outpatients
- [ ] Healthy volunteers
- [ ] Condition-matched controls

4.5 What is the age range of the subjects?

<table>
<thead>
<tr>
<th>Exact Age Range:</th>
<th>to</th>
<th>See information below for required supplemental materials.</th>
</tr>
</thead>
</table>

If age range includes

- [ ] Required Supplemental Materials

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Required Supplemental Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-7 years</td>
<td>Parental consent form and <a href="#">Appendix Y</a> required</td>
</tr>
<tr>
<td>8-17 years</td>
<td>Child’s assent, parental consent form and <a href="#">Appendix Y</a> required</td>
</tr>
</tbody>
</table>

4.6 List the criteria for subject INCLUSION in this study:

4.7 List the criteria for subject EXCLUSION from this study:

4.8 Are children included or excluded from this study?

- [ ] Included – [Appendix Y](#) required
- [ ] Excluded. Provide Justification below

- [ ] No direct benefit to participation (exclusion of children permissible)
- [ ] Potential for direct benefit exists for adults only (i.e. disease/condition does not occur in children)
- [ ] Potential for direct benefit exists for children. Provide justification for exclusion of children:

Note Regarding Exclusion of Children

[NIH guidelines](#) advise that the exclusion be justified, so that potential for benefit is not unduly denied. Indicate whether there is potential for direct benefit to subjects in this study and if so, provide justification for excluding children.

Note: If inclusion of children is justified, but children are not seen in the PI’s practice, the sponsor must address plans to include children in the future or at other institutions.

4.9 Indicate if the research includes or specifically targets the populations listed below for participation.

Inclusion of the populations below, either incidentally or by design, requires the investigator to provide additional information to the IRB. In some cases, such as the inclusion of prisoners, certification by the Office of Human Research Protection is required by federal regulations. If, after final approval, the subject population pool changes to include any listed below, complete a Change in Protocol Form and complete any relevant appendices.
<table>
<thead>
<tr>
<th>Population group/description</th>
<th>Resources and Required supplemental materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Children</td>
<td>Appendix Y required. Review the University of Minnesota policy regarding Safety of Minors</td>
</tr>
<tr>
<td>□ Prisoners</td>
<td>Appendix C required. See guidance at 45 CFR 46 subpart C.</td>
</tr>
<tr>
<td>□ Adults lacking capacity to consent and/or adults with diminished capacity to consent including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders and behavioral disorders.</td>
<td>Appendix I required. See HRP-Policy-110 Capacity to Consent and HRP-Policy-111 72 Involuntary Holds</td>
</tr>
</tbody>
</table>

4.10 Some potential research subjects could be uniquely vulnerable to coercion or exploitation that might influence their consent to research or their decision to continue participation in research. Is the proposed research likely to include such participants? Check all that apply

See Investigator Guidance – Vulnerable Participants

- □ Minority groups
  - □ Those difficulty understanding information about the research due to the complexity of the study (e.g. gene transfer research)
  - □ Non-English speakers
  - □ Those unable to read (illiterate)
  - □ Potential participants are approached during a stressful situation such as emergency room setting, childbirth (labor), etc.
  - □ Employees of researcher
  - □ Students of the researcher
  - □ Members of the military
  - □ Those with a serious health condition for which there are no satisfactory standard treatments
  - □ Those who are likely to have a heightened fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior)
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research:

Appendix I “Populations with Special Considerations” required.

Provide justification below for targeting/including these subjects:

Indicate below how the design or conduct of the research reflects an awareness of and defines approaches to mitigate the potential for coercion. Examples include use of short form consent form and process, use of a consent monitor, modifying the timing of consent (either before or after stressful situation). For more information, see Investigator Guidance: Research with Participants who are Vulnerable to Coercion or Exploitation.

Groups with socioeconomic or educational disadvantage

Appendix I “Populations with Special Considerations” required.

Non-English speakers targeted

Appendix I “Populations with Special Considerations” and consent forms in the language spoken by participants and an English translation.

Non-English speakers included (i.e., non-English speakers will not be turned away)

See guidance regarding the short form consent process. Consent short forms in Arabic, Croatian, French, Hmong, Khmer, Lao, Oromo, Russian, Somali, Spanish and Vietnamese are available for download.

Adults lacking capacity to consent and/or adults with diminished capacity to consent including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders and behavioral disorders.

Appendix I “Populations with Special Considerations” required.

Section 5 Study Location(s)
Indicate in the table below all of the locations where the research will take place.

