Education and Training of Investigators and Research Team Members:

Final Report
June 30, 2016

David Ingbar, M.D., Co-Chair
Timothy Schacker, M.D., Co-Chair

Appendix 1: Needs Assessment and Gap Analysis by Janet Shanedling, PhD, Education Manager
Executive Summary

The purpose of the University of Minnesota Human Subject Protection Program is to protect the rights and welfare of all research participants who participate in research, especially those with impaired or fluctuating capacity to consent. In response to an independent assessment of the University of Minnesota’s Human Research Protection program, President Eric Kaler charged the Vice President for Research (Brian Herman) and Vice President for the Health Sciences (Brooks Jackson) to create an implementation team to review and implement the recommendations of the external reviews. The implementation team developed a work plan, a key component of which addresses the education and training of investigators.

This report comprises the results of a Needs Assessment/Gap Analysis conducted by an independent consultant, Janet Shanedling, PhD, and concludes with recommendations for enhancing human research protection (HRP) training and education at the University of Minnesota.

To ascertain the current environment within which the University provides human research protection education and training to investigators and research personnel, the needs assessment process included:

- Online review of federal and accreditation (AAHRPP) training requirements and policies, and a review of National Clinical and Translational Science reports and documents pertaining to current GCP and research competency initiatives
- Survey of University of Minnesota websites and resources documenting current HRP and ethics training requirements and resources
- Interviews and discussions with University of Minnesota personnel involved in HRP education and training from multiple U of M offices and academic units
- Review and consideration of the recommendations and commitments in the work plan, Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program and CTSI Recommendations for Integration of Clinical Research Studies in the Department of Psychiatry into the University of Minnesota CTSI.
- Online exploration of HRP training resources and requirements from eight other universities, and interviews with HRP leaders at four of those institutions.

Based upon the review of federal and AAHRPP policies and requirements as well as current University HRP and research ethics training and education practices, the University does offer the required training framework and is satisfactorily addressing ‘areas of need’ for recertification. However, in question (at the University of Minnesota and other institutions) is whether almost completely online, knowledge-based education is sufficient to ensure that investigators and research personnel develop and can apply the appropriate skills and attitudes at the point of actual human participant research studies in a competent and ethical manner. Does completion of CITI modules actually result in the ethical and skilled behaviors that should characterize high quality research with human participants? In addition, metrics, monitoring, and evaluation of the results of training that would contribute to responding to such a question do not appear to be in place currently at the University.

The review of websites and interviews with HRP leadership at other institutions suggests quite clearly that the HRP and ethics training at the University of Minnesota has much in common with programs at other leading universities, for example:

- Collaborative Institutional Training Initiative (CITI) learning modules serve as the backbone of its HRP program
The Responsible Conduct of Research program is often a locally-developed offering.

With the exception of IND/IDE research, good clinical practice training is generally offered as an option for investigators or as part of recertification.

HRP renewal training is generally required every three – four years, and is typically a repetition of the same CITI modules originally completed.

Training across the institutions is predominantly online and knowledge-based, though a few of the institutions surveyed do require attendance at in-person training events.

The institutions surveyed included: Duke University/Duke Medicine, Emory University, Harvard University, Johns Hopkins University, UCSF, University of Michigan, Washington University, University of Pennsylvania, . All except for one of the institutions surveyed offer HRP and RCR training through enterprise learning management systems (LMS), which also track and provide reporting and audits of training completion. In most cases, the LMS is integrated with the institutions eIRB system.

Two of the institutions developed and mandated Clinical Research coordinator training that involves in-person workshops and ongoing recertification, including renewal of GCP training.

Other institutions are waiting to learn about the national decision from NCATS regarding the requirement for all study personnel involved in interventional human subject research to complete GCP training.

Interviews with University of Minnesota research personnel suggested needs to go beyond the current national requirements in the following high level areas:

- Address advanced training needs for research with vulnerable individuals and/or those with diminished or fluctuating capacity to consent
- Update and clarify the University's human research protection training and education policies
- Upgrade and establish a clear and supported HRP Education and Training infrastructure
- Engage departments and centers to create and participate in a university-wide ‘community’ supporting a ‘Culture of Ethics in Research’
- Ensure consistent, accessible, and transparent ongoing communication about HRP education and training across the university.

A series of priority recommendations are based upon the data and input summarized above. Details and descriptions of tasks supporting each recommendation are included in the final section of this report, some of which may already be underway within the HRPP/IRB, CTSI, and/or other research units.

1. Define a transparent UMN infrastructure to manage HRP education for investigators and the research workforce
2. Decide upon and implement a central human research protection education, training, and communication unit, to work with HRP subject matter experts University-wide, supported by enterprise commitment and funding
3. As part of the Community Engagement initiative, engage patients and prospective research participants in the design and development of training programs for investigators and the research workforce
4. Focus initial training development and implementation on:
   a. Advanced training for research with vulnerable individuals and those with diminished capacity to consent
   b. Upgraded initial and recurrent training in ethics and the conduct of human research
c. Build on current efforts to engage U of M colleges, departments, and centers to create a university-wide community supporting the development of a **Culture of Ethics for Human Participant Research**

d. Plan to pilot training programs in the **Department of Psychiatry**

5. Create a web-based, comprehensive learning platform—using current and recently implemented enterprise systems—to manage the functions of learning programs, including resource cataloging, registration, tracking, reporting, and prompting of research personnel for ongoing training requirements.

6. Over the next 3 years, develop, pilot and implement a competency-based curriculum plan that develops knowledge, skills, and attitudes and includes learner assessment as well as ongoing program evaluation (perhaps a systematic review and update of activities every two – three years).
Recommendations: University of Minnesota HRP Education and Training

At a high level, priority need for changes exist in the following high-level areas:

1. Define a transparent **UMN infrastructure to manage HRP education for investigators and the research workforce.**
2. Decide upon and implement a **central HRP education, training, and communication unit,** to work with HRP subject matter experts University-wide, supported by enterprise commitment and funding
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   d. Plan to pilot programs in the Department of Psychiatry
5. Create a web-based comprehensive learning platform—using current and recently implemented enterprise systems—to manage the functions of learning program, including resource cataloging, registration, tracking, reporting, and prompting for ongoing training requirements.
6. Over the next 3 years, develop, pilot and implement a competency-based curriculum plan that develops knowledge, skills, and attitudes and includes learner assessment as well as ongoing program evaluation (perhaps a systematic review and update of activities every two – three years).

The purpose of this section is to outline high-level recommendations for addressing these areas. The recommendations in this section largely represent the conclusions and opinions of Janet Shandeling, PhD, the curriculum and instructional designer authoring the Needs Assessment & Gap Analysis report, with some input from HRP leadership engaged with this initiative.) Specific details (e.g., tasks, roles and responsibilities, specific deliverables, and timeframes) could be included in a subsequent curriculum plan based upon review, and finalization of this report’s recommendations.

The following priority recommendations are organized into high-level categories. Recommendations are drawn from and integrate all of the sources of data summarized in this report:

- Federal requirements and policies, certification requirements, and national initiatives
- Current U of M HRP training requirements and resources
- HRP educational requirements at other universities
- Action commitments made in response to the U of M HRP External Review
- Input from research leaders at the U of M and at other universities.
**Priority Recommendations**

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<tr>
<td>1. Define a transparent UMN infrastructure to manage HRP education for investigators and the research workforce</td>
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<tr>
<td>a. Define and agree upon the HRP roles and responsibilities for all aspects of human research protection enterprise-wide, including: Center for Bioethics, Community, CTSI, Fairview, HRPP/IRB, OVPR/RCO, and Schools/Centers/Departments University-wide</td>
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<td>b. Establish a transparent, collaborative cross-unit executive HRP Educational Advisory Group with defined Responsibilities Accountability, Support, Consultation, and Information Network (RASCI) among the HRP executive leaders.</td>
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<td>c. Assign that cross-departmental infrastructure group the initial responsibility to review and decide upon University of Minnesota policies and mandates regarding:</td>
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<td>• Basic HRP training for investigators, CRCs, research staff, trainees and IRB members regarding content (e.g., should GCP training be included?), format (e.g., is CITI training sufficient or should learner assessment/demonstration of basic competencies be included)</td>
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<td>• Advanced HRP training for investigators, CRCs, research staff, and IRB members with a focus on ‘high risk’ research, for example, with vulnerable individuals and/or individuals with diminished decision-making capacity, international research, research with biospecimens, etc.</td>
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<td>• Content, format (e.g., online + in-person electives) and frequency for continuing renewal of HRP training for investigators, CRCs, research staff, and IRB members</td>
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<tr>
<td>• Requirements for and tracking of advanced level training for investigators and research teams for serious and/or continuing noncompliance</td>
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<td>• A mandated system and responsibilities for ensuring basic and renewal training of research teams is complete, particularly for vulnerable populations research, for all personnel involved in a study. This should align with protocol review and remediation for noncompliance, and specify timing of training in relationship to the date of protocol submission to the IRB.</td>
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<tr>
<td>d. Determine the locus for decision-making regarding the planning, purchase of and/or instructional design and development of HRP, RCR, and advanced training; recertification training; and ongoing Culture of Ethics U of M offerings. (See Recommendation 2 regarding an HRP Education and Training Unit.)</td>
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<tr>
<td>e. Address policies and mandates regarding training for all U of M clinical research coordinators, including challenges faced when reporting solely to investigators (as in c. above)</td>
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<td>f. Ensure a financial model that provides training and support to all investigators and research teams without cost being a barrier to access and ensuring compliance without excessive time requirements that dis-incent clinical research.</td>
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## Recommendations

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<th>Recommendation</th>
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| 2. Establish a central human research protection education, training, and communications unit | a. Create and resource a U of M HRP Education Specialist/Director (and necessary staff) to lead a centralized unit (based upon determination of 1d above) and work with U of M subject matter experts and existing resources to:  
- Develop HRP curriculum sourcing, development, learning assessments, training dissemination, program evaluation and QA, and ongoing updates. (IRB member training should be coordinated with these efforts but may be developed and managed separately.)  
- Carry out of guidelines for basic and advanced research compliance and human subjects protection training, under oversight from the Educational Advisory Board  
- Serve as the U of M liaison with national efforts such as the NCATS GCP initiative and ECRPTQ Researcher Competencies initiative, and suggest how to integrate into the U of M curriculum as those move forward  
- Collaborate on or manage the development and implementation of U of M Culture of Ethics forums, podcasts, webinars, etc. in collaboration with all other U of M units engaged in HRP leadership and management  
- Work with other institutions and instructional design consultants to source and/or develop learning programs to meet the goals of the U of M HRP curriculum plan that will include knowledge, skills, and attitudes for HRP  
- Ensure that timely, accessible, and clear communications regarding policies, training offerings, new regulations are created and disseminated to the research community  
- Monitor the changing national policies and ‘state of the art’ and externally available training resources, bringing advances and recommendations to the HRP Educational Advisory Group  

b. Either within or affiliated with the Education and Training unit, assign clear responsibility to a Communications specialist who will be responsible for developing and maintaining a comprehensive, easily accessible HRP website (e.g., humanresearch.umn.edu), creating and aligning regular and continuous communications in other media formats (e.g., newsletters, updates), and ensuring two-way communication with all of the U of M research audiences (community participants, investigators, coordinators and research staff, IRB members, faculty, etc.) This position will require appropriate staff resources, including information technology support.  
- Through a central Human Research Protection website, provide access to individualized training self-assessments, training reports, training offerings, CITI, and regular updates of U of M HRP offerings and other communications media, making access to all information about human participant research highly accessible and transparent for the research community. This should include pro-active automatic notifications of faculty and staff and should be linked closely to the IRB website.  
- Use the website to provide overviews and centralized access via the U of M learning management system (LMS) to all U of M and other training materials, including CITI, the CRC Orientation, Clinical Research Methodologies modules, etc.  
- Provide links on the website to consultation and support services, for example, from the IRB. |
## Recommendations

### 2. Establish a central human research protection education, training, and communications unit (cont’d)

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<th>c.</th>
<th>Within that HRP Education and Training Unit, strongly consider the creation of a new <strong>position of Human Research Procedures, Policies, and Ethics Education Coordinator</strong> linking to Center for Biomedical Ethics. (Depending upon the individual skill sets and time, it might be possible to consolidate this position with the 2a leadership position) This individual would ensure that required and optional training is available and current and easily accessible to the research community.</th>
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<td><strong>When determined and developed,</strong> this position would coordinate and administer interdepartmental forums, WebEx-based presentations, podcasts, or other U of M Culture of Ethics offerings.</td>
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<td><strong>Manage updates to all existing training and launch new offerings.</strong></td>
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<td><strong>Work with NIH and other training grants to help fulfill requirements for HRP and RCR training compliance</strong></td>
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<td><strong>Serve as the liaison with OVPR units responsible training documentation and reporting systems to continuously monitor that all training offerings are being appropriately tracked and reported on transparently (including RCR, HIPAA, GCP, CITI, advanced training)</strong></td>
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<td>d.</td>
<td>Develop the option of offering Continuing Education credit for advanced and recertification training, including a system to approve, track and credit HRP CE ‘one-of-a-kind’ activities offered at UMN or elsewhere (conferences, etc)</td>
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<td>e.</td>
<td>Collaborate with the IRB leadership to support, as needed, the design of training that can be integrated into the Protocol and Study design module being developed in collaboration with Huron Consulting.</td>
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### 3. Engage patients and prospective research participants in the development and delivery of training programs for investigators and the research workforce

| a. | Gather input and feedback from patients and families regarding their priorities and areas of concern with U of M human research protection (as part of this Needs Assessment Process) |
| b. | Within the Education and Training curriculum development process, engage community members/research participants and U of M community content experts as some of the ‘content experts’ in the development of HRP training for researchers as well as training for research participants |
| c. | Develop and implement learning materials (HRPP/IRB) for legally authorized representatives (LAR) to explain the LAR role, authority, and considerations for making decisions. |

### 4. Focus initial training development and implementation on a) vulnerable research populations, b) ethics and conduct of human research, c) creating a U of M Culture of Ethics, and d) piloting all programs in the Department of Psychiatry

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<th>a.</th>
<th><strong>Training for Research with Vulnerable Individuals and/or Those with Diminished Capacity to Consent</strong></th>
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<tr>
<td><strong>Develop advanced training (required and recommended) on <strong>consenting</strong> for investigators and research staff in collaboration with content experts from HRPP/IRB, CTSI, Center for Bioethics, patients and families from the community, Fairview psychiatrists, U of M psychiatry and psychology faculty, etc. This will include development, pilot testing (if necessary) and/or implementation of competency based training.</strong></td>
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<td>o Have the Educational Advisory Group consider a requirement that all researchers who consent in greater than minimal risk studies be qualified through demonstration of competencies to do so.</td>
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<td>o Develop template consent documents and processes with easily accessible examples and practice cases</td>
<td><strong>As tools are developed/sourced for assessing participants’ capacity to consent and for monitoring ongoing capacity, develop and implement experiential training on their use</strong></td>
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<td><strong>Adapt the learning programs to provide specialized training for an IRB panel (who will be charged with evaluating all research with these populations) on the unique needs of research with individuals with impaired or fluctuating capacity to consent or who belong to vulnerable populations.</strong></td>
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4. Focus initial training development and implementation on a) vulnerable research populations, b) ethics and conduct of human research, c) creating a U of M Culture of Ethics, and d) piloting all programs in the Department of Psychiatry (cont’d)

