**Work Plan Section:**

Scientific Review

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

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**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

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**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.

Does this plan require the identification of additional resources? 
*Resources could include money, equipment, space and personnel.*

- [ ] Yes.  - [ ] No
- [ ] I don’t know

If yes, describe: external reviewers and statistical consultants, as needed.

Does this plan require permissions or expertise from outside the University to fully implement it? 

- [ ] Yes.  - [ ] No
- [ ] I don’t know

If yes, describe: External reviewers may be solicited form outside the University as needed.

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)*

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

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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))

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Version Date: September 2015
from that perspective. A non-affiliated member is also a scientist\(^2\) or non-scientist\(^3\) 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 reassigned 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:**

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<th>PI Name:</th>
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<td>HSC#:</td>
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<td>Date:</td>
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**Expert Consultation requested:**

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<tr>
<th>Consultant name:</th>
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<tr>
<td>Indication of consultant expertise:</td>
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<tr>
<td>Please indicate any specific questions/concerns to be addressed:</td>
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**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.

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Expert Consultation Review
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/](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 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.

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></td>
<td>Chair</td>
<td>N/A</td>
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</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>
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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>
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<tbody>
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</table>

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

**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>
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<tr>
<td>Principal investigator:</td>
<td>Click here to enter text.</td>
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<tr>
<td>IRB number:</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Reviewer:</td>
<td>Click here to enter text.</td>
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<tr>
<td>Safety monitoring:</td>
<td>Choose an item.</td>
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<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
6. **Discussion notes**: "None" if 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:**

<table>
<thead>
<tr>
<th></th>
<th>For</th>
<th>Against</th>
<th>Abstain</th>
<th>Absent</th>
<th>Recused</th>
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<td>0(name)</td>
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</tr>
</tbody>
</table>

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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

No greater than minimal risk to children is presented

① Yes, because...

**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>
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<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>
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<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

① 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

① Yes, because...

The risk is justified by the anticipated benefit to the subjects

① 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

The research involves no more than minimal risk to the subjects

① The waiver or alteration will not adversely affect the rights and welfare of the subjects

① The research could not practicably be carried out without the waiver or alteration

① Whenever appropriate, the subjects will be provided with additional pertinent information after participation

①

### 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

① Yes, because…

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

① Yes, because…

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

① 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

① Yes, because…

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

① Yes, because…

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

① Yes, because…

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

① 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.

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:

Control subjects will be selected randomly from the available prisoners who meet the characteristics needed for the research

The principal investigator has provided written justification for following other procedures

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

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

① 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

Page 11 of 17

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 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

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<tr>
<td>①</td>
<td>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</td>
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<tr>
<td>①</td>
<td>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.</td>
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**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

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<td>①</td>
<td>Individuals engaged in the research will have no part in determining the viability of a neonate</td>
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<td>①</td>
<td>Vital functions of the neonate will not be artificially maintained</td>
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<td>①</td>
<td>The research will not terminate the heartbeat or respiration of the neonate</td>
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<tr>
<td>①</td>
<td>There will be no added risk to the neonate resulting from the research</td>
</tr>
<tr>
<td>①</td>
<td>The purpose of the research is the development of important knowledge that cannot be obtained by other means</td>
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<tr>
<td>①</td>
<td>For DHS, EPA, HHS, or VA research data, the important knowledge is important biomedical knowledge</td>
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<tr>
<td>①</td>
<td>Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate</td>
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<tr>
<td>①</td>
<td>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</td>
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<tr>
<td>①</td>
<td>Consent will not be obtained from a LAR</td>
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<tr>
<td>①</td>
<td>There is no waiver or alteration of the consent process</td>
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</table>
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

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

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

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

The research could not practicably be carried out without the waiver

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

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

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

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<td>Executive Director, HRPP</td>
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5.0 Revision History

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<tr>
<th>Revision</th>
<th>Reason for change</th>
<th>Date of release</th>
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<tr>
<td>12/19/15</td>
<td>Revisions Prompted by the Work Plan</td>
<td>TBD</td>
</tr>
<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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<tr>
<td>02/01/10</td>
<td>Revision</td>
<td>02/01/10</td>
</tr>
<tr>
<td>10/15/09</td>
<td>Update AAHRPP references</td>
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<tr>
<td>08/31/09</td>
<td>Revision</td>
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<td>08/24/09</td>
<td>Reformat, Revision</td>
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</tr>
<tr>
<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.
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- **Clinical and Translational Science Institute (CTSI) pilot funding awards**

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**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.