<table>
<thead>
<tr>
<th>LOCATION</th>
<th>Required Supplemental Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital/Clinic (specify below)</td>
<td></td>
</tr>
<tr>
<td>University of Minnesota Medical Center (UMMC) – Fairview, Amplatz</td>
<td></td>
</tr>
<tr>
<td>Fairview Health Services (Southdale, Ridges, Lakes, Northland</td>
<td></td>
</tr>
<tr>
<td>Gillette Children’s Specialty Healthcare</td>
<td></td>
</tr>
<tr>
<td>Location Category</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Clinical and Translational Science Institute (CTSI)</td>
<td>University of Minnesota Physicians (UMP) Clinics (Oncology Clinic, Phalen, Family Medicine, etc.)</td>
</tr>
<tr>
<td><strong>University Campus (Non-clinical location)</strong></td>
<td></td>
</tr>
<tr>
<td>Minneapolis/St Paul</td>
<td>Rochester</td>
</tr>
<tr>
<td>Duluth</td>
<td>Crookston</td>
</tr>
<tr>
<td>Morris</td>
<td>Other, specify:</td>
</tr>
<tr>
<td><strong>Veteran’s Administration Medical Center</strong></td>
<td>Veterans Administration IRB approval</td>
</tr>
<tr>
<td><strong>Center for Magnetic Resonance Research (CMRR)</strong></td>
<td>Submit Documentation of CMRR Safety Committee approval. CMRR users must submit the completed CMRR Device and Safety Review form to the CMRR prior to submission of their IRB application. A draft copy of the IRB application must be included for CMRR Safety Committee review. Documentation of approval by the CMRR Safety Committee will be provided to the researcher to include with the IRB application.</td>
</tr>
<tr>
<td><strong>Elementary school/secondary school</strong></td>
<td>Submit Appendix M “Research in Schools” and appropriate documentation of approval from school district</td>
</tr>
<tr>
<td><strong>University of Minnesota Child Care Center</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Prison/Halfway House</strong></td>
<td>Submit Appendix C “Prisoners as Subjects”</td>
</tr>
<tr>
<td>Federal Prison</td>
<td>State Prison</td>
</tr>
<tr>
<td>Halfway house, specify:</td>
<td></td>
</tr>
<tr>
<td><strong>International Location</strong></td>
<td>Submit Appendix K “International Research”</td>
</tr>
<tr>
<td><strong>Sovereign Nation within United States borders</strong></td>
<td>Submit documentation of approval from sovereign nation</td>
</tr>
<tr>
<td><strong>Military base or facility owned by any component of the Department of Defense</strong></td>
<td>Submit Appendix D “Department of Defense”</td>
</tr>
<tr>
<td>Nursing home, specify:</td>
<td>Documentation of approval from site administrators</td>
</tr>
<tr>
<td>Community center, specify:</td>
<td>Documentation of approval from site administrators</td>
</tr>
<tr>
<td>Research will be conducted online</td>
<td></td>
</tr>
<tr>
<td>Other, specify:</td>
<td></td>
</tr>
</tbody>
</table>

**Section 6 Recruitment & Compensation**

University of Minnesota policy prohibits researchers from accepting gifts for research activities.
Research staff must decline any incentive (i.e. finders fees, recruitment bonus, etc.) offered by the study sponsor connected with subject enrollment or completion of the research study. For more information, please see Code of Conduct


6.1 Which of the statements below describes the recruitment strategy? If both apply, select both.

☐ Statement A. Potential subjects will self-identify based on response to an advertisement, flyer, presentation or respondent driven sampling. **If ONLY statement A selected, go to question 6.2**

☐ Statement B. Potential subjects will be recruited based on information contained in private/protected records (medical records, student records). This also includes subjects who will be recruited from the PI or Co-I’s patient population.

If statement B is selected, answer the questions 6.1.1. – 6.1.3 below

6.1.1 Explain how the researcher has legitimate access to these records.

6.1.2 Identify who will make initial contact with potential subjects.

6.1.3 Will the records include MEDICAL records?

☐ No, go to question 6.2

☐ Yes. Indicate the mechanism the PI will use to confirm that the patient has agreed to release their PHI contained in their medical record for research purposes; for example, the patient has documented consent to research on their treatment, intake or hospital admitting form. (MN Statue 144.334 Subd. 3; Access to Medical Records for Research)

☐ Academic Health Center Information Exchange (AHC-IE)

☐ Other. Describe:

6.2 Check the box(es) that describe the recruitment strategy. Any required documents as detailed below should be submitted with this application.

<table>
<thead>
<tr>
<th>Method</th>
<th>Required Supplemental Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flyers</td>
<td>Submit Flyer with application</td>
</tr>
<tr>
<td>Newspaper ads</td>
<td>Submit draft of ad with application</td>
</tr>
<tr>
<td>Radio or television ads</td>
<td>Submit script with application</td>
</tr>
<tr>
<td>Social networking sites</td>
<td>Text, page mock up or description of posting including any images or videos</td>
</tr>
<tr>
<td></td>
<td>Indicate site(s):</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Letters or emails</td>
<td>Submit letter or email with application</td>
</tr>
<tr>
<td>Phone call</td>
<td>Submit phone script with application</td>
</tr>
<tr>
<td>Group presentations</td>
<td>Submit outline of presentation and any materials provided to participants with application</td>
</tr>
<tr>
<td>University of Minnesota research recruitment tool (e.g. REP, SONA or Carlson School Recruitment)</td>
<td></td>
</tr>
<tr>
<td>Non-University of Minnesota research recruitment tool (e.g. MTURK, Research Match)</td>
<td></td>
</tr>
<tr>
<td>Other method not described above</td>
<td>Specify:</td>
</tr>
</tbody>
</table>

6.3 Provide a brief narrative to describe the recruitment process. Include in the description how potential subjects will be informed of the research.

