Implementation Team  
Meeting Summary  
04/29/15

The meeting began with a welcome to a new member of the team, Dr. Naomi Scheman. The chair then asked members again if there were any new conflicts of interest to declare. There were no relevant conflicts to declare.

The team started with a discussion of the scientific review process and the associated action plan recommendations which the group had previously reviewed. There is agreement among members that the workplan will include a recommendation to eliminate department review as an option and to replace it with an institutionally-based strong, rigorous process for these industry or investigator initiated trials. This process will also allow for external expertise or outsourcing when necessary.

The team then discussed their charge to “form a committee of external experts and community members to provide input to our human subjects research program”. A small group of members volunteered to bring back recommendations for stakeholders that should be included on that committee at the next meeting.

The next task was to review a draft workplan outline and a request for members to think about sections to draft. Workplan will follow the same themes and sections of the external review final report.

The team discussed action plans for 13 recommendations.

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 requirement.

The action plan recommends that the IRB do more to develop advanced level training for investigators who have had compliance issues. There should also be a PAR monitor shortly after the investigator is back to research to ensure adherence to the protocol.

3.2.1 Implement guidelines regarding IRB meeting attendance in order to ensure that a larger, more critical mass of members are present at each meeting.

The action plan recommends that the IRB retire the rolling roster, that the number of panels is increased, that members are compensated (including community members), that agendas are limited to a reasonable number of items, and that relationships are developed with external scientific experts to ensure that we have the expertise necessary.
3.2.10 Evaluate the mechanisms through which IC findings and any corrective action required are disseminated, particularly with regard to follow-through with complainants.

The action plan recommends that when a complaint is received the complainant should receive a response that includes information about what will happen next and later a response about the resolution.

For a significant adverse event resulting in death, disability or injury, the University must have a system for response to subjects and families that is prompt, empathetic and informative. The team discussed the need to train PIs in these types of discussions.

3.3.20 PAR should regularly share summary reports of its findings with department chairs and other institutional leaders charged with research oversight responsibilities to ensure that key areas of investigator and programmatic noncompliance can be readily identified and addressed.

Department chairs are currently notified. The action plan recommends that the Dean also receive notifications of audits. The team also discussed sharing positive information with deans and department chairs.

3.3.21 Deficiencies in IRB review processes/functioning should also be addressed through existing reporting and supervisory hierarchies, and not be addressed solely within the more limited authority of the IRB and OVPR.

This recommendation was largely covered last week in 3.3.18.

3.3.22, 3.4.3 Improvements in subject recruitment and consent

The action plan recommends a policy that bundles related concerns covering from the time of recruitment to the completion of the study/care. The team discussed several issues including the variability of consent capacity over time, the difference in required capacity between studies, and the use of Legally Authorized Representatives (LARs). The plan recommends several enhanced safeguards through the process, appropriate training, a validated instrument, periodic monitoring of consent capacity, and independent monitors. The team discussed the need for research teams to listen to all involved in care who have noticed or are concerned about changes in consent capacity.

3.5.4 The investigators as the focus of ongoing concern and criticism, should receive supervision, coaching in leadership, and advanced training in human subjects protection.
The action plan recommends that when a researcher has an identified area of concern or non-compliance, they should be required a certain number of hours of training in that area by their dean.

3.4.2 The IRB should ensure that its review includes a substantive assessment of the scope and appropriateness of the protocol-specific procedures that address the capacity to consent in light of the subject population being approached.

The action plan recommends identifying a validated research consent tool. The team is working to do that.

3.4.9, 3.4.10 Re-assess policies and procedures related to the use of LARs and OHRP or DHHS should be consulted.

These policies are being evaluated and will be discussed with OHRP.

3.4.13 IRB policies should require: a. A process for informing prospective LARs about their responsibilities; b. Maximization of assent of an assent form in appropriate circumstances; c. A verification of the lack of dissent when assent is not possible; d. A plan for re-consent if a subject regains capacity; and e. A plan for monitoring subjects who are likely to have fluctuating capacity, including the steps to be taken if capacity diminishes.

These policies are being evaluated and will be discussed with OHRP.

3.4.11 The HRPP should develop effective strategies to educate research personnel on the legal use of surrogate decision-makers when considering the involvement of research subjects with limited decision making capacity.

The action plan recommends an evaluation of best practices and available training materials related to the use of surrogate decision-makers, including how to obtain assent from research subjects. Based on the findings, there should be a training plan completed that includes basic and advanced training. A community advisory board composed of research subjects and surrogate decision-makers should give feedback on the materials prior to final implementation. The team discussed CTSI’s work in curriculum and courses. CTSI and IRB are currently working on new trainings, and the AHC IP Ed office has trainings available.

Meeting adjourned.