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<tr>
<td><strong>b. Augment Training on the Ethics and Conduct of Human Research</strong></td>
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<td>- Develop and pilot test/source a cross-training (or even team-based training?), competency-based curriculum for investigators, clinical staff, and IRB members on the ethics, mechanics, and importance of research in collaboration with experts from HRPP/IRB, CTSI, Center for Bioethics</td>
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<td>- Include as topics for increased knowledge, skills, and attitudes: GCP, reporting adverse events, protocol deviations, source documentation, documenting informed consent, inclusion/exclusion, safety monitoring, etc.</td>
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<td>- Review the RCR basic program and integrate into a comprehensive curriculum with advanced and ongoing mandated and elective options</td>
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<td>- Consider in the future requiring a demonstration of ability to apply the knowledge learned in skill-based cases and simulations and learning assessments, particularly for non-compliance remediation</td>
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<td>- (Where is training on OnCore and REDCap offered?)</td>
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| **c. Engage U of M colleges, departments and centers to create a U of M Culture of Ethics** |
| - Enhance the availability of and access to a transparent centralized HRP website and regularly disseminated university-wide HRP updates, newsletters, presentations, podcasts, etc. |
| - Engage the University-wide research community in learning about and adapting the national Enhancing Clinical Research Professionals’ Training and Qualifications (ECRPTQ) competencies and NCATS’ GCP training framework as those are approved and adapted nationally. Update the community as standards evolve. |
| - Hold campus conversations and forums across the university, including Research Grand Rounds that provide for peer-to-peer learning, highlighting what works and what are the challenges in human participant research |
| - Develop required and recommended advanced and refresher training modalities to be promoted and/or implemented by academic units in faculty, investigator, and research staff meetings. |
| - Develop training materials and train facilitators and moderators (‘train-the-trainers’) to offer opportunities for discussions and peer-to-peer learning at department faculty meetings, Research Grand Rounds, college forums, or research team events on topics such as: vulnerable populations research; university policies related to study monitoring; scientific review; and new and evolving regulatory requirements. Offer CE credit as appropriate. |
| - Develop annual updates (perhaps in online format and/or in-person forums) regarding new regulations and policies, audit findings, best practices, etc. Consider collaborating on this with other institutions. Offer CE credit. |

| **d. Plan to Pilot All New Training (4a and b) in the Department of Psychiatry** |
| - Use feedback from pilot usage in Psychiatry research to finalize new training offerings prior to dissemination University-wide. |
## Recommendations

### 5. Develop an integrated learning platform

a. Identify an easily accessible, transparent, welcoming Learning Management System (LMS) through which all investigators, CRCs, research staff, IRB members, and research participants can access all HRP learning materials. Ensure that that system:

- Integrates with the University’s upcoming eIRB system being developed with Huron Consulting
- Is easily accessible through the central HRP Education and Training website
- Provides a clear self-assessment for determining what training each individual research professional requires initially and as they become involved in additional research activities
- Provides access to CITI as well as U of M online learning modules and courses (and links to external resources)
- Provides easy registration for other U of M forums, Research Grand Rounds, conferences
- Provides access to a wide variety of training materials in various formats such as synchronous and asynchronous webinars, podcasts, research papers, presentations
- Notifies faculty and staff of required training, upcoming deadlines, compliance status and other action items
- Manages CE if/when offered
- Documents and provides certificates of all online and in-person training that is completed

b. Integrate/enhance U of M reporting on all HRP training to provide accessible and clear reporting to users, departments, IRB, SPA, and a University-wide monitoring and quality assurance system

- Build into that system prompts for all research professionals and their departments regarding upcoming training recertification requirements (similar to REPA)
- Ensure that completion of all CITI modules (required and recommended) can be captured and reported upon by that system.

### 6. Develop over time a competency-based curriculum plan that includes learner assessment and metrics for program evaluation

a. Based upon the top priorities accepted and committed to from this needs assessment, develop a plan outlining the tasks, responsibilities, timeframes, and budget for developing, piloting, and finalizing the priority training programs identified and agreed to from report. Include wherever appropriate:

- Learning that addressing knowledge, skills, and attitudes
- Experiential and interactive learning formats
- Modular learning materials that can integrated and re-used for a variety of learner audiences and purposes
- Learning assessments and demonstration of competencies
- Metrics and process for program evaluation and ongoing quality assurance.

  - As one metric, benchmark the U of M’s training against peer institutions to ensure our HRPP training meets or exceeds the norm (p. 17, External Review Work Plan)
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<td>6. Develop a competency-based curriculum plan that includes learner assessment and metrics for program evaluation (cont’d)</td>
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<td>b. Following review and finalization of the previous priority recommendations, build into the curriculum plan goals and objectives for addressing some secondary priorities:</td>
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<tr>
<td>• Review currently-required CITI courses and determine the most appropriate for basic, advanced, and non-compliance training, particularly in relation to a competency-based, hybrid training programs</td>
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<td>• Identify other internal and external high quality resources for training and for knowledge or competency assessment</td>
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<td>• Develop modules and/or hybrid advanced programs on international research, research with biospecimens, research involving the use of medical records in clinical environments, and other topics</td>
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<td>• Completion of a hybrid curriculum for clinical research coordinators:</td>
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<tr>
<td>o Build upon the almost-complete competency framework developed by CTSI in conjunction with Mayo</td>
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<td>o Integrate the current online curriculum</td>
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<td>o Secure a pool of AHC-wide mentors available to support CRCs, particularly those in small studies, and adapt the Optimizing the Practice of Mentoring course for those mentors, as needed</td>
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<tr>
<td>o Develop and include an experiential- and case-based module on ‘Challenges of Research Management’ (or some such term). Address the challenges that CRCs can face when questioning ethical conduct of research that may differ from the perspective of their investigator/boss. Consider offering this as a ‘team-based’ course, and including all members of the research team—including investigators.</td>
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<td>• Create a module/hybrid program for investigators on ‘How to Do Clinical Research’ similar to the CRC course, ‘Navigating Research.’ That course could contain an interactive flow chart of the research process with call-outs explaining and giving examples of each step within the scope of the whole process. Use it as ‘just-in-time’ training for investigators at the point of need, and demonstrate how changes made in one step (e.g., change to a protocol) can affect others. Use case examples.</td>
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**Recommendations: Conclusion**

The section, 3.3.1.3 Conclusion, of the Final Report of the External Review states that “. . . it is essential that individuals at all levels of the human research protections program be knowledgeable about the ethical principles, as well as the specific regulatory, policy, and procedural requirements related to human subjects research. . . It is critical that training in human subjects protections not fall prey to the decision to ‘right-size’ educational requirements in the wake of ongoing institutional efforts to reduce the administrative burden placed on researchers. . . Advanced level training should allow for in-depth exploration of specific topics in human subjects protections.” We recommend that the University of Minnesota strengthen the current knowledge-based human research protection training and work to develop, assess and implement skill and attitude-based training over the next three years. The resulting training program should be comprised of a hybrid of online, discussion, peer-learning, case and simulation, problem-solving practice, learning assessment, and demonstration of competence. The training needs to insure the appropriate levels of training for the specific research being performed and that human subjects are appropriately protected. Simultaneously the training must be high quality and the potential burdens for investigators and staff to understand, obtain and remain compliant with the required training should be minimized. Advanced training should be strongly encouraged, supported and rewarded.
Appendix 1

Education and Training of Investigators and Research Team Members: Needs Assessment and Gap Analysis

Final Report
July 5, 2016

Submitted by Janet Shanedling, PhD
Education Manager
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Executive Summary

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• HRP renewal training is generally required every three – four years, and is typically a repetition of the same CITI modules originally completed
• Training across the institutions is predominantly online and knowledge-based, though a few of the institutions surveyed do require attendance at in-person training events.

The institutions surveyed included: Duke University/Duke Medicine, Emory University, Harvard University, Johns Hopkins University, UCSF, University of Michigan, Washington University, University of Pennsylvania. All except for one of the institutions surveyed offer HRP and RCR training through enterprise learning management systems (LMS), which also track and provide reporting and audits of training completion. In most cases, the LMS is integrated with the institutions eIRB system.

Two of the institutions developed and mandated Clinical Research coordinator training that involves in-person workshops and ongoing recertification, including renewal of GCP training.

Other institutions are waiting to learn about the national decision from NCATS regarding the requirement for all study personnel involved in interventional human subject research to complete GCP training.

Interviews with University of Minnesota research personnel suggested needs to go beyond the current national requirements in the following high level areas:
• Address advanced training needs for research with vulnerable individuals and/or those with diminished or fluctuating capacity to consent
• Update and clarify the University’s human research protection training and education policies
• Upgrade and establish a clear and supported HRP Education and Training infrastructure
• Engage departments and centers to create and participate in a university-wide ‘community’ supporting a ‘Culture of Ethics in Research’
• Ensure consistent, accessible, and transparent ongoing communication about HRP education and training across the university.

A series of priority recommendations are based upon the data and input summarized above. Details and descriptions of tasks supporting each recommendation are included in the final section of this report, some of which may already be underway within the HRPP/IRB, CTSI, and/or other research units.
1. Define a transparent UMN infrastructure to manage HRP education for investigators and the research workforce
2. Decide upon and implement a central human research protection education, training, and communication unit, to work with HRP subject matter experts University-wide, supported by enterprise commitment and funding
3. As part of the Community Engagement initiative, engage patients and prospective research participants in the design and development of training programs for investigators and the research workforce
4. Focus initial training development and implementation on:
   a. Advanced training for research with vulnerable individuals and those with diminished capacity to consent
   b. Upgraded initial and recurrent training in ethics and the conduct of human research
c. Build on current efforts to engage U of M colleges, departments, and centers to create a university-wide community supporting the development of a Culture of Ethics for Human Participant Research
d. Plan to pilot training programs in the Department of Psychiatry

5. Create a web-based, comprehensive learning platform—using current and recently implemented enterprise systems—to manage the functions of learning programs, including resource cataloging, registration, tracking, reporting, and prompting of research personnel for ongoing training requirements.

6. Over the next 3 years, develop, pilot, and implement a competency-based curriculum plan that develops knowledge, skills, and attitudes and includes learner assessment as well as ongoing program evaluation (perhaps a systematic review and update of activities every two – three years).
Background and Goals of the Needs Assessment

In response to an independent assessment of the University of Minnesota’s Human Research Protection program, President Eric Kaler charged the Vice President for Research (Brian Herman) and Vice President for the Health Sciences (Brooks Jackson) to create an implementation team to review and implement the recommendations of the external reviews. The implementation team developed a work plan, a key component of which addresses the education and training of investigators by stipulating:

- A new position of Human Research Procedures, Policies, and Ethics Education Coordinator
- Establishing guidelines and expectations for basic and advanced research compliance and research participant protection training
- Ensuring that required and optional training modules are available and kept current
- Specific attention be given to advanced training in the use of research participants with limited or fluctuating capacity to consent
- Collaborative development of training by the HRPP, CTSI, Center for Bioethics, other U of M resources, and community members (including research participants).

A curriculum and instructional design consultant was hired to address the action items in the Education and Training of Investigators section of the work plan, specifically to complete a comprehensive Needs Assessment/Gap Analysis and develop a curriculum plan to address the needs or gaps identified.

Based upon the recommendations and action items of the Implementation Team’s work plan as well as input from University leadership involved in human research training, the goals of the needs assessment were defined as:

1. Evaluate existing learning programs and materials (initially against regulatory standards, and with plans toward nationally-defined competencies) at the University of Minnesota and at other leading research institutions.

2. Identify training gaps, especially in ethics and research with vulnerable populations

3. Review and define mandatory basic and refresher training for investigators, needed areas for elective training, and potential required training in critical areas

4. Plan for integrated and coordinated training for investigators and workforce, including the implementation of a tool for individuals to easily self-assess and identify their research training requirements

5. Explore whether research learning competencies/target behaviors and metrics for assessing learning have been defined, and the possibility of adopting those for use at the University of Minnesota

6. As needed to cover gaps, define the needed curriculum development creation and implementation plan that outlines the development and acquisition of learning programs in the form of online, seminars, or printed materials, including small- and large-group discussion sessions:
   a. Plan to develop and implement a self-assessment tool for individual researchers to determine required and recommended training (ensuring alignment with the new IRB tool being developed by IRB/Huron Consulting with a possible focus on protocol development?)
b. Ensure that going forward the curriculum is engaging and interactive, using mixed methods in addition to lecture and online, including possibilities of train-the-trainer models, *modules adaptable and accessible for various types of research learners*, etc.

c. Develop a plan for regular updating and communication about the curriculum for and with the research community, including monitoring, reporting, and evaluation of the University’s training efforts.

d. Analyze current tracking tools and plan to ensure that they automatically track and report on all training required and completed, including communication regarding recertification training needed. This process needs to be user friendly for the investigators.

e. Determine the extent to which metrics and learning assessment should be enhanced in order to demonstrate clear learning and capability of application from training to actual research. {Note: It was determined that this is not really being done, apart from multiple choice questions in CITI – see the design document for the Informed Consent course for more details.}

7. Clearly define key responsibility roles—particularly decision-making—among U of M offices involved in AHRP (RCO, CTSI, HRPP-IRB, Center for Bioethics) for ongoing training management, development, and delivery, as well as policy-making.

**A set of Assumptions** related to carrying out the needs assessment were developed prior to beginning the needs assessment process and were vetted with the identified stakeholders. Those assumptions used in development of this report are listed below:

1. The *scope* of this needs assessment and curriculum plan involves human research protection training for biomedical and social/behavioral research workforce. Training requirements pertaining to HIPAA, COI, Environmental Health and Safety, and protecting animal subjects are outside the scope of this analysis.

2. To support the accomplishment of this educational resources gap analysis and ensure its alignment with other AHRP initiatives, the *Stakeholder Group* will be comprised of representatives from HRPP, RCO, CTSI, Center for Bioethics, SPA, and appropriate Fairview representation. Other input from the schools and departments community will be solicited as needed. Recommendations from the stakeholders will be forwarded for final decisions/approval to T. Schacker, D. Ingbar, and ultimately B. Jackson and B. Herman.

3. The *audiences* for whom we are defining training gaps include: investigators/co-investigators, key personnel (including graduate and undergraduate students, research assistants, study coordinators, faculty advisors, research fellows, etc.), IRB members, and department heads.

4. This gap analysis needs to *coordinate with similar needs* across other research compliance areas (e.g., animal research, environmental health and safety, etc.), specifically in areas of infrastructure such as an LMS or tracking system that can serve all areas.

5. While the U of M HRPP training does address the nine key areas defined by NIH in 2009 (built upon the 2000 OHR Objectives), we should define University of Minnesota standards (whether those areas or the 2015 Competency Domains and Statements from the NCATs work, or other) against which to evaluate the University’s current offerings and determine needs for the future. For the
purposes of this gap analysis, we will initially generate a plan that ensures that the U of M AHRP program meets the minimum regulatory requirements. Recommendations will be included in the gap analysis report and curriculum plan to subsequently implement ongoing standards or competencies that may result in moving the University toward being an exemplary program.

6. The programs established need to fulfill current requirements and should be designed to be ‘state of the art,’ but at the same time need to be designed and implemented in ways that facilitate high quality, safe research while minimizing non-essential required burdens on investigation.
Overview of the Process

The University’s President Kaler charged the Vice President of Research, Brian Herman, and the Vice President for the Health Sciences, Brooks Jackson, to oversee the AHRP team implementing the recommendations of the external reviews. David Ingbar, MD, Associate Director, Research Education, Training, and Career Development (CTSI-Ed) and Tim Schacker, MD, Associate Director, Clinical Translational Research Services, are the faculty co-leaders of the component addressing the Education and Training of Investigators, and thus, the Needs Assessment process. The following individuals have served as Stakeholders and reviewers of the process and deliverables for the Needs Assessment and Curriculum Plan.