6.4 Will gifts, payments, compensation, reimbursement, services without charge or extra credit be provided to the subject for participation in research?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>No</td>
<td>If no, go to Section 7 Confidentiality and Privacy</td>
</tr>
<tr>
<td>Yes</td>
<td>Complete 6.4.1 – 6.4.4</td>
</tr>
</tbody>
</table>

6.4.1 Indicate the type of compensation and the maximum value a subject may receive during the course of his/her participation.

6.4.2 When will compensation be provided? Include in the response if payment for multiple visits is prorated and the compensation schedule

6.4.3 Who will receive the compensation?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Other, specify:</td>
</tr>
</tbody>
</table>

6.4.4 Will Research Experience Points (REP) be awarded?
Section 7  Confidentiality and Privacy

Confidentiality refers to how the subject’s identifiable data will be handled, managed, stored, and, if applicable, disseminated.

Privacy refers to having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally or intellectually) with others.

7.1. Will researchers maintain any identifiers (e.g. names, addresses, telephone numbers, etc.)?

- □ No. Go to question 7.13
- □ Yes.

7.2 Indicate which of the direct identifiers below will be maintained?

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Full names</td>
<td>□ Initials</td>
<td>□ Photographs of participant</td>
</tr>
<tr>
<td>□ Telephone numbers</td>
<td>□ Email address</td>
<td>□ Videos of participant</td>
</tr>
<tr>
<td>□ Birth date</td>
<td>□ Postal Address</td>
<td>□ Other:</td>
</tr>
</tbody>
</table>

7.3 Why it is necessary to maintain direct identifiers?

7.4 Describe the coding system that will be used to protect against disclosure of these identifiers.

7.5 How long will the link between identifiers and code be maintained?

7.6 Could any disclosure of the participant’s responses place the participant at risk of criminal or civil liability or could the disclosure be damaging to the participant’s financial standing, employability, or reputation?

- □ No
- □ Yes  Explain how the researcher will mitigate these risks (e.g. limiting access to identifiers, obtaining a Certificate of Confidentiality, etc.)?
7.7 Will the researcher obtain a [Certificate of Confidentiality](#) for this project?

- [ ] No
- [ ] Yes  Documentation of Certificate of Confidentiality must be provided to the IRB when obtained.

7.8 How long will the identifiable data be maintained?

7.9 What format will be used to maintain the data (paper, digital, electronic media, video, audio or photographic)?

7.10 Where will data be stored?

7.11 What security provisions will be taken to protect the data (password protection, encryption, etc.)? See the University of Minnesota’s [Safe Computing recommendations](#)

7.12 Will a copy of the consent form or other research study information be placed in the subjects’ non-research records such as medical, employment or educational records?

- [ ] No
- [ ] Yes  This information must be included the confidentiality section of the consent form.

7.13 Even if direct identifiers are not recorded or maintained, are there potential ethical or legal circumstances when it would be necessary to break confidentiality (e.g. requirements for mandated reporting)?

- [ ] No
- [ ] Yes  This information must be included in the consent form. Explain below the circumstances when breaking confidentiality is required.

7.14 Describe the conditions under which interaction with subjects will occur (e.g., consent discussion occurs in a private room). Explain how these conditions adequately protect the PRIVACY interests of subjects.
Section 8  Expedited Review Eligibility

Federal criteria for risk assessment make some studies eligible for Expedited Review (see 45 CFR46.110 and 21 CFR 56.110). Expedited review categories are below and may also be found at http://www.irb.umn.edu/expedited.html

Studies eligible for Expedited Review must meet the federal definition of minimal risk which is:

*The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

8.1 What is the level of risk to subjects in this research study?

- **Greater** than minimal risk (full committee review required) – go to Section 9 Informed Consent Process
- **Not greater** than minimal risk.

Review the table in question 8.2 below and check the box next to the expedited review category the investigator asserts applies to this research.

Note: Final expedited review eligibility decisions are made by the IRB after initial review of the application. Studies involving drugs/biologics or devices are rarely eligible for expedited review.

8.2 Check the box next to the Expedited Review Categories (2-7) that apply to the proposed project. Per UMN IRB policy, clinical studies involving drugs or devices are not eligible for expedited review category 1.

<table>
<thead>
<tr>
<th>Not available per UMN IRB policy</th>
<th>1. Clinical studies of drugs and medical devices only when condition (1) or (2) is met.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)</td>
</tr>
<tr>
<td></td>
<td>2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.</td>
</tr>
</tbody>
</table>

- **Cat. 2** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  2. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- **Cat. 3** Prospective collection of biological specimens for research purposes by noninvasive means.

  Examples:
  1. hair and nail clippings in a nondisfiguring manner;
  2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  3. permanent teeth if routine patient care indicates a need for extraction;
  4. excreta and external secretions (including sweat);
  5. uncanannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
  6. placenta removed at delivery;
  7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
8. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
10. sputum collected after saline mist nebulization.

| Cat. 4 | Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
| 1. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;
| 2. weighing or testing sensory acuity;
| 3. magnetic resonance imaging;
| 4. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
| 5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. |

| Cat. 5 | Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) |

| Cat. 6 | Collection of data from voice, video, digital, or image recordings made for research purposes. |

| Cat. 7 | Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.) |

### Section 9  Informed Consent Process

**Document the Elements of the Informed Consent Process**

It is the responsibility of the investigator to assess comprehension of the risks and benefits of participation in the research and only enroll subjects who can demonstrate understanding of the research study (45 CFR 46.116). The federal regulations require that consent be in language understandable to the subject. If subjects do not comprehend English, translated consent forms are required, or the use of short forms with an oral explanation can be accepted.

