June 30, 2016

Background and Purpose

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

Overall comments regarding the recommendations

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

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

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

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

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

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

Response: A training plan was implemented to calibrate staff determinations for level of review and to identify actions that do not warrant a convened IRB review. The training plan is part of the larger initiative to adopt the Huron HRPP Toolkit and implementation of the electronic submission system for IRB review and management. The training plan involves close collaboration with the Huron Consulting Group and includes group training sessions and individual mentoring sessions.

6/16/2016
Recommendation 3: Consider developing a system for evaluating the appropriate number of action items per convened meeting agenda with consideration of the expertise of those present and the planned length of the agendas.

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

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

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

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

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

Relevant Documents:
- Audit of IRB Meeting Minutes Standard Operating Procedures
- Audit Checklist for IRB Meeting Minutes
- IRB Minutes Template
- Description of the Huron Toolkit