- Debra Dykhuis, Executive Director, Human Research Protection Program
- Lisa Johnson, Assistant Director, Clinical and Translational Research Services, Clinical and Translational Science Institute
- Lisa Warren, Ass’t Vice President, Office of the VP of Research
- Michelle Lamere, Assistant Director for Education Programs, CTSI
- Mickey Eder, Associate Director, Community Engagement to Advance Research and Community Health
- Pamela Webb, Associate Vice President for Research Administration
- Sarah Waldemar, Director, Research Education and Oversight, Office of the VP of Research
- Steven Miles, Professor, Center for Bioethics and Department of Medicine

Additional reviewers for the Needs Assessment and Curriculum Plan are being identified to represent Fairview and the Community.

The curriculum/instructional designer completed the following tasks as part of the Needs Assessment:

- **Reviewed federal, accreditation, and NCATS reports and documents pertaining to HRP training requirements:**
  - HRP training requirements for biomedical and social/behavioral research from federal agencies and national organizations including: CDC, DOD, FDA, HHS/OHRP, NIH, and SOCRA
  - Accreditation standards and the University of Minnesota 2015 Site Visit Report from the Association for the Accreditation of Human Research Protection Programs (AAHRPP)
  - Documentation and reports from the Enhancing Clinical Research Professionals’ Training and Qualifications (ECRPTQ) work force (for the National Center for Advancing Translational Sciences (NCATS)) that included recommendations for Good Clinical Practice (GCP) training, Competency Domains as well as Competency Statements for Research Professionals, Competency Assessments, and Catalog of training programs/links currently available nationally.

- **Surveyed University of Minnesota resources to document current training requirements, resources, processes, perceived needs, and recommendations:**
  - Explored U of M websites and documentation not only for HRP training requirements but also to experience how clear and transparent the information is for researchers to locate
  - Interviewed and communicated with 15 U of M personnel from HRPP/IRB, Department of Medicine, School of Public Health, CTSI Populations and Community Engagement, Research Compliance Office/OVPR, Pediatrics, Center for Bioethics, and other CTSI units
Considered the previous data and input with the work plan entitled: *Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program* as well as the *CTSI Recommendations for Integration of Clinical Research Studies in the Department of Psychiatry into the University of Minnesota CTSI*.

- **Surveyed HRP resources from eight other universities to document their current training requirements, resources, processes, and perceived needs:**
  - Explored websites at Duke University, University of Pennsylvania, Johns Hopkins University, Harvard University, University of Michigan, UCSF, Emory University, and Washington University.
  - Interviewed IRB Directors, research and training managers, and a VP for Research, Regulatory & Compliance Oversight at University of Michigan, Johns Hopkins University, Emory University, and University of Pennsylvania.

- **Concluded with a series of recommendations and tasks that integrate the priority needs and gaps identified from the data and input gathered.**
Requirements, Policies, and Initiatives for Human Research Protection

This section provides a summary of what was learned about:
1. Federal requirements pertaining to human research protection training
2. AAHRPP certification requirements
3. University of Minnesota HRP training requirements
4. Current initiatives from NCATS regarding recommendations for GCP training and for establishment of competencies and assessments for research professionals.

1. Federal Requirements for Biomedical and Social/Behavioral HRP Education and Training

<table>
<thead>
<tr>
<th>Agency</th>
<th>Human Subject Research Investigators: Training Requirements</th>
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<tbody>
<tr>
<td>CDC</td>
<td>• <strong>Scientific Ethics Training Basic Course</strong> (choice of):</td>
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<tr>
<td></td>
<td>o CITI RCR course (Biomedical or Social/Behavioral)</td>
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<td></td>
<td>o NIH Protecting Human Research Participants</td>
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<td></td>
<td>o FHI360 Research Ethics Training</td>
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<tr>
<td></td>
<td>o CITI GCP Course: Advanced/Special Requirements for PIs, supervisors, or administrators of biomedical research with drugs, devices, biologics</td>
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<tr>
<td></td>
<td>• The <strong>CDC Human Research Protections Policy</strong> (recertified July 2015), stipulates: Prior to serving as investigators, they must 1) certify HRPO-approved education in research ethics and human research regulations and obtain certification of competency. 2. Maintain competency in research ethics and human research regulations and certify at least once every 3 years.</td>
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<tr>
<td>DOD</td>
<td>Section 5, Education and Training, of DoD Directive (DoDD) 3216.02 states under paragraph (d): “When assessing whether to support or collaborate with a non-DoD institution for research involving human subjects, the DoD Components should evaluate the non-DoD institution’s education and training policies to ensure the personnel are qualified to perform the research. The rigor of the evaluation should be appropriate for the complexity and risk of the research.”</td>
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<tr>
<td>FDA</td>
<td>. . . the regulations require that sponsors select investigators who are qualified by training and experience as appropriate experts to investigate the drug. The regulations do not specify the minimum requirements nor do the regulations specify what qualifications an investigator must have in order to be considered qualified by training and experience to conduct a clinical investigation. Sponsors have discretion in determining what qualifications, training, and experience will be needed, based on the general recognition that this would include familiarity with human subject protection (HSP) regulations (i.e., 21 CFR Parts 50 and 56) and practices as well as good clinical practice (GCP) regulations (see 21 CFR Part 312) and standards (e.g., ICH E6) for the conduct of clinical studies.)</td>
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<tr>
<td>HHS/OHRP</td>
<td>The HHS regulations for protecting human research participants (45CFR, part 46) don’t specify required training for investigators of human subjects research. However, institutions conducting HHS-supported human subjects research must comply with HHS regulations. Therefore, OHRP recommends that institutions and their designated IRBs ensure that investigators maintain continuing knowledge to comply with: relevant ethical principles, relevant federal regulations, written IRB procedures, OHRP guidance, other applicable guidance, state and local laws, institutional policies for the protection of human subjects. In addition, the OHRP recommends that investigators complete training before conducting human subjects research.</td>
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### Agency | Training Requirements
--- | ---
**NIH** | For NIH-awarded human subjects research:
- Key personnel must be trained. Investigators who conduct studies with human specimens, tissues, or data that do not involve human subjects “do not need to fulfill the education requirement.”
- The NIH does not endorse any specific programs to fulfill the educational requirement for the protection of human subjects nor the frequency of training.
- **RCR** training is ‘integral’ to all research training programs; Individuals should be responsible for their own RCR instruction that they should take at their various career stages.
- **Instructional Components** for “all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award..., research education grant, and dissertation research grant”:
  - Substantial face-to-face discussions among participants; a combination of didactic and small-group discussions (e.g., case studies); and participation of research training faculty in instruction is highly encouraged. “...Online instruction is not considered adequate as the sole means of instruction.”
  - The following **topics** are “most acceptable”: 1) Conflict of interest, 2) Policies regarding human subjects . . ., 3) Mentor/mentee responsibilities and relationships, 4) Collaborative research, 5) Peer review, 6) Data acquisition, managing, sharing, and ownership, 7) Research misconduct, 8) Responsible authorship and publication, 9) Scientific responsibilities to society, ethical issues in biomedical research, and environmental and societal impacts of scientific research
  - Instruction should involve substantive contact hours between the ... participants and the participating faculty. Acceptable programs generally involve at least eight contact hours
  - RCR reflection and training should occur throughout a scientist’s career and be appropriate to the particular career stage(s) of the individual(s)—undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. “Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years.”
- **Compliance**: “It is expected that course attendance is monitored and that a certificate or documentation of participation is available upon course completion.” NIH expects institutions to maintain sufficient records to demonstrate that NIH-supported trainees, fellows, and scholars have received the required instruction.

**Summary: Federal Requirements for Biomedical and Social/Behavioral HRP Training**

Other than the Centers for Disease Control, none of the federal agencies surveyed mandate specific training programs for investigators leading research with human participants, instead, relying on the supported institution to ensure that investigators are appropriately educated. The agencies generally recommend that such training ensure that investigators are familiar with the following before conducting human subjects research:
- Human subject protection regulations and practices (federal, state, and local)
- Relevant ethical principles
- Written IRB procedures and institutional HRP policies.

In addition, the FDA ‘generally recognizes’ the need for familiarity with good clinical practice regulations and standards. The NIH cites that responsible conduct of research training is ‘integral’ to investigator preparation, and identifies nine topic areas. Furthermore, they stipulate that online training (such as CITI) is not adequate within their grant framework, but should be accompanied by face-to-face discussion and application, that it should include a minimum of eight contact hours, and that
investigators should participate in training at each stage of their career, in periods no longer than four years apart.

2. Association for the Accreditation of Human Research Protection Programs (AAHRPP) Standards Pertinent to HRP Education and Training

As the accrediting organization for institutions to demonstrate adherence to rigorous standards for ethics, quality, and protection for human research, AAHRPP certification represents important guidelines for the University’s human research protection program.

AAHRPP Standard I-1 contains elements that contribute to an institution’s systematic and comprehensive human research protection program for all research participants, and outlines methods that ensure that individuals conducting research at the institution are knowledgeable about and follow human research protection policies and procedures. Two elements within that standard pertain specifically to human research protection training and education.

- **Element I.1.E.** The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants

- **Element I.4.B.** The Organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.

AAHRPP Standard III-1 ... Researchers and research staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, researchers and research staff have the protection of the rights and welfare of research participants as a primary concern. Specifically:

- **Element III.2.A.** Researchers and research staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization’s policies and procedures regarding the protection of research participants.

To meet these elements, the following are required:

- **Element I.1.E.**
  - Written list of education activities for human subjects research teams
  - Policies and procedures including education requirements and timeframes, methods to monitor education requirements, continuing education and timeframes, corrective action that is taken if education requirements are not fulfilled
  - Education plans and records documenting the above.

- **Element I.4.B.**
  - Policies, procedures, and plans for enhancing the understanding of participants, prospective participants, and communities
  - Policies and procedures for evaluating outreach activities
  - Pamphlets, web sites, events, educational programs, evaluation reports, and QI plans to document the above.

- **Element III.2.1.**
  - Policies and procedures describing metrics/evidence for researchers and research staff to demonstrate competence in research roles and responsibilities
Demonstration of researcher and research staff's knowledge of laws, regulations, codes, guidance, and institutional policies and procedures that govern their research.

AAHRPP Reaccreditation

In the June 2015 accreditation report, a number of standards were cited as ‘areas of concern.’ The HRPP/IRB and CTSI have put into a place an implementation plan to address those areas of concern. The plan is being submitted in June 2016. Among the areas of concern are some pertinent to the education/training elements noted above, specifically:

- Element 1.4.B.: Needed process to evaluate and improve U of M’s outreach activities to prospective participants and the community to enhance their understanding of research
- Element 1.4.B.: Define education and monitoring that will be integrated into the enhanced community engagement and participant outreach plans.
- Domain II Standards for Institutional Review Board or Ethics Committee: Changes to SOPs and planning for education/training of IRB members is being managed by the U of M HRPP/IRB.

The HRPP has submitted two implementation progress reports (November 2015 and February 2016) to AAHRPP for reaccreditation. The progress reports highlight the HRPP’s progress, including progress and development of education and outreach activities.

The HRPP hired an Education and Outreach Specialist, developed new basic and advanced training offerings for IRB members, staff, and the research community in collaboration with departments and experts. An internal (IRB members and staff) and external (research workforce) newsletter was launched in fall 2015 highlighting important regulatory updates, IRB news, and educational content. Work is underway to relaunch the IRB website as a one-stop resource for the research community as it relates to human research protections.

In addition, the specialist launched monthly education reporting that includes information about training activities, results from training feedback surveys, and additional education and outreach activities underway or completed. Monthly reports are shared with HRPP leadership, the Executive IRB Committee, IRB members, and HRPP staff.

Training required for IRB members has been defined to include:

- Attendance at one orientation session facilitated by HRPP leadership
- **E-ROC**, Ethical Research Oversight Course (formerly the Ethical Oversight of Human Subjects Research online course), is a four and a half hour, online course that presents an in-depth exploration of the function and purpose of institutional review boards (IRBs) through an interactive, realistic interface. The course addresses the roles of IRB members who tackle the challenging, ethical, and regulatory issues of human subjects research.
- IRB Membership Training (Online Moodle Course): An advanced online course that includes units on research integrity and IRB review, vulnerable populations, and evaluation of several case studies. This online course was developed and will be maintained by Courtney Jarboe and HRPP staff to ensure that training includes local context issues.
- Mock IRB Committee meetings: An opportunity to learn about the committee review process and develop relationships with IRB colleagues
In addition, all IRB committee meetings and bi-weekly HRPP staff meetings include an educational agenda item (basic or advanced) facilitated by the Education and Outreach Specialist.

**Summary: AAHRPP Requirements**
The University of Minnesota is addressing AAHRPP concerns, with resubmittal of implementation plans in place by June 2016.

**3. Enhancing Clinical Research Professionals’ Training and Qualification (ECRPTQ)**
Sponsored by the National Center for Advancing Translational Sciences (NCATS), the ECRPTQ project seeks ‘to improve the efficiency, safety and quality of clinical research, as well as reduce redundant training requirements.’

**Phase I—GCP Training:** The first phase of the project engaged representatives from each CTSA hub in 2014 to compose recommendations for addressing Good Clinical Practice (GCP) standards and training. Consensus on recommendations for GCP training was reached by individuals from all 62 CTSA hubs, after which they were forwarded to NCATS for endorsement. A summary of those recommendations includes:

- **Who:** All study personnel engaged in a drug, device, biologic, and/or behavioral intervention study that meets the new NIH definition* of a clinical trial should receive GCP training.
  
  *A research study in which one or more human subjects are prospectively assigned to one or more interventions... to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.* (Summary Report and Consequent Recommendations for GCP Training Expectations for CTSA Consortium Hubs, 11/25/2014) ‘Engagement’ in a clinical trial was defined as “any clinical research professional involved in the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of a clinical trial.” In the early phase of adoption, this would include research investigators and clinical research coordinators formally listed as members of the study team. (Subsequent discussion may endorse training for all team members in future phases of implementation.)

- **What:** GCP content taught should be at a baseline level, and be offered at a methodology selected by each CTSA site. The selection of a training platform will be informed by the CTSA hubs. Minimum criteria for International Conference on Harmonisation GCP training include: GCP Overview, the Principles of ICH GCP, and investigator responsibilities. Research personnel should complete GCP training at a minimum of every three years. CTSA hubs will be expected to track GCP training completion, reporting to their CTSA hub and NCATS.

- **Metrics:** No consensus was reached on exact metrics to be tracked and reported; therefore, a working group was assigned the task of addressing determination of metrics.

**Phase II—Competency Domains and Statements:** The aim of the second phase of work for the ECRPTQ initiative is to identify the minimal competencies necessary for research personnel to execute safe, high quality, and efficient clinical trials and develop a training approach that will teach and assess those competencies. In September 2015, the ECRPTQ working groups agreed upon eight competency domain areas, for which specific competency statements (for both biomedical and social/behavioral research), assessments, training resources, and current training gaps are being identified. The competency domains that have been forwarded to NCATS for acceptance are:

1. Scientific Concepts and Research Design
2. Ethical and Participant Safety Considerations
3. Investigational Products Development and Regulation
4. Clinical Trials Operations (GCPs)
5. Study and Site Management
6. Data Management and Informatics
7. Leadership, Professionalism, and Team Science
8. Communication.