Consent forms must be submitted for IRB review. It is highly recommended that researchers use the sample consent for template available on the [IRB Forms page](http://www.research.umn.edu/consent/). Do not submit sponsor prepared forms without editing the form to include University of Minnesota IRB standard language and all essential elements of informed consent.

Resources for preparing consent forms are available at:
[Informed Consent Online Tutorial](http://www.research.umn.edu/consent/)
If the researcher is requesting a waiver of consent, complete question 9.9 only. Be advised that waiver of consent is rarely granted.

### 9.1 Document the informed consent process timeline.
Detail when consent will be discussed and documented in relation to research data collection, if there will be any waiting period or if process will occur over multiple contacts or clinical visits.

### 9.2 Will anyone not listed on this application obtain consent?
Except in rare circumstances, all individuals who will obtain consent must be listed as research personnel on the IRB application so that basic human subjects’ research training is documented. If in-person consent will not be obtained, select the option below and provide rationale.

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ No</td>
<td>If no, go to question 9.3</td>
</tr>
<tr>
<td>☐ Yes</td>
<td>Explain who, other than those listed as personnel on this application, will obtain consent</td>
</tr>
<tr>
<td>☐ N/A</td>
<td>In-person consent will not be obtained. Explain below:</td>
</tr>
</tbody>
</table>

### 9.3 Provide a brief description of the plan to train those individuals who will be obtaining consent from subjects to participate in this project.

**Note:** Everyone obtaining consent must complete [CITI training](#).

### 9.4 Will all subjects consent for themselves?

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>☐ Yes</td>
<td>If yes, adults lacking capacity to consent must be listed in the exclusion criteria (question 4.7).</td>
</tr>
<tr>
<td>☐ No</td>
<td>If no, indicate below who, when appropriate, will provide consent</td>
</tr>
<tr>
<td>☐ Parent/guardian</td>
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<tr>
<td>☐ Legally authorized representative – <a href="#">Appendix I required</a></td>
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</table>

### 9.5 What questions will be asked to assess the subjects’ understanding? Questions should be open-ended and go beyond requiring a yes/no response.

### 9.6 Participation in research must be voluntary. Describe the steps taken to minimize the possibility of undue influence on potential subjects.

**Care of Subjects in Case of Accident**

*If this research involves a potential for injury, injury compensation language must be included in the consent form (see 21 CFR 50.25). If a contract to pay for research-related injuries exists, the language in the consent form should not contradict the language in the contract.*

### 9.7 Is there a potential for research related injury?

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
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<tbody>
<tr>
<td>☐ No</td>
<td>If no, go to question 9.8</td>
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<tr>
<td></td>
<td>Yes</td>
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</table>
9.9 Does the researcher wish to waive consent?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
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<tbody>
<tr>
<td>If no, go to section 10 - Funding</td>
<td>Indicate if the following statements apply</td>
<td></td>
</tr>
</tbody>
</table>

**The research involves no more than minimal risk to subjects.**

- Yes
- No – waiver may not be requested

**Granting a waiver will not adversely affect the rights and welfare of the subjects.**

- Yes
- No – waiver may not be requested

**The research could not practically be carried out without a waiver or alteration.**

- Yes
- No – waiver may not be requested

If consent is waived, whenever appropriate the subjects will be provided with additional pertinent information after participation. Describe below the process for providing subjects with this information.

---

**Section 10  Funding**

10.1 Has funding for this project been applied for, requested or received or do you intend to request/apply for funding?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explain how the research will be conducted without funding:</td>
<td>Indicate in the table below who will provide/manage funds.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Funds provided/managed by</th>
<th>Required Supplemental Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal University of Minnesota (departmental funds, internal grant program, etc.)</td>
<td>none</td>
</tr>
<tr>
<td>University of Minnesota Sponsored Project Funding</td>
<td>Appendix A required</td>
</tr>
<tr>
<td>Non-University of Minnesota source or management</td>
<td>Appendix A required</td>
</tr>
</tbody>
</table>

---

**Section 11  Conflict of Interest**

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human subjects. Reporting of financial interests is required from all individuals responsible for the design, conduct or reporting of the research. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the IRB.

Examples of conflicts of interest may include, but are not limited to:

- A researcher participating in research on a technology, process or product owned by a business in which the researcher or family member holds a significant financial interest or a business interest.
- A researcher participating in research on a technology, process or product developed by that researcher or family member.
- A researcher or family member assuming an executive position in a business engaged in commercial or research activities related to the researcher’s University responsibilities.
- A researcher or family member serving on the Board of Directors of a business from which that member receives University supervised Sponsored Research Support.
- A researcher receiving consulting income from a business that funds his or her research.
- A researcher receiving consulting income from a business that could benefit from the results of research sponsored by a federal agency (i.e. NIH).

