Implementation Team
Meeting Summary
05/06/15

The meeting began with a discussion of the deadlines for sections of the workplan to be written by members and the process for submitting a draft workplan to the President by May 15. The team also discussed several new reports being released regarding human subjects research. The team will receive the Oakes report and a draft report from the Office of the Legislative Auditor to inform them in their recommendations.

Lynn Zentner, Director of the Office of Institutional Compliance, joined the first part of the meeting to educate team members about the University's current policies regarding conflict of interest. The team decided to advance a recommendation to change policy to ensure that researchers cannot receive personal income from a company that is the sponsor of their current research. The team also noted that since this would be a policy change that it would need to go through faculty governance for approval.

The team discussed action plans for 10 recommendations.

3.3.3 Evaluate whether additional mandatory training requirements, comparable to the new mandatory training for sponsor-investigators, 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.

The action plan recommends that there be clear expectations of education for investigators and their teams and again that there be a single leader to manage trainings. Also, it is noted that the only practical way to offer mandatory trainings is on-line but that additional trainings should be available and investigators aware of them. It is also important to have trainings tailored to the level of the investigator.

3.4.1 Policies, guidance, application and review forms, and the IRB review process itself, should be redrafted and/or restructured for clarity and consistency to ensure that they will be appropriately used to prompt consideration of the methods used for assessing capacity to consent.

The action plan notes that this was discussed previously in recommendation 3.4.12 and that the IRB has already implemented appendix I. There will need to be additional guidance for investigators.
3.4.5 Develop standards that protect against real or perceived coercion in psychiatric treatment settings in which individuals fear involuntary court proceedings.

The action plans recommends adoption of the National Bioethics Advisory Commission outline on vulnerability. The plan also recommends that the IRB expect investigators to: demonstrate awareness of vulnerability of subjects and create procedures to avoid coercion or exploitation of vulnerable persons by ensuring the subject understands the study is voluntary and that services are available regardless. The IRB will ensure safeguards, use reviewers with appropriate expertise to address vulnerability and record the extra protections in the minutes. Studies would need tailored plans, the IRB will provide educational materials to researchers, and researchers will receive training on this issue.

3.4.6 Encourage and support the use of independent consent monitors, particularly in cases where the treating physician is also the investigator, so as to minimize the possibility for undue influence or coercion.

The action plan recommends adding monitoring of vulnerability to the recommendation in 3.3.22 for live monitoring. The team discussed requiring someone other than the PI to do the consent with exceptions.

3.4.7, 3.4.8 IRB policies should more clearly require that protocols involving adults with potentially limited decision-making capacity include a plan for subjects that may have fluctuating capacity, including the steps to be taken if capacity diminishes over the course of study participation. IRB policies should more clearly require a plan for re-consent when a subject regains capacity.

The action plan recommends a process for longitudinal assessment of capacity. An assessment could be periodic (as noted in study design) or triggered by observation of an engaged individual including the investigator, a clinician or other clinical caregivers, an advocate, or a family member. Any change should be assessed, documented and should include the concerns noted.

3.3.24, 3.3.25, 3.3.26 Develop mechanisms to regularly solicit, evaluate, and respond to research subject feedback.

The action plan recommends new mechanisms including a satisfaction survey. Data from surveys will be used for programmatic changes in response to the needs of the research community. Other options could include a 1-800 number and a website for patients and families to share feedback. These opportunities will need to be included in the consent form and also distributed in flyers. In addition, the team suggested a small card to be given to patients and families that includes information regarding these opportunities. CTSI can be a partner in this effort.
3.5.3 Fairview staff should be involved in protocol review, in gatekeeping functions, and in research monitoring.

The action plan recommends cross-training of clinical staff with IRB personnel on the ethics, mechanics, and importance of research. The plan also recommends a new Fairview/University committee to do an early protocol review, possibly as a subcommittee of the UM Health Education and Research committee, and joint monitoring after IRB approval. The plan emphasizes the importance of involvement of the clinical team in research. The team also heard plans for a climate assessment of the Department of Psychiatry by UMP and Fairview with an external consultant. A plan to improve climate will be based on that assessment and must include feedback to the UMP and Fairview staff on the findings of monitoring visits.

3.2.8 Reconsider the reliance on IRB membership to staff ICs looking into incidents of noncompliance and consider whether one or more non-IRB individuals might be appointed to ICs and/or expand the panel to ensure sufficient expertise to meet this charge.

The action plan recommends moving investigations out of the IRB and into a University Research Compliance office.

Meeting adjourned.