Summary: ECRPTQ Initiatives
The Enhancing Clinical Research Professionals’ Training and Qualifications initiative supported by the National Center for Advancing Translational Science is actively in the process of defining both GCP training standards for research professionals as well as competencies to be demonstrated by investigators, research coordinators, and possibly, all research team personnel. The results of NCATS’ review of those recommendations is likely to be announced in the near future.

Conclusion: Requirements, Policies, and Initiatives for Human Research Protection
A determination of the training needs of University of Minnesota personnel engaged in all roles of research with human participants must be based upon standards of behavior as well as content and topic areas determined to be essential to high-quality, ethical performance of human subject research. Today, nationally-defined NIH and OHRP topic areas, AAHRPP certification standards, and (soon) national consensus on ECRPTQ domains and competencies can serve as frameworks against which the University of Minnesota can build and continuously evaluate its training programs. Ideally, those standards would be defined by evidence-based measures and ‘best practices.’ And ideally, assessment of research personnel’s competence at applying the knowledge they have learned in those training programs would be an essential component for ensuring implementation of safe and effective human subject research at the University.
This section addresses the HRP education/training requirements, resources and tracking/reports for University of Minnesota investigators and co-investigators, key personnel, and the research workforce. (Education and training of IRB members is being addressed under the auspices of the U of M HRPP/IRB.)

1. **HRP Training Requirements**

**Principal Investigators**

<table>
<thead>
<tr>
<th>Prior to Submitting Protocol for any U of M Research</th>
<th>Human Subjects Research</th>
<th>NIH-Sponsored Research</th>
<th>NSF/USDA/NIFA-Sponsored Research</th>
<th>Research on Drugs or Devices</th>
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| RCR Core Curriculum (41xx) based on discipline. Research integrity topics: social and professional responsibilities; reporting misconduct; mentoring; authorship; plagiarism; peer review; fiscal responsibilities; intellectual property; research data management. (6 – 8 hours) Or: Standards for Research with Human Participants (BTHX5000; RC6150) * Three lectures from the semester-long course fulfill RCR requirements: Standards for Publication; Data Integrity/Confidentiality; Research Misconduct* And: Additional courses in topics specific to the research (e.g., COI, Environmental Health & Safety, HIPAA) | CITI Basic Training Module (review every 3 years). Biomedical Research Basic Course includes: 1. Belmont Report 2. History and Ethics of Human Subjects Research 3. Basic IRB Regulations and Review Process 4. Informed Consent 5. Social and Behavioral Research for Biomedical Researchers 6. Populations in Research Requiring Additional Considerations and/or Protections 7. Conflicts of Interest in Research Involving Human Subjects 8. University of Minnesota | Applicants to NIH Research Training Grants, Individual Fellowship Awards, Career Development Awards, Research Education Grants, Dissertation Research Grants must complete and document: • **RCR core curriculum**  
• **Applicants must** “also seek opportunities for formal and informal training that is in-person, ongoing, relevant to their own disciplines, and appropriate to their career stage. Applicants are required to provide detailed descriptions of these activities as part of their applications for funding and reports.” | • PIs, co-PIs, and others in upper management positions on these projects must complete the University’s RCR core curriculum Or: • **Research Ethics Training**  
○ (CITI curriculum – 14 modules + 3 Supplemental) Or:  
○ Approved U of M courses and seminars that include core topics:  
  ○ Authorship and plagiarism  
  ○ Data/research integrity  

This is a U of M requirement for all sponsors, investigators, and sponsor-investigators on drug or device investigational research.
## Research Personnel

If you are staff on:  
And are a: | Sponsored Project on Human Subjects Research: Required Training | NIH Sponsored Project: Required Training | NSF/USDA/NIFA Sponsored Project: Required Training | Research on Drugs or Devices: Required Training |
---|---|---|---|---|
Clinical Research Coordinator | CITI Basic Training Module |  | Research Ethics Training (CITI Curriculum) |  |
Graduate Student | CITI Basic Training Module |  | Research Ethics course, seminar, or activity from approved list (Appendix A) |  |
Post-Doctoral Fellow | CITI Basic Training Module |  | Research Ethics Training (CITI Curriculum) |  |
Clinical Staff /Lab Personnel | CITI Basic Training Module |  | Research Ethics Training (CITI Curriculum) |  |
Undergraduate Student |  |  | Research Ethics Training (CITI Curriculum) or: Course, seminar, or activity from approved list (Appendix A) |  |

## Research Coordinator Training Recommendations or Requirements (if CTSI affiliated CRC)

<table>
<thead>
<tr>
<th>CTSI-Recommended Orientation for Clinical Research Coordinators</th>
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<tbody>
<tr>
<td>1. U of M New Employee Orientation (in person sessions)</td>
<td>9. Good Clinical Practice in Clinical Research (U of M online course)</td>
</tr>
<tr>
<td>2. HIPAA &amp; Privacy</td>
<td>10. Hazardous Material Shipping</td>
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<tr>
<td>3. Human Subjects’ Protection Training</td>
<td>11. Navigating Research at the University of Minnesota</td>
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<tr>
<td>4. NERS (as required)</td>
<td>12. Participant Recruitment &amp; Retention</td>
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<tr>
<td>5. Research 101 for Clinical Research Coordinators</td>
<td>13. Research Ethics</td>
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<tr>
<td>7. CPR Training (in person)</td>
<td>15. Time and Study Collection System (TASCS)</td>
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### Other CTSI Career Development, Education, and Training Activities (Current and Planned)

<table>
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<tr>
<th>Current</th>
<th>Planned</th>
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<tr>
<td>• Bi-weekly Clinical Research Professional Development Seminar (staff)</td>
<td>• Practice-Oriented research Training (PORT)—conversion/ adoption of UMich program. Likely content: Research design, securing funding, research conduct, presenting findings and writing manuscripts, study feasibility, research ethics (faculty)</td>
</tr>
<tr>
<td>• Monthly Career Development Seminar (faculty, staff, students)</td>
<td>• Blended learning foundational training and orientation for research professionals (will build on existing CRC modules) and complementary preceptor program. Goals are to ensure staff has knowledge and skills to implement high-quality, ethical research; recruit and train a more diverse workforce, and share with other CTSA hubs. (staff)</td>
</tr>
<tr>
<td>• Clinical Research Professional Development Advisory Group (staff)</td>
<td>• Community Engagement Studios (with CEARCH) to advance education and training for community and researchers (faculty)</td>
</tr>
<tr>
<td>• Specialized training re: research for CSC clinical staff (staff)</td>
<td>• (In development): Informed Consent training modules and workshop (hybrid program) to be piloted in Psychiatry (faculty, staff)</td>
</tr>
</tbody>
</table>
2. Additional Resources for Research Training

Additional training opportunities are available at the University, offered by the University of Minnesota, professional organizations, and other institutions. Some can be found at http://www.research.umn.edu/irb/advanced.html. In addition, HRPP offers training sessions by request to help support researchers and research personnel with the IRB process.

Training Recordings
- Keep Calm & Carry On: Preparing for FDA Inspections of Clinical Investigators
- Information Session on the Notice of Proposed Rulemaking (NPRM)
- HIPAA & Research

Introduction to Clinical Research Methodologies
These stand-alone, interactive modules were authored by research experts at the University of Minnesota. The authors of the modules are indicated in parenthesis following each course title.
(Note that the links found at the website indicated are in the process of being updated and replaced by the new modules listed below, which are available at: www.18education.umn.edu:
- Basic Statistics for Clinical Research (John Connett, PhD, Professor, Division of Biostatistics, SPH)
- Critical Appraisal of Observational Studies (Jim Pacala, MD, MS, Professor & Associate Head, Dept. of Family Medicine and Community Health)
- Ethics in Clinical Research (Debra DeBruin, PhD, Associate Professor, Center for Bioethics)
- Good Clinical Practice in Clinical Research: An Introduction (contains a graded exam at the end) (Debra Dykhuis, Executive Director, HRPP)
- Integrating Research Into Clinical Environments (Debra Dykhuis, Executive Director, HRPP; Moira Keene, MA, CIP; Mark Paller, MD)
- Introduction to Biomedical Health Informatics (Connie Delaney, PhD, RN, Dean, SON)
- Introduction to Clinical Trials (Jim Neaton, PhD, Professor, Division of Biostatistics, SPH)
- Introduction to Epidemiologic Methods (Russell Luepker, MD, Professor, Epidemiology and Community Health, SPH)
- Translational Research: An Overview (Mark Paller, MD, MS, Sr. Associate Dean for Research and Medicine, Medical School)

Online Ethics Center Training Modules
Published by the National Academy of Engineering, the modules below also provide readings on each of the following topics:
- Responsible Collection, Retention, Sharing, and Interpretation of Data
- Special Issues in Conducting Human Genetic Research
- Ethical Challenges in Research with Human Biological Materials
- Ethics of Research on Vulnerable Populations
- Ethics of Research with Subjects Who Have Dementia
- Ethics of Research with Children
- Ethics of Research with Human Subjects Who are Mentally Ill

**U of M Courses to Meet NSF and USDA/NIFA Ethics Training Requirements**
To meet this requirement, students enrolled in ‘specific degree programs,’ can complete one or more for-credit or non-credit courses (See Appendix A) including seminars or activities on umn.edu core topics:
- Authorship and Plagiarism
- Data/Research Integrity
- Reporting Misconduct.

**Center for Bioethics Courses**
The Center for Bioethics offers the course, *Standards for Research with Human Participants*, which can be taken for credit or in ‘a la carte’ format, in which learners are welcome to attend the lectures of most interest to them. That course is focused on understanding the regulations (e.g., use of IRBs, consent, international) from the federal, state, and University. The Center’s *Research Ethics* course can be taken for credit or for continuing education credit as well.

**3. Tracking and Reporting**
- *Research Education Reports* accessed through the OVPR Research Reporting Center show RCR and Human Subjects training that have been completed, both online as well as approved University courses.
- *UM Reports* show an employee’s or student’s entire history of completed training (RCR, HIPAA, Organizational Effectiveness, etc.)
- *ULearn* Transcripts display an employee’s or student’s courses that they have taken through ULearn only
- A direct feed from CITI has been established so that all training completed under a University x.500 address is fed into the ULearn system and is ultimately available in either the ULearn transcripts or UM Reports.

**Conclusion: Current University of Minnesota HRP Training Requirements and Resources**
Based upon University websites and from interviews with OVPR/RCO, HRPP, and CTSI personnel, the University does offer the required training framework to meet current federal guidelines for human subjects research, including requirements from specific agencies (e.g., NIH, NSP). A tracking system (or three) is in place for tracking and reporting most training completion. Questions that are apparent from this initial overview include:

1. Beyond the honor system of reporting training completion on application forms, how do IRB reviewers ascertain currency of training of investigators and research teams identified on protocols?
2. How is renewal of training tracked and reinforced, and through what infrastructure?
3. What type of in-person training is provided to meet NIH RCR training grant requirements, and how is that administered and monitored?

4. How much and which specific advanced or additional training should be required for investigators and/or staff doing research with vulnerable populations, international studies, biospecimens, and/or other research beyond that covered by core courses? How should requirements be implemented and monitored?

5. What advanced training options are available and typically offered in noncompliance situations? For whom? How is that administered and tracked?

6. What metrics are in place to ensure that investigators can apply at the point of need in their research what they have covered in online courses?

7. What evaluation metrics are in place and being used to continuously monitor the quality of the University’s HRP training programs?

8. How can the entire HRP education and training system be developed into a highly accessible, transparent, and welcoming system for all investigators and research personnel?
In order to learn about human research protection education and training at other universities, the author of this report explored the websites of eight other universities known for excellence in research, and interviewed leaders at the IRBs and/or offices of the vice president of research at four of those. A summary of the training programs and requirements derived from that exploration follows. (Appendix B contains one ‘best practice’ example from Emory University of a role-based website clearly showing HRP training requirements.)

<table>
<thead>
<tr>
<th>Prior to Submitting Research Protocol or RCR Training</th>
<th>CITI?</th>
<th>Human Subjects Research</th>
<th>CITI?</th>
<th>Training Registration &amp; Tracking</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duke University &amp; Duke Medicine</strong></td>
<td></td>
<td><strong>Investigators and key personnel, Postdoctoral fellows, PhD students, CRCs and Clinical Staff</strong></td>
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<tr>
<td>Postdoctoral Fellows: 4-hour RCR Orientation or 5-Session course (for NIH Training Grants)</td>
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<td>History &amp; Ethical Principles (Duke ORS Initial Certification)</td>
<td></td>
<td>Duke Human Research Training is delivered through the Duke LMS</td>
<td>Duke ORS requires 1 CE credit each year for 2 years following initial certification</td>
</tr>
<tr>
<td>PhD Students: 12-hour RCR Orientation + 2-hours RCR Forums + 4-hour course</td>
<td></td>
<td>Human Subject Protection Training (8 modules)</td>
<td></td>
<td>Other courses are tracked</td>
<td>Duke Medicine requires CITI modules every 3 years</td>
</tr>
<tr>
<td>Graduate Students: 4-hour RCR Orientation course</td>
<td></td>
<td>Duke Human Research Training (instructor-led or online) (Duke Medicine)</td>
<td></td>
<td></td>
<td>Duke’s Office of Clinical Research (DOCR) provides services and training to support Investigators, Coordinator</td>
</tr>
<tr>
<td><strong>Emory University</strong></td>
<td></td>
<td><strong>All key research personnel must complete:</strong> Online Training: Protection of Human Subjects in Research</td>
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<tr>
<td>Investigators:</td>
<td></td>
<td></td>
<td></td>
<td>Investigators, fellows, residents, students, and research staff can document all training (online and in-person) using the Emory Learning Management System (ELMS)</td>
<td></td>
</tr>
<tr>
<td>Online RCR Training offered as a ‘resource for those interested in obtaining training on RCR…”</td>
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</tr>
<tr>
<td>Key Concepts in Clinical Research for Investigators, required to cover Emory-specific content.</td>
<td></td>
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<tr>
<td>To meet NIH in-person requirements, Office of Compliance offers monthly in-person case studies based on issues that have arisen regarding RCR.</td>
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</table>