### 11.1 Do any of the Investigators or personnel listed on this research project have a business interest or a financial interest of $10,000 or more ($5,000 or more if research is funded by a Public Health Service (PHS) agency or researcher is involved in clinical health care) associated with this study when aggregated for themselves and their family members?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes List the investigator(s) with conflicts:</td>
</tr>
</tbody>
</table>

### 11.2 Do any of the investigators or personnel (when aggregated for themselves and their family members) listed on this research have:

#### 11.2.1 Ownership interests more than $10,000 ($5,000 if research is funded by PHS or researcher is involved in clinical health care) when the value of interest could be affected by the outcome of the research?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes List the investigator(s) with conflicts:</td>
</tr>
</tbody>
</table>

#### 11.2.2 Ownership interests exceeding 5% interest in any one single entity (or any equity interest in a non-publicly traded entity if research is funded by PHS or researcher is involved in clinical health care)?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes List the investigator(s) with conflicts:</td>
</tr>
</tbody>
</table>

#### 11.2.3 Compensation greater than $10,000 ($5,000 if research is funded by PHS or researcher is involved in clinical health care) when the value of the compensation could be affected by the outcome of the research?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
</tr>
</thead>
</table>
|   | Yes List the investigator(s) with conflicts:
### 11.3 Have all business or financial interests indicated above been reported?

- [ ] No
- [ ] Yes
- [ ] N/A There are no conflicts of interest on this study

- University of Minnesota researchers need to report business or financial interest online via the [Report of External Professional Activities (REPA)](mailto:).
- Fairview Health System researchers need to complete the [Fairview Health Services Conflict of Interest Disclosure forms](mailto:).
- Gillette Children’s Specialty Healthcare researchers must contact the Director of Research Administration, at 651-229-1745.

The IRB will verify that a management plan is in place with the Conflict of Interest (COI) Program. If the COI Program does not have an approved management plan in place for this research, they will contact the individual(s) for additional information. Final IRB approval cannot be granted until the IRB has reviewed the management plan and all potential conflict matters are settled. The IRB receives a recommendation from the Conflict of Interest Review Committee regarding disclosure to subjects and management of any identified conflict. The convened IRB determines what disclosure language should be in the consent form.

### Section 12 Research Services, Assessment and Oversight

#### Section 12.1 RESEARCH COLLABORATIONS

12.1 Does this research project involve collaborations with any sites or personnel outside of the University of Minnesota, its coordinate campuses, the Fairview Health Systems or Gillette Children’s Specialty Healthcare?

- [ ] No  Go to question section 12.2
- [ ] Yes  Briefly describe the collaboration (with whom and for what purpose):

Additional requirements for ensuring appropriate IRB oversight may apply. These requirements are often dependent on whether or not the site/personnel is considered “engaged” in human subjects research according to federal definitions. Contact the UMN IRB office ([irb@umn.edu](mailto:)) to determine how IRB oversight of the research activity with the external site/personnel should be address.

#### Section 12.2 AFFILIATED ENTITIES WITH OVERSIGHT RESPONSIBILITIES

12.2.1 Will this research use services, resources, or funding from the Clinical and Translational Science Institute? Examples include pilot funding, career development awards, biostatistics support, facilities, staffing, project management, regulatory assistance, or informatics consultation and support

- [ ] No  Go to question 12.2.2
12.2.2 Does this research require Masonic Cancer Center Protocol Review Committee (CPRC) review?

The CPRC is required to evaluate, approve or reject, monitor, and re-review on an annual basis all University of Minnesota clinical cancer research protocols including those with non-therapeutic intent.

<table>
<thead>
<tr>
<th>Yes</th>
<th>Provide CTR Portal ID#:</th>
</tr>
</thead>
</table>

12.2.3 Will this research utilize Gillette Children’s Specialty Healthcare resources or medical records?

| No | Go to section 12.3 |
| Yes | If using Gillette resources, please contact: |
|     | Joyce Trost, PT       |
|     | Research Administration Manager |
|     | Gillette Children's Specialty Healthcare |
|     | 651-325-2339/651-312-3182/jtrost@gillettechildrens.com |

12.2.4 Will this research use Magnetic Resonance (MR) Devices housed at the Center for Magnetic Resonance Research (CMRR) facilities?

| No | Go to section 12.3 |
| Yes | Review and approval by the CMRR Safety Committee is required prior to IRB submission. |
|     | CMRR users must submit the completed CMRR Device and Safety Review form to the CMRR prior to submission of their IRB application. A draft copy of the IRB application must be included along with the CMRR Device and Safety Review form for CMRR Safety Committee review. Documentation of approval by the CMRR Safety Committee will be provided to the researcher to include with the IRB application submission. |

Section 12.3 PAYMENT FOR RESEARCH RELATED SERVICES

12.3.1 Does the protocol require the use of tests, procedures, clinic space, clinic visits, professional fees, lab services, pharmacy services, or hospital services in order to answer the research question?

| No | Go to section 12.4 |
| Yes | Explain: |
|     | Provide written documentation from the FDA to charge for investigational products. |

<table>
<thead>
<tr>
<th>Yes</th>
<th>Provide CTR Portal ID#:</th>
</tr>
</thead>
</table>
12.3.3 Will Services be provided by Fairview Health Service or U of M Physicians?

