Fairview University Research Oversight Committee (FUROC)

August 31, 2016  Meeting Summary

Attendees: Brooks Jackson (co-chair), Beth Thomas (co-chair), Jill Cordes, Levi Downs, Dan Weisdorf, Debra Cathcart.

Guests: Debra Dykhuis, Linnea Anderson, and Lisa Johnson

The meeting primarily focused on an update from HRPP on implementation of the advancing human research participant protections work. At this point, most of the reports are final and the Office for the Vice President for Research, primarily HRPP and RCO, will operationalize the improvements. A report describing this stage of implementation must be completed by December 31, 2016.

HRPP has created a new advisory group to include representatives from all the relevant functions to meet quarterly and review issues affecting the protection of human subjects. The committee stressed the importance of having the investigators represented clearly and purposefully in these discussions in order to ensure there is not a gap between planning and the work on the ground. HRPP stated that their intention is to work closely with investigators and to improve transparency, communication and collaboration.

HRPP reported on the reports they were assigned for implementation.

- Scientific assessment: Departmental scientific assessment was no longer accepted as of March of 2016. There will be a process separate from IRB review but the details are not finalized yet.
- Monitoring: HRPP received significant feedback on the report and is working to incorporate it and to ensure CTSI’s role is accurately reflected. FUROC plans to review this report at the next meeting.

The committee discussed the need to communicate with investigators about what is found through monitoring and to give them a chance to respond. There is still work to be done to improve communication in this area.

- A new policy regarding research participants with diminished, fluctuating or absent capacity to consent is posted, along with supporting documents, on the IRB website. This information is being communicated to researchers in a number of ways. There is also an online training that is required for researchers working with participants with fluctuating or diminished capacity to consent.
- Participant contact cards are final and active. They are being used by investigators at the state fair.
- The IRB panels are full. Four medical panels are already active and four more will be by the end of September. These panels now have smaller agendas and designated staff support. The new panel members are a much more diverse group than previously.
The committee suggested that the IRB think about creating a faculty advisory committee to provide advice to the director and to help address some of the real or perceived communication gaps. HRPP stated that they are working at improving communicating and transparency by posting their review tools, metrics, and results of the feedback survey. They are also working to communicate more with investigators about the timing and the process of review.

The last part of the meeting was an update by Lisa Johnson from CTSI about the management of clinical trials in the department of Psychiatry. She reported that they are seeing improvements in coordination and information sharing among the staff. Competency assessments have been done for research staff and training will follow. They have hired a Regulatory Specialist for the department and are continuing to search for the Manager position. In the meantime, CTSI continues to provide monitoring and project management for researchers in the department and have found very few issues. Those that are found are elevated quickly to the Department head and the Vice Chair for Research.

The committee discussed an on-going need to understand which reports need to go to Fairview and also which should be forwarded to FUROC.

Meetings occur every other month. The next meeting is October 17, 2016.

The group’s meeting summaries will continue to be posted on the Advance HRP website: research.umn.edu/advancehrp. Questions can also be submitted through that sites email address: advancehrp@umn.edu.