They are the largest commercial IRB in the world.
CITI HRP training and Key Concepts in Clinical Research renewed every 3 years
12 AMA PRA CE credits offered for Key Concepts course
IRB does not require RCR and GCP training. They are waiting to hear about the NCATS initiative.
<table>
<thead>
<tr>
<th>Emory University (cont’d)</th>
<th>Prior to Submitting Research Protocol or RCR Training</th>
<th>CITI?</th>
<th>Human Subjects Research</th>
<th>CITI?</th>
<th>Training Registration &amp; Tracking</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residents and Fellows:</td>
<td>• RCR online and in-person training if associated with NIH or NSF grants.</td>
<td></td>
<td>•</td>
<td></td>
<td>•</td>
<td>• New coordinators are mandated by the University to attend a 3-day, Emory-developed program. Completion is verified by the IRB. Any CRC who consents participants must attend. They may adopt the CITI GCP course for CRCs with a couple Emory-specific modules.</td>
</tr>
<tr>
<td></td>
<td>• Key Concepts in Clinical Research for Investigators (every 3 years; 12 AMA PRA credits)</td>
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<td></td>
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<td></td>
<td>Renewal for CRCs, residents, and fellows is the CITI course.</td>
</tr>
<tr>
<td></td>
<td>• Online Introduction to Clinical Research at Emory (every 3 years; 7 AMA PRA credits)</td>
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</tr>
<tr>
<td>Clinical Research Coordinators:</td>
<td>• 2-day Classroom Intro to Clinical Research at Emory (every 3 years; 14 AMA PRA credits)</td>
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</tr>
<tr>
<td>Harvard University</td>
<td>Harvard’s RCR course meets the NIH requirement for all trainees and fellows receiving support from NIH ... Graduate students, post-doctoral fellows, and junior faculty members must attend a minimum of 6 lectures and complete all case studies. “This course is separate from CITI Training, encompassing far more than strictly Human Subjects Research, and must be completed in person per NIH requirements. (Renewal: each career stage or every 4 years)</td>
<td></td>
<td>Required Ethics Training*</td>
<td></td>
<td>Training certification (except for NIH online course) is tracked in the eIRB submission system, ESTR.</td>
<td>• CITI Ethics Training for social/behavioral research includes 10 required modules + 5 electives. (Did not find Biomedical Research requirement.)</td>
</tr>
<tr>
<td></td>
<td>• CITI Online Training or:</td>
<td></td>
<td>• C  I T I  O n l i n e  T r a i n i n g  o r :</td>
<td></td>
<td></td>
<td>Office of Human Research Administration offers</td>
</tr>
<tr>
<td></td>
<td>• NIH Certification Online Training or:</td>
<td></td>
<td>• N  I H  C e r t i f i c a t i o n  O n l i n e  T r a i n i n g  o r :</td>
<td></td>
<td></td>
<td>o Monthly IRB Clinics</td>
</tr>
<tr>
<td></td>
<td>• Committee on the Use of Human Subjects undergraduate training</td>
<td></td>
<td>• C o m m i t t e e  o n  t h e  U s e  o f  H u m a n  S u b j e c t s  u n d e r g r a d u a t e  t r a i n i n g</td>
<td></td>
<td></td>
<td>o QI Program Monthly Education Series</td>
</tr>
<tr>
<td></td>
<td>* Required for anyone working directly with human subjects, data, including PIs, Co-Investigators, and NIH-defined ‘Key Personnel.’</td>
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<td></td>
<td>o Small-group In-Services</td>
</tr>
<tr>
<td></td>
<td>Renewal: Every 3 years:</td>
<td></td>
<td>• C  I T I  R e f r e s h e r  C o u r s e  o r :</td>
<td></td>
<td></td>
<td>o One-on-One Study Staff Orientation</td>
</tr>
<tr>
<td></td>
<td>• 3 QI education sessions</td>
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</tbody>
</table>
All faculty, postdoctoral trainees, and staff engaged in research at JHU SOM are required to complete RCR training every 4 years. Three required components:

- Complete RCR CITI Online Course (7 modules)
- Attend 2 Dean’s Research Integrity Lectures Series (8 offered each year with interactive discussion and panels led by faculty; CME credit offered)
- Attend one Department/Division Meeting at which an RCR topic is discussed.

RCR Program components satisfy the NIH and NSF guidelines for responsible conduct of research.

IRB Compliance Training for Human Subjects Research
(Required for PIs and Study team members):
- Basic Human Subjects Research Course (CITI online)
- Conflict of Interest and Commitment (online)
- HIPAA (online)
- Clinical Research Billing and Clinical Research Management Systems (online and live training)

Research Ethics Workshops About Responsibilities and Duties of Scientists (REWards) (PIs and Fellows must attend 2 workshops.)

PI Recertification will include 4 required online modules + 1 in-person activity.

Study team members recertify within 3 years of initial HSR compliance training, and then every 3 years.

The University’s ‘mylearning’ system and CITI are used to track training completion. The electronic IRB submission system has training data within it, and might be future system for tracking.

- IRB for Medicine and Nursing reports up to the Vice Dean of Clinical Research of Medicine. Public Health has a separate IRB.
- As of March, 2016, PIs will be required to complete HSR recertification training every 3 years.
- PI recertification training includes 4 required CITI modules (GCP, Informed Consent, Research with Vulnerable Subjects, RCR) + in-person workshops.
- Study team recertification requires 4 online CITI modules + 2 elective online modules.
- Continuing education credit is not offered.
### Prior to Submitting Research Protocol or RCR Training

<table>
<thead>
<tr>
<th>UCSF</th>
<th>CITI?</th>
<th>Human Subjects Research</th>
<th>CITI?</th>
<th>Training Registration &amp; Tracking</th>
<th>Comments</th>
</tr>
</thead>
</table>
| • Required by the University of California Office of the President: [Compliance & Conflict of Interest for Research (COIR)](every 2 years). Satisfies NIH and UC requirements. And:  
• Required by UCSF Office of Ethics and Compliance:  
  o UCOP General Ethics and Compliance Briefing (PowerPoint)  
  o UCOP Sexual Harassment Prevention (web page)  
  o Responsible Conduct of Research Training (Undefined. Link on ‘Required Training’ page leads to NSF site.) | | PIs and key study personnel must complete CITI training (required).  
• 5 core modules + 2 elective modules required (2 – 4 hours)  
• Renewal every 3 years by completing 3 modules of your choice | | Retain CITI certificates in individual files and provide copy to administrative team. | “Trainings are required as part of the conduct of one’s research. The [UCSF] Ethics & Compliance office is leading efforts to reduce, combine, streamline, and optimize the number and presentation of required courses.”  
• CME/CE credit available for GCP courses.  
• CRC training is ‘recommended,’ and includes print-based, classroom, and online materials.  
• UCSF [Training in Clinical Research](program offers:  
  o Summer Workshop  
  o Advanced Certificate  
  o Master's in Clinical Research  
  o Certificate in Implementation/Translation Science |
### University of Michigan

<table>
<thead>
<tr>
<th>Prior to Submitting Research Protocol or RCR Training</th>
<th>CITI?</th>
<th>Human Subjects Research</th>
<th>CITI?</th>
<th>Training Registration &amp; Tracking</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigators on a project proposal must complete the Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS) (every 3 years):</td>
<td></td>
<td>PEERRS Training is required for anyone listed as a study team member on a human subject study application. Renewal: 3 years. For Biomedical &amp; Health Sciences:</td>
<td></td>
<td>myLINC, the University’s online Learning and Information Center</td>
<td>The U-M Office of Research develops PEERRS courses. Human Subjects courses are adapted from CITI.</td>
</tr>
<tr>
<td>• Conflict of Interest</td>
<td></td>
<td>• Belmont Report &amp; CITI Course Intro</td>
<td></td>
<td></td>
<td>U-M has 4 IRB offices reporting up through an IRB council, recommending policy to the VP of Research. Council includes CTSA</td>
</tr>
<tr>
<td>• Research Practice Foundations</td>
<td></td>
<td>• History &amp; Ethical Principles</td>
<td></td>
<td></td>
<td>Training is ‘weak link’ and understaffed.</td>
</tr>
<tr>
<td>• Research Administration</td>
<td></td>
<td>• Basic IRB Regulations &amp; Review Process</td>
<td></td>
<td></td>
<td>Refresher course system isn’t good because it’s just repetition.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Informed Consent</td>
<td></td>
<td></td>
<td>NSF requirements and remediation programs are pushed down to the departments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Research with Protected Populations-Vulnerable Subjects</td>
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<td></td>
<td>Practice Oriented Research Training (PORT): didactic &amp; experiential mentored research training program for clinicians</td>
</tr>
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<td></td>
<td></td>
<td>PEERRS is now integrating with CITI so that people have options between the two.</td>
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</tbody>
</table>

### Washington University

<table>
<thead>
<tr>
<th>Washington University</th>
<th>Program for the Ethical and Responsible Conduct of Science and Scholarship (PERCSS). This is a voluntary web-based and/or online program to the Washington University research community: 8 online modules:</th>
<th>Human Subjects Education (CITI) (The Research Gateway system assigns modules appropriate to the type of research)</th>
<th></th>
<th>The Research Gateway is Washington University’s online resource for faculty and staff to access research-related resources, tools, forms, and applications to propose, perform, manage, and close research projects.</th>
<th>HRP Office offers education programs that include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to Submitting Research Protocol or RCR Training</td>
<td>Intro to Ethical and Responsible Research</td>
<td></td>
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<td>o Lectures &amp; presentations</td>
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<tr>
<td></td>
<td>Authorship &amp; Publication</td>
<td></td>
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<td>o Open-access publication of conferences and discussions on HRPP best practices</td>
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<tr>
<td></td>
<td>Collaborative Research</td>
<td></td>
<td></td>
<td></td>
<td>o Videos and podcasts on HSP protection and IRB review</td>
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<tr>
<td></td>
<td>Conflict of Interest</td>
<td></td>
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<td>o Consultations</td>
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<td></td>
<td>Data Ownership &amp; Mgmt</td>
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<td></td>
<td>o FDA regulation and oversight guidance</td>
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<td></td>
<td>Mentor-Trainee Relationships</td>
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<td>Peer Review</td>
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<td></td>
<td>Research Integrity</td>
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<tr>
<td>Prior to Submitting Research Protocol or RCR Training</td>
<td>CITI?</td>
<td>Human Subjects Research</td>
<td>CITI?</td>
<td>Training Registration &amp; Tracking</td>
<td>Comments</td>
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<tr>
<td>University of Pennsylvania</td>
<td>For anyone mandated through NIH or NSF grants: The CITI RCR Course covers the nine instructional areas related to ethics and practice of research endorsed by NIH and the Office of Research Integrity. It fulfills the NSF requirement for RCR training and supplements the face-to-face instruction that NIH requires.” (4 – 6 hours)</td>
<td>The CITI Human Subjects Protection Course ethical principles underlying the federal regulations governing human subjects, outlines the rules for conducting research with various populations of human subjects, and covers IRB procedures. Completion of a Human Subject Protection Course is required by the Penn IRB for participation on an approved protocol. No ongoing training requirements</td>
<td></td>
<td></td>
<td>All Clinical Research (CR) staff are required to complete the 2-day Clinical Research Coordinator training offered by OCR within 6 months of their start date. This requirement includes the following research staff: Clinical Research Nurse, Clinical Research Coordinator, Clinical Research Nurse Coordinator, and Clinical Research Assistant. Knowledge Link, Penn’s learning management system (LMS), provides access to classroom and on-line training. It is the primary repository for administrative, compliance and certification training, along with professional development courses. Knowledge Link training is integrated with the University’s compliance training survey, Penn Profiler. CR Certification Program Topics: • Research infrastructure at Penn • Best standards of practice and regulatory requirements for CRCs and methods to achieve them • Practical suggestions, tips, and resources • Comprehensive training in GCP for investigator-initiated, industry-sponsored, and grant-funded research</td>
</tr>
</tbody>
</table>
Conclusion: HRP Educational Requirements at Other Universities

From explorations of university websites as well as interviews with personnel at IRB and offices of vice presidents of research at eight other universities, it appears that those universities—both public and private—provide and require HRP training and education in much the same manner as does the University of Minnesota. Some of the key findings from this exploration include the following:

1. The Collaborative Institutional Training Initiative (CITI) training is the ‘standard’ used among universities for providing online training on human subjects research topics, good clinical practice, and research ethics. All of the universities in this sampling subscribed to CITI for HRP and/or RCR training.

2. While the number of and specific CITI courses vary amongst the Universities, it appears that the nine categories of NIH responsible conduct of research (see 12 of this report) guide training content for general research training.

3. All of the Universities—with the exception of Washington University—have developed their own training programs for general research or responsible conduct of research training. Some integrate or adapt CITI training in those programs.

4. Human Subjects Research training, however, is universally offered in online (CITI) format by all universities. (Johns Hopkins supplements this training with a requirement for investigators and fellows to attend two in-person REWards workshops.)

5. With the exception of requirements for IND/IDE research, Good Clinical Practice training may be offered for investigators either as optional (e.g., UCSF) or as part of recertification. (The Emory informant mentioned that their IRB doesn’t require RCR and GCP training, though they are interested in following the NCATS GCP training initiative.)

6. Six of the eight universities surveyed require recertification training for investigators on responsible conduct of research, ranging from every two – four years.

7. All of the universities researched—with the exception of University of Pennsylvania and Washington University—require recertification of investigators conducting research with human participants every 3 – 4 years. Typically, the training is a repetition of or additional CITI modules. Some institutions, including Duke, Harvard, and Johns Hopkins, also require in-person training as part of the renewal process.

8. Only a few institutions provide CE credit for RCR, recertification, and/or GCP training.

9. Emory University and University of Pennsylvania have developed and mandated Clinical Research Coordinator training that involves in-person workshops and ongoing recertification, including renewal of GCP training.

10. With the exception of UCSF, it appears that all of the universities researched use enterprise learning management systems for registration and tracking of RCR and HRP training. In most cases, the learning management system is/will soon be integrated with the institution’s eIRB system.

11. In general, a question arises from this exploration of the extent to which all of the training content covered at the University of Minnesota as well as the other Universities (including CITI) is ‘knowledge’ based (e.g., regulations, policies, roles and responsibilities) vs. attention to developing and demonstrating skills and attitudes for implementing ethical, conscientious, and team-based participant-focused human research.
**Needs and Perspectives**

The purpose of this section is to gather and summarize—in light of the federal and accreditation HRP requirements and current status of HRP training at the University of Minnesota—input about the primary gaps that the University must address in order to ensure satisfactory compliance and exemplary performance of investigators and research teams conducting research with human participants. The identification of gaps and needs will be derived from:

- *An External Review of the Protection of Human Research Participants at the University of Minnesota with Special Attention to Research with Adults Who May Lack Decision-Making Capacity: Final Report (February 23, 2015)*
- *Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program: Work Plan (June 11, 2015)*
- *CTSI Recommendations for Integration of Clinical Research Studies in the Department of Psychiatry into the University of Minnesota Clinical and Translational Science Institute (CTSI) (February 11, 2016)*
- Input from interviews with University of Minnesota research personnel
- Input from interviews with IRB and research leadership at other universities.

Attempts to interview research participants and their families in focus groups were pursued for the purpose of listening to the experiences and preferences of patients and families regarding interactions with research teams that can contribute to their understanding of their research role, the protection mechanisms in place, input and feedback mechanisms available to and preferred by them, and resources for addressing challenges they may encounter during research. However, in spite of significant effort to set up these focus groups, this component could not be accomplished within the time span of generating this report.

**1. Action Commitments in Response to the External Review**

The report of the External Review (February 2015), the Work Plan response (June 2015), and the CTSI Recommendations for the Department of Psychiatry (February 2016) contain a number of commitments to change regarding the education and training of investigators and individuals engaged in research with human participants at the University of Minnesota. Listed below are the External Review recommendations included in the Implementation Work Plan that specifically pertain to education and training.

3.3.1 Conduct an evaluation of the resources of the HRPP specifically dedicated to the education and training of the research community to ensure that appropriate resources are in place to offer basic and advanced training opportunities in human subjects protections

3.3.2 Create opportunities for advanced training in human subjects protections for all individuals involved in human subjects protections including investigators, IRB members and staff, research personnel, and clinical staff on units that conduct research

3.3.3 Evaluate whether additional mandatory training requirements, comparable to the new mandatory training for sponsor-investigators (which includes GCP), should be implemented. Careful attention should be given to areas of research that are considered to be ‘high-risk,’ including those involving vulnerable populations, such as individuals with the potential for limited decision-making capacity
3.3.4 Institute a more substantive requirement for advanced level training for investigators and research teams when a determination has been made by the IRB of serious or continuing noncompliance, and develop a mechanism for ensuring compliance with this request.