☐ No

☐ Yes  Provide TASCS Number:

Provide a copy of the TASCS billing grid noting whether the study does or does not meet Medicare criteria for a Qualifying Clinical Trial.

Applications will not be assigned for review until the TASCS information is submitted.

CLINICALTRIALS.GOV REGISTRATION
Important Information about clinicaltrials.gov registration
Resources available, penalties for failure to register and publication requirements

Potential risks associated with failure to register with clinicaltrials.gov:

- Loss of funding (National Institute of Health)
- Financial penalty levied against the PI
- Denial of publication (ICMJE)
- Denial of payment to healthcare providers.

Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) establishes penalties for Responsible Parties who fail to comply with registration or results submission requirements. Penalties include civil monetary penalties and, for federally funded studies, the withholding of grant funds.

The International Committee of Medical Journal Editors (ICMJE) defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

Research projects that meet the ICMJE definition may not be accepted for publication if they are not registered in a registry that is electronically searchable and accessible to the public at no charge. For more information on this requirement see http://www.icmje.org  Note that retrospective registration of projects is not allowed.

Additionally, healthcare providers are required to include the clinicaltrials.gov number on all claims during the time period the patient participates in the study.

The Clinical and Translational Science Institute (CTSI) will assist University of Minnesota investigators to comply with the registration requirement. Complete the section below to document status or determine if registration is required. Applications submitted without a Clinicaltrials.gov registration number (either received or pending) will be forwarded to the CTSI for review.

Section 12.4 CLINICALTRIALS.GOV REGISTRATION DETERMINATION

12.4.1 Is this project registered with clinicaltrials.gov?

☐ No  Go to 12.4.2
Does this project meet the Food and Drug Administration Amendments Act (FDAAA) definition of “applicable clinical trial”? Applicable clinical trials generally include controlled, clinical investigations of drugs and biologics; and controlled trials of devices that include health outcomes, including pediatric postmarket surveillance.

12.4.2 Is registration with clinicaltrials.gov required?

☐ Yes Clinicaltrials.gov registration number: If registration is pending enter “pending” in the space provided.

Section complete. Go to Section 12.5

☐ No The PI understands the registration requirements and the consequences, as described above, of failure to register if applicable. CTSI will review this application for concurrence with the PIs decision. CTSI will contact the PI and the IRB to confirm registration requirement. If registration is required, the PI may request assistance with this process from CTSI. Go to Section 12.5

☐ Unsure CTSI will contact the PI and the IRB with a determination regarding the registration requirement. If registration is required, the PI may request assistance with this process from CTSI. Go to Section 12.5

☐ Yes Answer the questions below to determine who (either the PI or other entity) is responsible for registration with clinicaltrials.gov

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Yes – registration by PI required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this study initiated by a University of Minnesota investigator?</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is this study federally sponsored and the University of Minnesota is the only study OR the study’s coordinating center?</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is a University of Minnesota investigator the holder of an Investigational New Drug (IND) application for the test article OR it has been determined the proposed use of the test article is IND exempt?</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is a University of Minnesota investigator the holder of an Investigational Device Exemption (IDE) for the device being studied OR a non-significant risk (NSR) determination has been made for the device being studied?</td>
<td></td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

If registration is required, the registration number must be provided before final IRB approval is granted. Email ctsi@umn.edu for additional information and registration assistance. CTSI will evaluate all applications not registered with clinicaltrials.gov.

Section 12.5  SCIENTIFIC ASSESSMENT

Research involving human subjects must be reviewed for sound scientific design prior to review by the IRB committee. Documentation of scientific assessment including the content of the review must be provided before the project will be reviewed by the IRB. Scientific assessment is not required for new studies that meet the federal criteria for expedited review. If a study is submitted for expedited review but is determined by the IRB to NOT meet the criteria for expedited review, then scientific peer review will be required before IRB review.

12.5.1 Has the IRB scientific assessment requirement been met?

☐ N/A Project qualifies for expedited review. Sections 12.5, 12.6 and 12.7 are not required if expedited review eligible. GO TO Section 13 Additional Staff.
<table>
<thead>
<tr>
<th>Yes</th>
<th>Indicate below how the requirement has been met</th>
<th>Required supplemental materials</th>
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</thead>
<tbody>
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</tbody>
</table>

**Option 1**  
Reviewed by a **federal funding agency** (National Institutes of Health, National Science Foundation, etc.) employing peer review mechanisms for awarding of funding.

**Option 2**  
Reviewed by a **nationally based non-federal funding agency** (March of Dimes, American Academy of Pediatrics, etc.) employing peer review mechanisms for awarding of funding.  
*Note: industry-sponsored clinical trials designed by the sponsor with or without external consultants do not satisfy this criterion for independent peer-review.*

**Option 3**  
Reviewed by **locally constituted mechanisms using peer review** for awarding of funding, or for permission to use resources: Cancer Protocol Review Committee (CPRC); CTSI funded pilot awards; Vikings.  
*Note: Departmental review no longer satisfies this requirement.*

**Option 4**  
Reviewed by **HRPP facilitated Scientific Assessment** committee  
Submit approval notification with application.

