Implementation Team  
Meeting Summary  
04/13/15

The meeting began with the chair asking members again if there were any conflicts of interest to declare. There were no relevant conflicts to declare.

The team discussed the need to have longer conversations about the big overarching issues involved in human subjects research. There was agreement that in addition to talking through each of the report recommendations that there would be time reserved to discuss the larger systemic and culture issues and the overall approach to improving these clinical research procedures in order to address concerns.

The team discussed action plans for 15 recommendations.

3.2.4 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 rationale for requesting modifications to the study.

The action plan showed that a new form has been drafted. IRB staff and committee members will need to be trained on the new approach.

3.2.5 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 discussion of more complex and challenging protocols.

The action plan stated that during the review the IRB was temporarily short-staffed, leading to more issues being brought to the full IRB. That position has been filled and this issue is largely resolved.

3.3.14 Revise the template titled “Departmental Scientific Assessment Form” (used pursuant to Method 3) to ensure that this form includes a statement defining potential conflicts of interest and affirming that individuals with such a conflict of interest may not serve as a scientific reviewer.

The action plan stated that the form has been revised. It will be posted for feedback on the attestation of conflict of interest.

There was discussion about the conflict of interest in a supervisor/supervisee relationship. There was general agreement that a faculty member would have a potential for coercion in reviewing a Department Head’s work; there will be more discussion about the reverse interaction.
3.2.7 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.

It was noted that this recommendation is about fact-finding and in and of itself does not solve any problems. It was also noted that there will be considerable cost. The action plan stated that IRB staff does plan to attend IRB meetings at other sites and are currently working on questions of where and when.

3.2.3 Consider providing compensation, or alternate incentives (e.g. released teaching time, reduction of other responsibilities, consideration during promotion etc.) to foster and support qualified faculty participation on an IRB.

The action plan recommends a review of the AAHRPP metrics which indicate that many academic institutions do compensate faculty for this service. The University currently pays only chairs. The team agreed that going forward some kind of meaningful compensation will be necessary to ensure qualified membership of the IRB, considering all the demands on faculty time. The specifics will be discussed further. The action plan also recommends more communication to the faculty about the impact of participating in the IRB and its role in promotion and tenure.

3.2.6 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.

The action plan noted the large volume of active protocols managed by the IRB. Currently meetings have a substantial number of agenda items of varying levels of complexity. Also, the expertise varies from meeting to meeting based on availability. The plan recommends that meeting agendas are balanced taking complexity into account and there be a maximum number of items based on that complexity. There will be further discussion about this at the IRB member and staff level.

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

The action plan recommends that options be considered for separate reporting. This item will require additional discussion regarding alternative placement of the PAR.

3.3.15 Consider whether additional protections are needed to ensure that scientific reviews of research proposed by senior faculty are not reviewed by subordinates. Given these concerns, the University should determine whether department-based review is feasible for individual departments.
The action plan recommends that the team consider a different system to ensure expertise and appropriate staffing and avoid conflict of interest. Options to consider include the IRB, the CTSI, external IRBs, and central IRBs. This item will require additional discussion.

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

The action plan recommends an inventory of existing training, a review of training available at other institutions, and a centralization of training options. The team also discussed reframing the training as an educational opportunity to improve research and to include updates, newsletters and other additional information.

3.3.12 If the University chooses to maintain a department-based process for scientific review: a. Ensure the applicable policies delineate departmental and IRB responsibilities regarding the assessment of study design; b. Develop guidelines for careful scientific review and ensure that the de minimis requirements are adhered to when department-level scientific review is used.

The team is considering a recommendation around an alternative approach to department-level review but agree that there should be better guidance regardless of who is doing the review.

3.3.13 Revise the HRPP policy on scientific review and related guidance on the IRB's website to state that individuals with a conflict of interest or conflict of commitment may not serve as a scientific reviewer. Conflict of interest should be operationally defined in these documents.

The action plan recommends that the policies be changed to reflect changes already being made on IRB forms.

3.2.2 Broaden the membership of the Medical IRB to ensure that it includes individuals with expertise reflecting the nature and volume of the University's research.

The action plan recommends an incentive system for faculty to serve. The plan also recommends increasing the number of committees and the number of meetings each week so that the review process can be faster. The team agreed that leadership can play a role in both ensuring a real incentive and to communicating this as a critically important service role.

3.3.10 Carefully consider the impact on the IRB’s overall ability to conduct an appropriate risk-benefit analysis when the evaluation of study merit is delegated to the department.
The action plan recommends discontinuing department reviews and consideration of an internal review process through the IRB or CTSI. This change would require resources. This item requires further discussion.

3.3.11 Carefully consider whether a robust review at the department level is feasible for each department, taking into consideration the size of each department, reporting relationships, and the volume of research.

This action plan recommends an alternative approach to departmental reviews.

3.3.5 Evaluate the mechanism 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.

The action plan recommends reviewing current training, updating educational resources, providing periodic updates and newsletters about changes and also to add news about enhanced educational efforts to public websites to inform the public and potential subjects. The team again discussed reframing training as something that enhances research rather than simply a requirement.