3.3.5 Evaluate the mechanisms through which HRPP policies and procedures are communicated to the broader University research community in order to ensure that all its members are knowledgeable about and have ready access to the policies and procedures related to human subjects research.

3.3.6 Create expectations for the involvement of research departments and centers in the development of educational programs tailored to the nature and context of their research activities.

3.3.7 Consider ways to involve the University’s Center for Bioethics in the educational programs on the ethics of research and the University’s HRPP.

3.3.8 Consider efforts to engage the local community of patients and prospective subjects with programs on the ethics of research and the University’s HRPP.

3.3.9 Upgrade and professionalize education in, among other subjects, the responsible conduct of research and research ethics.

The Management Plan for the Department of Psychiatry contained additional recommendations pertinent to HRP education and training:

IV. Faculty members/investigators participate in a competency-based training program for research staff in the UMN CTSI. Key areas are likely to include: clinical research requirements for conducting studies; Good Clinical Practices; reporting of adverse events; protocol deviations; source documentation; documentation of informed consent; inclusion/exclusion; criteria assessment prior to consenting; and safety monitoring.

VIII. Develop a quality assurance (QA) program. Training development is likely a necessary component to support such a program, when implemented.
2. Input from Interviews with University of Minnesota Research Personnel

Discussion and interviews were conducted in January – February 2016 with the following University of Minnesota research personnel representing various leadership roles and responsibilities within the University.

Amanda Galster  Research Support Manager, Pediatrics, MS
Brenda Prich  Research Support Manager, CTSI
Corinne Komor  Administrative Manager, Biomedical Engineering
Courtney Jarboe  Education & Outreach Coordinator, HRPP/IRB, OVPR
David March  Assistant Director, RCO, OVPR
Debra Dykhuis  Director, HRPP/IRB, OVPR
Karen Cook  Research Support Manager, CTSI
Leslie Kennedy  Grants/Contracts Manager, Department of Medicine, MS
Megan Hoffman  Workforce Development Program Manager, CTSI
Michelle Hintz  Research Project Specialist, Department of Medicine, MS
Mickey Eder  Associate Director, Community Engagement to Advance Research and Community Health, CTSI
Russell Luepker  Professor, Public Health Epi & Community Health, SPH
Sandra Wells  Research Project Specialist, CTSI
Sarah Waldemar  Director, Research Accountability and Education, RCO, OVPR
Steven Miles  Professor, Center for Bioethics, Department of Medicine, MS

Discussions and interviews with University of Minnesota personnel generally addressed the following questions, as appropriate to the role of the individual being interviewed.

1. What training is currently required in your school or department in addition to University requirements for human research protection training?
2. What HRP resources and curriculum is being offered in your academic unit?
3. What is working well?
4. What needs or issues have arisen?
5. What particular issues have arisen pertaining to research with vulnerable populations or research with individuals with diminished capacity to consent?
6. What recommendations do you have?

A summary of a) current HRP training requirements and resources, b) needs and issues, and c) ideas and recommendations from these discussions and interviews follows. In most cases, these are summaries of comments, rather than direct quotations. (Exact quotations are indicated by quotation marks.) If multiple interviewees had similar comments, they are listed together. Some of the comments reflect individual perceptions, which may not be completely accurate.
Current HRP Training Requirements and Resources within U of M Academic Units

- “We do a poor job of ensuring that PIs and CRCs are adequately trained.”
- The Department of Medicine has developed its own internal QA procedures for chart review for research, and have their own training.
- The School of Public Health doesn’t do anything specific or unique for training, above and beyond the University requirements. The School relies on the IRB for certifications for training both nationally and internationally.
- The Center for Bioethics offers the *Standards for Research with Human Participants* and *Research Ethics* courses. These are offered for credit or for CE credit. The Research Ethics course is also offered in the School of Public Health. The Standards for Research course is purposely offered as ‘a la carte’ lectures so that individuals with specific research needs can obtain information about federal regulations, state laws, University policies and other information pertinent to their area of research.
- In the Department of Medicine, some effort is made to train trainees on training grants, but nothing extra is really required outside of the institutional guidelines. (Note: While this perception was expressed, there is a joint working group of T32 P.I.s in the Department of Medicine that has a required dedicated monthly RCR conference and that includes faculty participation from each T32 grant. It is led by Greg Vercellotti MD, with administrative support from Barbara Porwitt.)
- People often don’t know what the requirements are for doing human subjects research. In 2000, the Medical School held a 2-day event on HRP, ethics, RCR at the Radisson for faculty. Some haven’t done any training since.
- There’re no teeth to the three-year recertification. Only from sponsors. Whether it’s bench or blood-drawing research, there’s no more training, unless it’s a clinical trial with a human interface.
- The Responsible Conduct of Research course is a good resource. We make it available for our faculty who receive any kind of funding, and require it for the research staff. This makes them feel they have institutional support.
- The training that the investigators we work with receive is what’s required by the IRB. But, we aren’t sure it is sufficient to keep subjects safe.
- The Clinical Research Methodologies modules (ctsieducation.umn.edu) contain a lot of information that would be useful for investigators and research teams.
- Only two faculty in Bioengineering are currently engaged in human participant research, which is mostly NIH-funded. The school and departments have no special requirements for human participant research.

**Tracking and Reporting Training:**

  - Within the department, we don’t track training. We assume that investigators will do what’s needed. Departments don’t have time to check on faculty and track their training, so it’s pretty ad hoc on human subjects training and certificates.
  - The UM Reports training record is hard to read, so we just use CITI certificates if needed.
  - There’s no way for the department to know or require additional training, say for vulnerable populations. Only the user sees this. It’s probably not transmitted to the University systems and is probably not visible to the IRB or SPA if they look you up.
  - The CITI gradebook listing of many refresher courses completed by one of the interviewees contains the following standardized disclaimer: “Note: Your completed gradebook is provided for your general interest and suggested reading only! You do not receive “extra credit” for completing them. They do not show up on any completion reports. They will be credited in a grade book if you subsequently enroll in a course that includes them.”
Clarify if and how SPA and/or the IRB connects funding to protocols submitted to training needs. How does HRPP/IRB check to see what CITI training individuals have completed?

- **Coordinator Training:**
  - If new coordinators are hired there’s no required training. It seems that CTSI has a lot of materials, but it’s not available or else no one knows where to find it. {Note: This perception is not universally correct, but likely depends upon the hiring unit.}
  - There’s currently no mandate in our department for coordinator training. “We need to get to that and track it so that supervisors can see what’s been done and use it in performance reviews annually.”
  - CRCs may complete CRC training, but not all staff do. And CRCs and staff may or may not attend the regular training sessions. It’s not a high priority.

- **Format:**
  - The Departments of Medicine and Pediatrics don’t offer in-person training on human research topics, nor is CME provided for research training.
  - Online learning is preferred to in-person. However, the value of in-person learning is the conversation, and the opportunity to instill in investigators and research teams that, no matter what cost or risk, we always need to do the right thing.

- **Additional Training**
  - In Medicine, no special training is being done for research with vulnerable populations, for example, for research with the elderly.
  - Pediatrics research relies on CITI training. If you identify research with children in CITI, it directs you to complete additional modules.

**Needs and Issues (University of Minnesota)**

- Investigators want to do the right thing, but don’t know what/how to run a research project, particularly junior investigators. A good example is how to write a protocol. There’s a push to conduct research, but the conflict is a lack of tools to create research that can get the results through the plan/protocol developed.
- RCR is fine as a core concept. However, researchers wander beyond it, for example, into international research where they must understand international standards pertaining to data safety and monitoring, or diverse research that requires community consultation or dealing with biospecimens. That’s not included in RCR.
- What’s important is for investigators to know what they need and when they need it—so they get the training at the right point of readiness. #2: The University isn’t consistent about what’s required and for whom. Or where to go to find out.
- The three-year refresher is not consistently enforced; if you aren’t actively doing research, people don’t do it.
- CTSI Research Support services doesn’t have any special resources regarding working with vulnerable populations, and feel there’s a need to educate research teams about such research.
- For some Medical School grants, practice facilitators conduct government-funded research throughout the state. They visit clinics, and—although not necessarily reading through patient records—they gather experimental (de-identified) data. Some of those data could be identifiable. What training is required?
• The MS in Clinical Research involves learners from pharmacy, lab medicine, dentistry, and other professions. They need more training. CTSI provides some, but it is too expensive. Training may be reverting back to the ‘do it yourself’ model.
• We need a training program for international research.
• When individuals are hired in the middle of a study, the names of the new research staff typically aren’t shared with the IRB (they aren’t key personnel). However, those new staff members need to be trained.
• Investigators need mentors, sometimes from the larger academic unit. Do we have a mentor pool?
• We have a cultural issue, which is not one of collaboration. For example, Coordinators report to investigators, and many don’t participate in the monthly Coordinator meetings because it’s a cultural challenge to do so.

Training Formats
  o We need in-person training because investigators don’t remember what was in CITI training.
  o Good papers and tools to use and follow for helping research teams work with vulnerable populations
  o In-person training for working with vulnerable populations is a big need.

• Research Coordinators
  o We need to encourage research coordinators to complete the CTSI modules. They are great for baseline, but we also need to supplement them with in-person training, mentoring, and reinforcement.
  o We should explore who are possible mentors outside our specialty division for new coordinators.

Ideas and Recommendations of Interviewed Individuals (University of Minnesota)

Research with Vulnerable Individuals or Those with Diminished Capacity to Consent
• Create a training program on Consenting (for all research populations and for special populations)
• The specialized CITI modules are probably sufficient for vulnerable populations, though they may be lacking in addressing vulnerable adults with mental health challenges (e.g., dementia and others)
• The goal is to address consent as a process; have it carry through multiple visits over time. Devise a few questions to ascertain the understanding participants have about the research. Make a commitment to help them understand, and educate them.
• Create learning resources on consent, including a link to a consent form template with examples of completed ones
• Use case simulations and skill-based training so that research teams can demonstrate competence.

Update Human Research Protection Training and Education Policies
• Mandate Coordinator training, and use it for annual reviews. #2: Require the CRC modules; no one can be enrolled in a study until the research team has completed the training.
• Implement an infrastructure in which research staff members are not supervised by investigators. That will allow Coordinators to experience less pressure (e.g., for job security), and have options to connect with others in the event they have concerns about the conduct of their research study.
  {Note: This may not be realistic given the likelihood that the faculty or unit responsible for paying salaries is not likely to completely relinquish supervision.}
• Ensure that investigators and faculty have time to complete REPAs and get them tracked. Add more ‘teeth’ to the REPA process, perhaps by having protocols put on HOLD or some consequence to ensure they are completed.
• The mandate needs to come from the institutional level. We don't need a variance at the departmental level, especially since researchers work across departments. For example, all Coordinators have the same training or skill set. Could this be mandated even at the AHC level? Should we do the same for investigators?
• Require GCP training for anyone doing any investigational trial.
• Who is the holder of the requirements for GCP training through CITI? It would be useful to clarify who is the source of requirements. And what the requirements are.
• What if we had GCP training month/quarter each year for investigators? Like REPA. It would make sense that at certain times, you do certain things. Easier to keep track, and it could the ‘season for refresher courses.’

HRP Education and Training Infrastructure
• We need more infrastructure to support education and training, and more resources to serve the Ethics support needs. Ongoing funding must be a part of this.
• Encourage the VP of the Health Sciences to mandate that no grant funding will be accepted unless all staff have been trained.
• Resources all need to be in one place and easy to find.
• We need to make it easier to find the training requirements. “Here’s where you need to go to find out what training you need. Every three years, this is the requirement…” Which modules will satisfy which components of research. (This isn’t easy to find on the CITI website.)
• The IRB needs a more complete infrastructure to support human subjects research. Expand it vastly not only for protocol review, but also for prospective and retrospective Ethics review and education. Putting compliance in a separate office is a good idea.
• Could we have a ‘Recertification Time’ like we do for REPA? For example, if you are on the REPA list and you are engaged in human subjects research, could the requirement add in the CITI modules?
• Establish an Education Council to determine training and curricula for the University and Gillette for all aspects of research.
• Create a Director or Associate Director of Ethics Education, someone who would keep up-to-date on national and international changes in regulations and update training programs accordingly.
• The IRB could offer consultation services for investigators, including a) quick protocol review and identification of red flags, b) review and assistance with institutional requirements, including those from Fairview, c) methodology, including review of scientific design, d) writing support, etc.
• We need to agree on a common IRB for multi-center studies. Ours is too slow for industry-sponsored studies. Consider the multi-IRB structure at the University of Michigan.
• We need a One-Stop-Shop to find training and information at CTSI, HRPP/IRB, and Center for Bioethics.

• Content and Format
  o Need online resources as well as handy guidance documents at point of need on topics such as:
    ▪ Writing a protocol
    ▪ Tools for thinking about the feasibility of a project (e.g., do you have the population? dedicated staff? feasibility assessment?)
    ▪ Investigator responsibilities
- Sponsor and investigator responsibilities regarding IND and FDA studies
- Consent process, including screening before consent.
- Consenting people with diminished capacity
  - Create a module (similar to the Navigating Research module for Coordinators) that has a flow plan of the clinical research timeline and milestones (CTSI Research Services has a model for this.) Use it as a tool to show the scope of a whole project, the effect of changes to a protocol, and include case examples.
  - Use existing resources currently offered through CTSI such as the Clinical Research Methodologies modules (ctsieducation.umn.edu) or the Clinical Research Coordinator Training program.
  - Develop programs for investigators and students who do international research to learn to apply the same ethical standards as they do here, and be familiar with the regulations that apply in other countries.
  - Create training for working with medical records.
  - Case simulations and skill-based training so that research teams can demonstrate competence.
  - Don’t train investigators on how to be investigators, but train them on some of the consequences of mismanagement of research

- Tracking and Reporting Training
  - Develop a system to confirm that individuals working with children or vulnerable populations have completed applicable training and that it has been recorded and reported.
  - Include ‘additional training’ for specific types of research in the training reports, and ensure that they are accessible to the IRB, SPA, and departments.
  - Wherever training is tracked, make it transparent for everyone to read and understand.
  - Implement a method to track if someone is out of scope three years after completing training.

- Learning Assessment
  - Ensure that training is competency-based.
  - Core competencies for coordinators would be of great benefit, and we could document them.
  - Consider using the Onboarding Tool that CTSI is creating for CRCs with Mayo

**Engagement of Departments and Centers to Create a Culture of Ethics in Research**
- Create Grand Rounds for Research, led by faculty, particularly junior faculty. Provide CE credit. Consider it an elective for recertification or basic training.
- Research Grand Rounds would fill the need for in-person discussions and Q&A. It could be used as opportunities to discuss relevant examples, questions, and issues that need to be shared. For example, do a debrief and report on FDA audits for clinical trials for business and industry. That might be interesting even to those who aren’t involved (yet). Talk also about topics such as informed consent. Involve multiple departments and other schools.

