Implementation Team
Meeting Summary
04/22/15

The meeting began with a discussion of conflict of interest and a review of the CoI team statement for the webpage and the letter from the University Office of Institutional Compliance (both are now available on the Advancing Human Subjects research website). The chair asked members again if there were any new conflicts of interest to declare. There were no relevant conflicts to declare.

The chair also informed the team that Dr. Naomi Scheman has agreed to join the implementation team and was unable to attend tonight but is already actively participating.

The team discussed action plans for 16 recommendations.

3.3.1, 3.3.2, 3.3.6, 3.3.7, 3.3.27, 3.5.1 Team members grouped the recommendations related to education in order to develop a comprehensive action plan.

The action plan recommends that the University conduct an evaluation of resources dedicated to education and training of the research community to ensure appropriate resources are in place to offer basic and advanced training opportunities in human subjects protections. There should be a dedicated position to conduct the review, which should be completed before the end of 2015 and as soon as possible. The team agreed that there should be a program of oversight and accountability at a high level, be systemwide and be coordinated under one roof. The team also agreed there should be an emphasis on ethics training as an enhancement of research and that there should be input from the Center for Bioethics.

3.1.3 Explore ways in which an acknowledgement of the primacy of research subject protections and ethical research could be integrated into relevant University publications, materials, and web pages.

The action plan recommends an audit of materials and websites to look for existing portals to which information can be added; creating, a document explaining the University’s commitment to research subject protection (including metrics), a plan for broad dissemination, and the inclusion of an explicit commitment to ethical research. The team discussed the need for metrics that measure research quality and that much of that information is already tracked. The team also agreed that there is a need to communicate more effectively about the protections we have and that we need more feedback from volunteers and the community.
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.

The action plan recommends that the U and Fairview need to publicize and broadly communicate commitment to HRPP, ethics of research, and the benefits of research. The plan also emphasizes the need to educate clinical staff about the commitment to HRPP. Tactics could include videos, patient stories, posters, flyers, websites, visiting advocacy groups and a town hall or research forum to address patient concerns. It is critical that all efforts include the opportunity for feedback and response. The team discussed that there is currently a lot of misinformation out there and that the challenge with this recommendation is the question of who would own this work. There was general agreement that we currently have a lot of public forums that could include this information and that it has to become a part of everything we do. The team also agreed that a document laying out clearly the protections in place would be useful. We could also do more to expand the Mini Bioethics program offered by the Center for Bioethics and possibly host a national forum on research ethics.

3.2.9 More rigorously make use of other internal resources (such as the PAR Monitoring Program discussed in section 3.3.3 below) and external resources to supplement the work of the ICs.

The action plan recommends that the HRPP review and revise procedures related to the composition of the ICs to insure that membership includes at least 2 members with relevant expertise. Procedures should also for a non-IRB member with expertise if needed. The team discussed where the ICs should be housed and report. This recommendation will require more discussion.

3.3.28 Consider systematic approaches to express appreciation for subject participation, develop mechanisms to share research findings, and where appropriate, individual research results with subjects as a method of demonstrating partnership, showing respect and building trust.

The action plan recommends revising IRB application forms to include a section to describe the plan for expressing appreciation or a justification for why there is not a plan. It also recommends developing a tip sheet for researchers describing best practices for expressing appreciation. The team discussed how best to share results. It is already a requirement to post results on clinicaltrials.gov and sometimes results are so long after the trial that many participants have lost interest. Participants currently have the opportunity to request results.

3.3.21 Rework institutional messaging in policies and procedure to include unequivocal statements on the administration’s intention to create and nurture a culture of ethics, and adopt communication strategies to bring these
core values to life by investing in their visibility and adoption at all levels of the University community and beyond.

The action plan recommends seeking out best practices for creating a culture of ethics and communication strategies from other universities. It also suggests creating a task force to review relevant policies and procedures and consultation with faculty governance on messaging and the appointment of a University Ethics Officer. This action plan recommends creation of a community advisory board of research subjects and surrogates. The team discussed a need to communicate better with our faculty and that advice from this team will be important in creating a Community Advisory Board.

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

The action plan recommends consideration of a joint Fairview/University/Community oversight committee on reporting to review monitoring findings. Monitoring would be done by CTSI, FRA, and PAR and any adverse findings would be investigated by this committee. Information about these committees, activities, and findings would need to be communicated to research personnel. The team discussed the need for additional FTEs or possible reprioritization of FTEs. It is also possible that current Fairview members of the IRB could be directed to provide more feedback.

3.3.16 Develop a mechanism for systematically incorporating scientific reviews into the IRB review process to ensure that scientific concerns impacting the criteria for IRB approval are sufficiently addressed.

The action plan notes that the team has spent much time discussing scientific review and there will need to be a decision about whether it will remain separate from the IRB committee member review. It should be a part of the scientific reviewer’s checklist to discuss the type of review that occurred on a protocol and whether the reviewer has questions or concerns and how those issues are subsequently addressed. The team discussed that the IRB needs to receive more information from the scientific reviews in order to do this work effectively.

3.2.12 The IRB’s review of protocols proposing the use of surrogate decision-makers be rigorous and in keeping with applicable laws and best practices, as well as University policies.

The action plan indicates that the IRB has now added an appendix to applications to have investigators address this issue in detail. This appendix focuses on those with cognitive limitations, diminished capacity from mental health issues or no ability to
consent. Guidance needs to be available and evident to investigators to guide with the plans and data should be collected on who consents in order to track and audit.

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

The action plan recommends that an early re-approval and possibly yearly for high enrolling or high risk protocols, that a standardized report is created that would identify compliance with protocol specified procedures and measures modified to enhance subject’s safety. This could be performed in conjunction with scientific review but should go beyond the review of accrual alone. The team also discussed whether there was enough accountability for department chairs in this process currently.

**3.6.1 Define a hierarchy of accountability for human research ethics and thereby expand oversight responsibilities beyond the IRB. Department chairs should be expected to review and approve the submission of IRB protocols, be engaged in follow-up compliance activities, develop department-specific educational programs, and share ultimate responsibility for human subjects protections within their departments.**

The action plan recommends that oversight accountability must be shared by the IRB and academic units while avoiding duplication. The IRB and its supervising officials must remain the prime accountable hierarchy. Broader education for interested parties would be valuable. Presentations to academic units, preferably by members of those academic units could reinforce the material and emphasize the broader community benefit of compliance and responsibilities for reporting. The plan also recommends easy access to consolidated information regarding IRB policies, educational materials and programs, and resources for advice and ethics topics, and clarified reporting mechanisms for problems related to research oversight. The team discussed the need for transparency for accountability and the importance of making the IRB policies and procedures accessible to the academic community.

**3.5.2 Best practices regarding consent and capacity should be introduced and made routine.**

The action plan recommends considering the University of Kentucky’s impaired consent capacity policy with changes consistent with Minnesota law. The teams discussed that Minnesota’s law is imprecise and that there are uncertainties regarding the qualifications and roles of research advocates. It was suggested that there may be a simpler way to address this issue and additional recommendations will be brought forward.

Meeting adjourned.