**Section 12.6 DATA AND SAFETY MONITORING PLAN**

A data and safety monitoring plan (DSMP) is meant to assure that each clinical investigation has a system for oversight and monitoring of the conduct of the clinical investigation. This oversight is intended to ensure the safety of the participants and the validity and integrity of the data. A DSMP should be commensurate with the risks.

A DSMP can be as simple as the investigator reporting adverse event information to the IRB. A DSMP can be as complex as having a Data and Safety Monitoring Board.

A DSMP can include clinical trial monitoring. Clinical trial monitoring refers to the methods used to oversee the conduct of, and reporting of data from, clinical investigations including appropriate clinical investigator supervision of study site staff. Monitoring activities include communication with the investigator and the study site staff; review of the study site’s processes, procedures, and records; and verification of the accuracy of the data.

**12.6.1 In addition to the Principal Investigator, are there other DATA monitoring entities responsible for this function? Select all that apply.**

- [ ] No, the PI is the only entity monitoring DATA.
- [ ] Yes  
- [ ] A review entity will provide ongoing DATA monitoring
  
  - Clinical and Translational Science Institute (CTSI)
  
  - Data coordinating center or project principal investigator (multi-center studies)
  
  - Commercial sponsor, contract research organization (CRO)
  
  - Other:
12.6.2 In addition to the Principal Investigator, are there other SAFETY monitoring entities responsible for this function? Select all that apply.

[ ] No, the PI is the only entity monitoring SAFETY.
[ ] Yes Select all below that apply

- [ ] A Data Safety Monitoring Board (DSMB) will be appointed.

When established, the list of the DSMB members including their affiliation and credentials and the DSMB charter must be submitted to the IRB. A description of the DSMB must be provided with the application.

A Data and Safety Monitoring Board (DSMB) is an independent group of experts that advises the study investigators. Primary responsibilities of a DSMB are to 1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and 2) make recommendations concerning the continuation, modification, or termination of the trial. The DSMB considers study-specific data as well as relevant background knowledge about the disease, test agent, or patient population under study.

The DSMB reports should be provided to the IRB as they are received.

- [ ] Medical Monitor
- [ ] Cancer Center Data Safety Monitoring Council
- [ ] Other, describe:

### Section 12.7 DATA AND SAFETY MONITORING RESPONSIBILITIES

<table>
<thead>
<tr>
<th>Data to be monitored</th>
<th>PI</th>
<th>Review entity</th>
<th>DSMB/other</th>
<th>Unassigned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Safety (e.g., collection, reporting, and management of AEs, SAEs, and other study risks).</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Data Accuracy &amp; Quality Assurance (e.g., data collection, entry, transmission and analysis).</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Trial Management (e.g., site coordination, enrollment and population distribution).</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Regulatory Issues (e.g., SAE reporting, IRB Actions, disclosures of conflict of interest).</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Interim Analysis.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

It is the investigator’s opinion that this protocol does not require a data safety monitoring plan. Provide justification:

### Section 13 Additional Research Staff

**Co-Investigators**

Co-Investigators, responsible for knowing and following the protocol, should be listed below. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.

**Note:** If emailing this application to the IRB, all co-investigators must be cc’ed on the submission email.
<table>
<thead>
<tr>
<th>Co-Investigator Name (Last name, First name MI):</th>
<th>Highest Earned Degree:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Affiliation and contact information</strong></td>
<td></td>
</tr>
<tr>
<td>[ ] University of Minnesota (complete contact info section 1 only)</td>
<td>[ ] Gillette (complete contact info section 2 only)</td>
</tr>
<tr>
<td>[ ] Fairview (complete contact info section 2 only)</td>
<td>[ ] Other (complete contact info section 2 only)</td>
</tr>
<tr>
<td><strong>Required Contact information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Section 1 - U of M only</strong></td>
<td><strong>U of M Internet ID (x.500):</strong></td>
</tr>
<tr>
<td></td>
<td><strong>U of M Employee/student ID Number:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>University Department:</strong></td>
</tr>
<tr>
<td><strong>Required contact information</strong></td>
<td><strong>Address:</strong></td>
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<td><strong>Section 2 Non-U of M only</strong></td>
<td><strong>Phone number:</strong></td>
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<td><strong>Email address:</strong></td>
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<td><strong>Occupational Position:</strong></td>
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<tr>
<td>[ ] Faculty [ ] Physician [ ] Staff [ ] Student [ ] Other:</td>
<td></td>
</tr>
<tr>
<td><strong>Project responsibilities:</strong></td>
<td></td>
</tr>
<tr>
<td>[ ] Obtain consent from subjects [ ] Provide access to patient population [ ] Other:</td>
<td></td>
</tr>
<tr>
<td><strong>Conflict of Interest:</strong></td>
<td></td>
</tr>
<tr>
<td>Does this person have a reportable conflict as defined in Section 11 of the application?</td>
<td>[ ] Yes [ ] No</td>
</tr>
<tr>
<td><strong>Required CITI Human Subjects Training</strong></td>
<td><strong>HIPAA TRAINING</strong></td>
</tr>
<tr>
<td>Date CITI completed (either initial or refresher course):</td>
<td>Check box below if HIPAA training is required.</td>
</tr>
<tr>
<td>Note: The IRB requires researchers to complete refresher courses every three years after completion of initial course. For more information on training requirements see <a href="#">IRB Training</a>.</td>
<td>[ ] HIPAA Required – Data contains PHI</td>
</tr>
<tr>
<td></td>
<td>HIPAA Training completed through:</td>
</tr>
<tr>
<td></td>
<td>[ ] UMN</td>
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<tr>
<td></td>
<td>[ ] Other:</td>
</tr>
<tr>
<td><strong>Signature/Digital signature/x.500 of Co-PI</strong></td>
<td><strong>Title of Co-PI</strong></td>
</tr>
<tr>
<td><strong>Co-Investigator Name (Last name, First name MI):</strong></td>
<td><strong>Highest Earned Degree:</strong></td>
</tr>
</tbody>
</table>
### Affiliation and contact information