**Ongoing Communicating and Training**
- Investigators need consistent prompting, which should also be copied to department heads. Give investigators a three-month heads-up on what training is due. Maybe add reminders at 60 days, 30 days, two weeks.
3. Input from Interviews with IRB and Research Leaders at Other Universities

Email invitations for online interviews were sent in January 2016 to Associate VPs or Deans of Research at eight other universities. Subsequent correspondence and referrals resulted in scheduled interviews with research leadership at four universities:

Anthony Keyes  Director, Research Staff Compliance, Education, and Training Institute for Clinical and Translational Research, Johns Hopkins University

Janelle Maddox-Regis  Training Manager, SOM clinical Investigations with Human Subjects Johns Hopkins University

Lois Brako  Ass’t VP for Research, Regulatory & Compliance Oversight, University of Michigan

Rebecca Rouselle  Director, Emory University IRB

Tracy Ziolek  Director, University of Pennsylvania IRB

Interviews generally addressed the following questions:

1. What human subjects research training is required for investigators, coordinators, and others on the research team?
2. What is the University infrastructure regarding HRP, specifically interaction with schools and programs?
3. How do you manage tracking, reporting, and alerts for recertification?
4. What works well?
5. What are your challenges and opportunities for improvement?

A good deal of the input from the interviews has been integrated in the earlier section, HRP Educational Requirements at Other Universities. However, other pertinent comments and input provided by one or more of those interviewed is provided below.

Training Requirements at Other Universities

- Investigators have a ‘self-policing’ approach based on what they individually need. “If you compliantly conduct research, and we never hear from you, it’s no issue.” PIs can take whatever training they decide they need. Most of our training occurs when an issue arises. We don’t want to ‘rock the boat’ for the majority, so we focus on providing individual corrective action when needed. “We are too big to require more training for everyone."

- No ongoing training requirements for the research community. However, we’ve recently developed a new document of Responsibilities for Research Investigators. The investigators need to confirm that they have reviewed that document each year.

- At one site, investigators and study teams doing research with vulnerable populations must complete recertification training that includes: GCP, RCR, Informed Consent, Vulnerable Subjects modules, plus two electives. Everyone on the study must do the training.
University Infrastructure
- At the University of Pennsylvania, the Office of Clinical Research in the Perelman School of Medicine has now taken the lead in compliance monitoring, clinical operations and support (including developing training for investigators and staff), and INDs/IDEs.
- Most coordinators who consent subjects report to investigators. Some—such as those in the Cancer Center—have regulatory offices and report centrally.
- Our IRB manages Biomedical and Social/Behavioral training. We are adding more requirements for renewal. We also provide annual updates on new policies and a module on common audit findings.

Tracking, Reporting, and Alerts
- The IRB requires up-front and ongoing training, and checks CITI training at initial funding and recertification milestones. They review and require all members of the research team to renew training, and don’t leave this up to the investigators. Investigators must confirm online that everyone on their team has been trained.

What Works Well
- We have a library of online training programs with PowerPoint/Voice-overs. We are working to increase this (but are too busy).
- We are starting to adopt the CITI Coordinator course with GCP and are adding a couple University-specific modules.
- The IRB collected and ran a report to see who was out of compliance, then gave everyone a year to complete required training. Now, the IRB will not review new applications unless everyone is up-to-date on HSR training.

Challenges and Opportunities for Improvement
- We don’t require GCP training now, but are waiting to hear more about the NCATS initiative.
- Our refresher course system is not good. People just repeat what they’ve already done, and they hate it. We need new programs.
- Training is our weak link. We only have one person to manage it, so no capacity to continuously update or change training content.
- We need to share more nationally, and have workshops/webinars that can be shared.
- Washington University is a leading model in offering papers, podcasts, and conferences through their Human Research Protection Office.

Conclusion: Needs and Perspectives
Clearly, the University of Minnesota needs to take some steps—and has committed to doing so—to improve education and training for investigators and the research staff who are engaged in research with human participants. From the results of and response to the External Review, and from interviews with research leadership in Minnesota and across the country, it appears that the University of Minnesota faces very similar challenges to both the public and private universities surveyed. The following section synthesizes the needs identified throughout this report, and makes recommendations for addressing those needs and gaps in the U of M human research protection program.
Recommendations: University of Minnesota HRP Education and Training

At a high level, priority need for changes exist in the following high-level areas:

1. Define a transparent **UMN infrastructure to manage HRP education for investigators and the research workforce.**
2. Decide upon and implement a **central HRP education, training, and communication unit,** to work with HRP subject matter experts University-wide, supported by enterprise commitment and funding
3. As part of the Community Engagement initiative, engage patients and prospective research participants in the development and delivery of training programs for investigators and the research workforce
4. Focus initial training development and implementation on:
   a. Advanced training for **research with vulnerable individuals and those with diminished capacity to consent**
   b. **Upgrade initial and recurrent training in ethics and the conduct of human research**
   c. Build on current efforts to engage U of M colleges, departments, and centers to create a **Culture of Ethics for Human Participant Research**
   d. **Plan to pilot programs in the Department of Psychiatry**
5. Create a web-based, comprehensive learning platform—using current and recently implemented enterprise systems—to manage the functions of learning program, including resource cataloging, registration, tracking, reporting, and prompting for ongoing training requirements.
6. Over the next 3 years, develop, pilot, and implement a competency-based curriculum plan that develops knowledge, skills, and attitudes and includes learner assessment as well as ongoing program evaluation (perhaps a systematic review and update of activities every two – three years).

The purpose of this section is to outline high-level recommendations for addressing these areas. The recommendations in this section largely represent the conclusions and opinions of Janet Shanedling, PhD, the curriculum and instructional designer authoring the Needs Assessment & Gap Analysis report, with some input from HRP leadership engaged with this initiative. Specific details (e.g., tasks, roles and responsibilities, specific deliverables, and timeframes) could be included in a subsequent curriculum plan based upon review and finalization of the recommendations in this report.

The following priority recommendations are organized into high-level categories. Recommendations are drawn from and integrate all of the sources of data summarized in this report:
- Federal requirements and policies, certification requirements, and national initiatives
- Current U of M HRP training requirements and resources
- HRP educational requirements at other universities
- Action commitments made in response to the U of M HRP External Review
- Input from research leaders at the U of M and at other universities.
### Priority Recommendations

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<th>Recommendation</th>
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| 1. Define a transparent UMN infrastructure to manage HRP education for investigators and the research workforce | a. Define and agree upon the HRP roles and responsibilities for all aspects of human research protection enterprise-wide, including: Center for Bioethics, Community, CTSI, Fairview, HRPP/IRB, OVPR/RCO, and Schools/Departments University-wide  
   b. Establish a transparent, collaborative cross-unit executive HRP Educational Advisory Group with defined Responsibilities Accountability, Support, Consultation, and Information Network (RASCI) among the HRP executive leaders.  
   c. Assign that cross-departmental infrastructure group the initial responsibility to review and decide upon University of Minnesota policies and mandates regarding:  
      - Basic HRP training for investigators, CRCs, research staff, trainees, and IRB members regarding content (e.g., should GCP training be included?), format (e.g., is CITI training sufficient or should learner assessment/demonstration of basic competencies be included)  
      - Advanced HRP training for investigators, CRCs, research staff, and IRB members with a focus on 'high risk' research, for example, with vulnerable individuals and/or individuals with diminished decision-making capacity, international research, research with biospecimens, etc.  
      - Content, format (e.g., online + in-person electives) and frequency for continuing renewal of HRP training for investigators, CRCs, research staff, and IRB members  
      - Requirements for and tracking of advanced level training for investigators and research teams for serious and/or continuing noncompliance  
      - A mandated system and responsibilities for ensuring basic and renewal training of research teams is complete, particularly for vulnerable populations research, for all personnel involved in a study. This should align with protocol review and remediation for noncompliance, and specify timing of training in relationship to the date of protocol submission to the IRB.  
   d. Determine the locus for decision-making regarding the planning, purchase of and/or instructional design and development of HRP, RCR, and advanced training; recertification training; and ongoing Culture of Ethics U of M offerings. (See Recommendation 2 regarding an HRP Education and Training Unit.)  
   e. Address policies and mandates regarding training for all U of M clinical research coordinators, including challenges faced when reporting solely to investigators (as in c. above)  
   f. Ensure a financial model that provides training and support to all investigators and research teams without cost being a barrier to access, and ensure compliance without excessive time requirements that disincent clinical research. |
### Recommendations

#### 2. Establish a central human research protection education, training, and communications unit

**a.** Create and resource a U of M HRP Education Specialist/Director (and necessary staff) to lead a centralized unit (based upon determination of 1d above) and work with U of M subject matter experts and existing resources to:

- Develop HRP curriculum sourcing, development, learning assessments, training dissemination, program evaluation and QA, and ongoing updates. (IRB member training should be coordinated with these efforts but may be developed and managed separately.)
- Carry out of guidelines for basic and advanced research compliance and human subjects protection training, under oversight from the Educational Advisory Board
- Serve as the U of M liaison with national efforts such as the NCATS GCP initiative and ECRPTQ Researcher Competencies initiative, and suggest how to integrate into the U of M curriculum as those move forward
- Collaborate on or manage the development and implementation of U of M Culture of Ethics forums, podcasts, webinars, etc. in collaboration with all other U of M units engaged in HRP leadership and management
- Work with other institutions and instructional design consultants to source and/or develop learning programs to meet the goals of the U of M HRP curriculum plan that will include knowledge, skills, and attitudes for HRP
- Ensure that timely, accessible, and clear communications regarding policies, training offerings, new regulations are created and disseminated to the research community
- Monitor the changing national policies and ‘state of the art’ and externally available training resources, bringing advances and recommendations to the HRP Educational Advisory Group.

**b.** Either within or affiliated with the Education and Training unit, assign clear responsibility to a Communications specialist who will be responsible for developing and maintaining a comprehensive, easily accessible HRP website (e.g., humanresearch.umn.edu), creating and aligning regular and continuous communications in other media formats (e.g., newsletters, updates), and ensuring two-way communication with all of the U of M research audiences (community participants, investigators, coordinators and research staff, IRB members, faculty, etc.). This position will require appropriate staff resources, including information technology support.

- Through a central Human Research Protection website, provide access to individualized training self-assessments, training reports, training offerings, CITI, and regular updates of U of M HRP offerings and other communications media, making access to all information about human participant research highly accessible and transparent for the research community. This should include pro-active automatic notifications of faculty and staff, and should be linked closely to the IRB website.
- Use the website to provide overviews and centralized access via the U of M learning management system (LMS) to all U of M and other training materials, including CITI, the CRC Orientation, Clinical Research Methodologies modules, etc.
- Provide links on the website to consultation and support services, for example, from the IRB.
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<td>**2. Establish a central human research protection education, training, and</td>
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<td>communications unit (cont’d)**</td>
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<td><strong>c.</strong> Within that HRP Education and Training Unit, strongly consider the</td>
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<tr>
<td>creation of a new <strong>position of Human Research Procedures, Policies, and Ethics</strong></td>
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<td><strong>Education Coordinator</strong> linking to Center for Biomedical Ethics. (Depending</td>
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<td>upon the individual skill sets and time, it might be possible to consolidate</td>
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<td>this position with the 2a leadership position.) This individual would ensure</td>
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<td>that required and optional training is available and current and easily</td>
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<td>accessible to the research community.</td>
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<td>- When determined and developed, this position would coordinate and administer</td>
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<td>interdepartmental forums, WebEx-based presentations, podcasts, or other U of M</td>
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<td>Culture of Ethics offerings</td>
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<td>- Manage updates to all existing training and launch new offerings.</td>
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<td>- Work with NIH and other training grants to help fulfill requirements for</td>
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<td>HRP and RCR training compliance</td>
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<td>- Serve as the liaison with OVPR units responsible training documentation</td>
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<td>and reporting systems to continuously monitor that all training offerings</td>
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<td>are being appropriately tracked and reported on transparently (including</td>
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<td>RCR, HIPAA, GCP, CITI, advanced training)</td>
</tr>
<tr>
<td><strong>d.</strong> Develop the option of offering Continuing Education credit for advanced</td>
</tr>
<tr>
<td>and recertification training, including a system to approve, track and credit</td>
</tr>
<tr>
<td>HRP CE ‘one-of-a-kind’ activities offered at UMN or elsewhere (conferences, etc)</td>
</tr>
<tr>
<td><strong>e.</strong> Collaborate with the IRB leadership to support, as needed, the design</td>
</tr>
<tr>
<td>of training that can be integrated into the Protocol and Study design module</td>
</tr>
<tr>
<td>being developed in collaboration with Huron Consulting.</td>
</tr>
<tr>
<td>**3. Engage patients and prospective research participants in the development</td>
</tr>
<tr>
<td>and delivery of training programs for investigators and the research workforce**</td>
</tr>
<tr>
<td><strong>a.</strong> Gather input and feedback from patients and families regarding their</td>
</tr>
<tr>
<td>priorities and areas of concern with U of M human research protection (as part</td>
</tr>
<tr>
<td>of this Needs Assessment Process)</td>
</tr>
<tr>
<td><strong>b.</strong> Within the Education and Training curriculum development process,</td>
</tr>
<tr>
<td>engage community members/research participants and U of M community content</td>
</tr>
<tr>
<td>experts as some of the ‘content experts’ in the development of HRP training</td>
</tr>
<tr>
<td>for researchers as well as training for research participants</td>
</tr>
<tr>
<td><strong>c.</strong> Develop and implement learning materials (HRPP/IRB) for legally</td>
</tr>
<tr>
<td>authorized representatives (LAR) to explain the LAR role, authority, and</td>
</tr>
<tr>
<td>considerations for making decisions.</td>
</tr>
</tbody>
</table>
## Recommendations

### 4. Focus initial training development and implementation on a) vulnerable research populations, b) ethics and conduct of human research, c) creating a U of M Culture of Ethics, and d) piloting all programs in the Department of Psychiatry

<table>
<thead>
<tr>
<th>a.</th>
<th>Training for Research with Vulnerable Individuals and/or Those with Diminished Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Develop competency-based advanced training (required and recommended offerings) on <strong>consenting</strong> for investigators and research staff in collaboration with content experts from HRPP/IRB, CTSI, Center for Bioethics, patients and families from the community, Fairview psychiatrists, U of M psychiatry and psychology faculty, etc. This will include development, pilot testing (if necessary), and/or implementation of competency-based training.</td>
</tr>
<tr>
<td></td>
<td>o Have the Educational Advisory Group consider a requirement that all researchers who consent in greater than minimal risk studies be qualified through demonstration of competencies to do so.</td>
</tr>
<tr>
<td></td>
<td>o Develop template consent documents and processes with easily accessible examples and practice cases</td>
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<tr>
<td></td>
<td>As tools are developed/sourced for assessing participants' capacity to consent and for monitoring ongoing capacity, develop and implement experiential training on their use</td>
</tr>
<tr>
<td></td>
<td>Adapt the learning programs to provide specialized training for an IRB panel (who will be charged with evaluating all research with these populations) on the unique needs of research with individuals with impaired or fluctuating capacity to consent or who belong to vulnerable populations.</td>
</tr>
</tbody>
</table>

b. Augment Training on the Ethics and Conduct of Human Research

- Develop and pilot-test/source a cross-training (or even team-based training?), competency-based curriculum for investigators, clinical staff, and IRB members on the ethics, mechanics, and importance of research in collaboration with experts from HRPP/IRB, CTSI, Center for Bioethics
- Include as topics for increased knowledge, skills, and attitudes: GCP, reporting adverse events, protocol deviations, source documentation, documenting informed consent, inclusion/exclusion, safety monitoring, etc.
- Review the RCR basic program and integrate into a comprehensive curriculum with advanced and ongoing mandated and elective options
  - Consider in the future requiring a demonstration of ability to apply the knowledge learned in skill-based cases and simulations and learning assessments, particularly for non-compliance remediation
- (Where is training on OnCore and REDCap offered?)
### Recommendations

<table>
<thead>
<tr>
<th>4. Focus initial training development and implementation on a) vulnerable research populations, b) ethics and conduct of human research, c) creating a U of M Culture of Ethics, and d) piloting all programs in the Department of Psychiatry (cont’d)</th>
<th>c. Engage U of M colleges, departments and centers to create a U of M Culture of Ethics</th>
</tr>
</thead>
</table>
|  | - Enhance the availability of and access to a transparent centralized HRP website and regularly disseminated university-wide HRP updates, newsletters, presentations, podcasts, etc.  
  - Engage the University-wide research community in learning about and adapting the national Enhancing Clinical Research Professionals’ Training and Qualifications (ECRPTQ) competencies and NCATS’ GCP training framework as those are approved and adapted nationally. Update the community as standards evolve.  
  - Hold campus conversations and forums across the university, including Research Grand Rounds that provide for peer-to-peer learning, highlighting what works and what are the challenges in human participant research  
  - Develop required and recommended advanced and refresher training modalities to be promoted and/or implemented by academic units in faculty, investigator, and research staff meetings.  
  - Develop training materials and train facilitators and moderators ('train-the-trainers') to offer opportunities for discussions and peer-to-peer learning at department faculty meetings, Research Grand Rounds, college forums, or research team events on topics such as vulnerable populations research; university policies related to study monitoring; scientific review; and new and evolving regulatory requirements. Offer CE credit as appropriate.  
  - Develop annual updates (perhaps in online format and/or in-person forums) regarding new regulations and policies, audit findings, best practices, etc. Consider collaborating on this with other institutions. Offer CE credit. |
|  | d. Plan to Pilot All New Training (4a and b) in the Department of Psychiatry |
|  | - Use feedback from pilot usage in Psychiatry research to finalize new training offerings prior to dissemination University-wide. |
| 5. Develop an integrated learning platform | a. Identify an easily accessible, transparent, welcoming Learning Management System (LMS) through which all investigators, CRCs, research staff, IRB members, and research participants can access all HRP learning materials. Ensure that that system:  
  - Integrates with the University’s upcoming eIRB system being developed with Huron Consulting  
  - Is easily accessible through the central HRP Education and Training website  
  - Provides a clear self-assessment for determining what training each individual research professional requires initially and as they become involved in additional research activities  
  - Provides access to CITI as well as U of M online learning modules and courses (and links to external resources)  
  - Provides easy registration for other U of M forums, Research Grand Rounds, conferences  
  - Provides access to a wide variety of training materials in various formats such as synchronous and asynchronous webinars, podcasts, research papers, presentations  
  - Notifies faculty and staff of required training, upcoming deadlines, compliance status, and other action items  
  - Manages CE if/when offered  
  - Documents and provides certificates of all online and in-person training that is completed |
Recommendations

6. Develop over time a competency-based curriculum plan that includes learner assessment and metrics for program evaluation

- Based upon the top priorities accepted and committed to from this needs assessment, develop a plan outlining the tasks, responsibilities, timeframes, and budget for developing, piloting, and finalizing the priority training programs identified and agreed to from report. Include wherever appropriate:
  - Learning that addressing knowledge, skills, and attitudes
  - Experiential and interactive learning formats
  - Modular learning materials that can integrated and re-used for a variety of learner audiences and purposes
  - Learning assessments and demonstration of competencies
  - Metrics and process for program evaluation and ongoing quality assurance.
    - As one metric, benchmark the U of M’s training against peer institutions to ensure our HRPP training meets or exceeds the norm (p. 17, External Review Work Plan)

- Following review and finalization of the previous priority recommendations, build into the curriculum plan goals and objectives for addressing some secondary priorities:
  - Review currently-required CITI courses and determine the most appropriate for basic, advanced, and non-compliance training, particularly in relation to a competency-based, hybrid training programs
  - Identify other internal and external high quality resources for training, and for knowledge and competency assessment
  - Develop modules and/or hybrid advanced programs on international research, research with biospecimens, research involving the use of medical records in clinical environments, and other topics
  - Completion of a hybrid curriculum for clinical research coordinators:
    - Build upon the almost-complete competency framework developed by CTSI in conjunction with Mayo
    - Integrate the current online curriculum
    - Secure a pool of AHC-wide mentors available to support CRCs, particularly those in small studies, and adapt the Optimizing the Practice of Mentoring course for those mentors, as needed
    - Develop and include an experiential- and case-based module on ‘Challenges of Research Management’ (or some such term). Address the challenges that CRCs can face when questioning ethical conduct of research that may differ from the perspective of their investigator/boss. Consider offering this as a ‘team-based’ course, and including all members of the research team—including investigators.
### Recommendations

| 6. Develop a competency-based curriculum plan that includes learner assessment and metrics for program evaluation (cont’d) | • Create a module/hybrid program for investigators on ‘How to Do Clinical Research’ similar to the CRC course, ‘Navigating Research.’ That course could contain an interactive flow chart of the research process with call-outs explaining and giving examples of each step within the scope of the whole process. Use it as ‘just-in-time’ training for investigators at the point of need, and demonstrate how changes made in one step (e.g., change to a protocol) can affect others. Use case examples. |

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### Recommendations: Conclusion

The section, 3.3.1.3 Conclusion, of the Final Report of the External Review states that “. . . it is essential that individuals at all levels of the human research protections program be knowledgeable about the ethical principles, as well as the specific regulatory, policy, and procedural requirements related to human subjects research. . . It is critical that training in human subjects protections not fall prey to the decision to ‘right-size’ educational requirements in the wake of ongoing institutional efforts to reduce the administrative burden placed on researchers. . . Advanced level training should allow for in-depth exploration of specific topics in human subjects protections.” We recommend that the University of Minnesota strengthen the current knowledge-based human research protection training and work to develop, assess and implement skill and attitude-based training over the next three years. The resulting training program should be comprised of a hybrid of online, discussion, peer-learning, case and simulation, problem-solving practice, learning assessment, and demonstration of competence. Training programs need to ensure the appropriate levels of training for the specific research being performed and that human subjects are appropriately protected. Simultaneously, the training must be of high quality, and the potential burdens for investigators and staff to understand, obtain and remain compliant with the required training should be minimized. Advanced training should be strongly encouraged, supported, and rewarded.
Appendix A: Approved Courses to Satisfy NSF and USA-NIFA Ethics Training Requirements

**Approved For-Credit Courses**

All of the below courses satisfy the NSF and USDA-NIFA ethics training requirements. If you have completed and passed an approved course, you have satisfied the requirement and no further action is required.

**Twin Cities campus**

All of the following are graduate courses, unless otherwise noted.

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSC 8134</td>
<td>Ethical Conduct of Animal Research</td>
</tr>
<tr>
<td>APEC 8901</td>
<td>Graduate Seminar - Applied Economics</td>
</tr>
<tr>
<td>APEC 8902</td>
<td>Graduate Seminar - Applied Economics</td>
</tr>
<tr>
<td>APEC 8123</td>
<td>Research Ethics in the Plant and Environmental Sciences</td>
</tr>
<tr>
<td>BBE 8001</td>
<td>Graduate Seminar - Bioproducts and Biosystems Science, Engineering &amp; Management; Natural Resources Science &amp; Management</td>
</tr>
<tr>
<td>BBE 8002</td>
<td>Graduate Seminar - Bioproducts and Biosystems Science, Engineering &amp; Management; Natural Resources Science &amp; Management</td>
</tr>
<tr>
<td>BICB 8401</td>
<td>Ethics in Bioinformatics and Computational Biology</td>
</tr>
<tr>
<td>BIOC 8401</td>
<td>Ethics, Public Policy and Careers in Molecular and Cellular Biology</td>
</tr>
<tr>
<td>BTHX 5000</td>
<td>Standards for Research with Human Participants: A Lecture Series for Researchers (undergrad)</td>
</tr>
<tr>
<td>BTHX 8000</td>
<td>Standards for Research with Human Participants: A Lecture Series for Researchers</td>
</tr>
<tr>
<td>CBIO 8001</td>
<td>Conservation Biology Seminar</td>
</tr>
<tr>
<td>CE 8581</td>
<td>Research and Professional Ethics in Water Resources and Environmental Sciences</td>
</tr>
<tr>
<td>CHEM 8066</td>
<td>Professional Conduct of Chemical Research</td>
</tr>
<tr>
<td>CI 8133</td>
<td>Research Methods in Curriculum and Instruction</td>
</tr>
<tr>
<td>CMB 8134</td>
<td>Ethical Conduct of Animal Research</td>
</tr>
<tr>
<td>DES 8181</td>
<td>Research Ethics</td>
</tr>
<tr>
<td>DHA 8181</td>
<td>Ethics and Research</td>
</tr>
<tr>
<td>EE 8925</td>
<td>Ethics and Professional Conduct in EE</td>
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<tr>
<td>ENT 5920</td>
<td>Special Lectures in Entomology</td>
</tr>
<tr>
<td>ENT 8061</td>
<td>Scientific Communication and Ethics</td>
</tr>
<tr>
<td>ESCI 8001</td>
<td>Introductory Graduate Seminar in Earth Sciences</td>
</tr>
<tr>
<td>FR 8107</td>
<td>Seminar: Forest Resources</td>
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<tr>
<td>FSCN 8318</td>
<td>Current Issues in Food Science</td>
</tr>
<tr>
<td>N7100</td>
<td>DNP Seminar I: Project Planning</td>
</tr>
<tr>
<td>N7101</td>
<td>DNP Seminar II</td>
</tr>
<tr>
<td>NSc 8321</td>
<td>Career Skills and Understanding Responsibilities as a Neuroscientist</td>
</tr>
<tr>
<td>NURS 8181</td>
<td>Protection of Research Subjects</td>
</tr>
<tr>
<td>NUTR 8621</td>
<td>Presentation Skills</td>
</tr>
<tr>
<td>OLPD 5080/8095</td>
<td>Surviving in the Research World (grad/undergrad)</td>
</tr>
<tr>
<td>OLPD 5087</td>
<td>Masters Research Seminar</td>
</tr>
<tr>
<td>PBS 8123</td>
<td>Research Ethics in the Plant and Environmental Sciences</td>
</tr>
<tr>
<td>PHYS 5980</td>
<td>Introduction to Research Seminar</td>
</tr>
<tr>
<td>PLPA 8123</td>
<td>Research Ethics in the Plant and Environmental Sciences</td>
</tr>
<tr>
<td>PSI 4994V</td>
<td>Honor's Research Practicum (undergrad)</td>
</tr>
<tr>
<td>PSI 5993</td>
<td>Research Laboratory in Psychology (grad/undergrad)</td>
</tr>
<tr>
<td>PSI 8542</td>
<td>Ethics in Psychology</td>
</tr>
<tr>
<td>PSI 8993</td>
<td>Research Methods in Industrial and Organizational Psychology</td>
</tr>
<tr>
<td>PubH 6348</td>
<td>Writing Research Grants</td>
</tr>
<tr>
<td>SOIL 8123</td>
<td>Research Ethics in the Plant and Environmental Sciences</td>
</tr>
<tr>
<td>STAT 8801</td>
<td>Statistical Consulting</td>
</tr>
<tr>
<td>VMED 8134</td>
<td>Ethical Conduct of Animal Research</td>
</tr>
<tr>
<td>WRS 8581</td>
<td>Research and Professional Ethics in Water Resources and Environmental Sciences</td>
</tr>
</tbody>
</table>
For-credit, Duluth campus

All of the following are graduate courses, unless otherwise noted.

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS 8993</td>
<td>Seminar</td>
</tr>
<tr>
<td>CSD 5100</td>
<td>Research Methods in Communication Disorders</td>
</tr>
<tr>
<td>EDUC 8020</td>
<td>Doctoral Seminar</td>
</tr>
<tr>
<td>EMGT 4110</td>
<td>Engineering Professionalism and Practice (undergrad)</td>
</tr>
<tr>
<td>GEOL 8200</td>
<td>Professional Issues in Geological Sciences</td>
</tr>
<tr>
<td>IBS 8099</td>
<td>The Biological Practitioner</td>
</tr>
<tr>
<td>MBA 8111</td>
<td>Business, Government and Society</td>
</tr>
<tr>
<td>MED 5085</td>
<td>Medical Research Ethics, Responsible Conduct of Research (undergrad/grad)</td>
</tr>
<tr>
<td>PHYS 5090</td>
<td>Physics Seminar (undergrad/grad)</td>
</tr>
<tr>
<td>SW 8102</td>
<td>Advanced Research</td>
</tr>
<tr>
<td>WRS 8581</td>
<td>Research and Professional Ethics</td>
</tr>
</tbody>
</table>

Approved Non-Credit Activities

All of the below courses satisfy the NSF and USDA-NIFA requirements. If you have completed one of the below non-credit activities, you must fill out and submit a completion form to fulfill the ethics requirement.

- Ecology, Evolution and Behavior: Ethics in Research and Scholarship Seminar Series (grad)
- Mechanical Engineering: Research Ethics and Professional Practice (grad)
- Electrical and Computer Engineering: Ethics and Professional Conduct in Electrical Engineering (grad)
- Chemical Engineering & Materials Science: Ethics in Science & Engineering
- Biomedical Engineering: Ethics in Science & Engineering
- Biomedical Engineering Graduate Program Orientation
- UMD Chemistry and Biochemistry: Ethics and Responsible Conduct of Research
- Computer Science and Engineering: Ethics and the Computer Science Graduate Student
## Appendix B: Sample Role-Based HRP Training Website (Emory University)

### Emory: Training for Clinical Research Staff

Click on the name of the role to review content information.

**Investigators (PI, Co-I, Sub-I)**

*Investigators include PIs, Co-Is, Sub-Is, and residents/fellows/nurses functioning in the role of an investigator.*

<table>
<thead>
<tr>
<th>Courses</th>
<th>Description</th>
<th>CMEs?</th>
<th>Renewal</th>
<th>Who to contact about the course?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Collaborative Institutional Training Initiative (CITI)</strong></td>
<td>An on-line course facilitated in CITI and offered by the University of Miami in collaboration with Emory University Institutional Review Board (IRB). The course is web-based and required prior to submitting research protocols for review and approval for all Key Personnel listed on the Emory IRB submission, regardless of their position.</td>
<td>No</td>
<td>Yes, every 3 years.</td>
<td>Emory's IRB at <a href="mailto:IRB@emory.edu">IRB@emory.edu</a> or 404-712-0720. For course details and registration information, please review the CITI Training page at <a href="http://www.irb.emory.edu/training/courses/citi.html">http://www.irb.emory.edu/training/courses/citi.html</a>.</td>
</tr>
<tr>
<td><strong>Conflict of Interest (COI)</strong></td>
<td>An on-line course facilitated in eCOI and offered by the Office of Conflict of Interest (COI) for faculty and staff to certify that they have received information about Emory's policies and the federal regulations on Objectivity in Research.</td>
<td>No</td>
<td>Yes, every 4 years.</td>
<td>Emory's COI at <a href="mailto:COI-Office@listserv.cc.emory.edu">COI-Office@listserv.cc.emory.edu</a> or 404-712-0046. For course details and registration, please review these COI User Guide.</td>
</tr>
<tr>
<td><strong>Key Concepts in Clinical Research for Investigators</strong></td>
<td>An on-line facilitated by ELMS for Emory Investigators conducting clinical trials at Emory per the NIH definition. The course aims to move beyond the required CITI modules and provide Investigators with useful, Emory-specific content.</td>
<td>Yes</td>
<td>12 AMA PRA Category 1 Credits™ are issued as continuing credits when requested.</td>
<td>Yes, every 3 years.</td>
</tr>
</tbody>
</table>