- [ ] University of Minnesota (complete contact info section 1 only)
- [ ] Fairview (complete contact info section 2 only)
- [ ] Gillette (complete contact info section 2 only)
- [ ] Other (complete contact info section 2 only)

#### Required Contact information

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<td>Email address:</td>
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</table>

**Occupational Position:**
- [ ] Faculty
- [ ] Physician
- [ ] Staff
- [ ] Student
- [ ] Other

**Project responsibilities:**
- [ ] Obtain consent from subjects
- [ ] Provide access to patient population
- [ ] Other

**Conflict of Interest:**
Does this person have a reportable conflict as defined in Section 11 of the application?
- [ ] Yes
- [ ] No

**Required CITI Human Subjects Training**

Date (Month/Year) CITI completed (either initial or refresher course):  

Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see [IRB Training](#).

#### HIPAA TRAINING

Check box below if HIPAA training is required.
- [ ] HIAPPA Required – Data contains PHI

HIPAA Required – Data contains PHI completed through:
- [ ] UMN
- [ ] Other:

Signature/Digital signature/x.500 of Co-PI | Title of Co-PI
---|---

### Research Staff

Research staff, including study coordinators, responsible for knowing and following the protocol, should be listed below. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.

<table>
<thead>
<tr>
<th>Study Staff Name (Last name, First name MI):</th>
<th>Highest Earned Degree:</th>
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</table>
### Affiliation and contact information

- □ University of Minnesota (complete contact info section 1 only)
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**Section 2 - Non-U of M only**

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### Occupational Position:

- □ Faculty  □ Physician  □ Research Coordinator  □ Staff  □ Student  □ Other:

### Project responsibilities:

- □ Obtain consent from subjects  □ Other:

### Conflict of Interest:

- Does this person have a reportable conflict as defined in Section 11 of the application?
  - □ Yes  □ No

### Should This Person Be Copied on All Correspondence?

- □ Yes  □ No

### Required CITI Human Subjects Training

- Date (Month/Year) CITI completed (either initial or refresher course):

**Note:** The IRB requires researchers to complete refresher courses every three years after completion of initial course. For more information on training requirements see [IRB Training](#).

### HIPAA TRAINING

- Check box below if HIPAA training is required.
  - □ HIPAA Required – Data contains PHI

**HIPAA Training completed through:**

- □ UMN  □ Other:

### Study Staff Name (Last name, First name MI):

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- □ Physician
- □ Research Coordinator
- □ Staff
- □ Student
- □ Other:

### Project responsibilities:

- □ Obtain consent from subjects
- □ Other:

### Conflict of Interest: Does this person have a reportable conflict as defined in Section 11 of the application?

- □ Yes
- □ No

### Should This Person Be Copied on All Correspondence? □ Yes □ No

### Required CITI Human Subjects Training

Date (Month/Year) CITI completed (either initial or refresher course):

Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see [IRB Training](#).

### HIPAA TRAINING

Check box below if HIPAA training is required.

- □ HIPAA Required – Data contains PHI

HIPAA Training completed through:

- □ UMN
- □ Other:
The University of Minnesota is committed to the ethical and responsible conduct of research and to ensuring the rights and welfare of participants are protected. Research involving vulnerable participants requires careful planning by investigators and special consideration by the Institutional Review Board (IRB) before approval can be granted.

Vulnerable research participants include adults who are vulnerable to coercion or exploitation that might influence their consent to research or their decision to continue in research¹. Vulnerability differs from impaired consent capacity in that it arises from the situational context and relationships of the potential research participant rather than from cognitive impairment. Furthermore, not every person of a vulnerable group is susceptible to coercion. Vulnerable research participants and persons from communities that are vulnerable and persons with characteristics that mark them as vulnerable deserve an equitable opportunity to participate as research participants. Research is necessary on vulnerable populations to enable them to benefit from biomedical research.

Vulnerable persons have the capacity to consent. Research involving persons who lack capacity to consent or are adjudicated by law to be incompetent is addressed in separate UMN policies/requirements.

The study protocol should identify any vulnerable populations that may be enrolled in the research and also address in the design or conduct of the research, the approach(es) to mitigate the potential for coercion.

See HRP-333- WORKSHEET: Vulnerable Populations for examples of vulnerable populations, as well as research design/conduct considerations to mitigate the potential for coercion.