Fairview University Research Oversight Committee (FUROC)

October 17, 2016   Meeting Summary

Attendees: Brooks Jackson (co-chair), Beth Thomas (co-chair), Jill Cordes, Levi Downs, Dan Weisdorf, Debra Cathcart, Sophia Vinogradov, Trudi Trysla, Steve Miller.

Guests: Bethany Hanson, Courtney Jarboe, and Kelvin Lim

The meeting primarily focused on two agenda items: a new Patients Bill of Rights being developed by HRPP and updates from the Department of Psychiatry.

A Patients’ Bill of Rights was a recommendation of the Engaging Research Participants workgroup part of the implementation of human research participants protections. Bethany and Courtney shared drafts of both a Bill of Rights and a pamphlet that has that information and more about participating in clinical trials. These items have been through a phase 1 review including the Community Oversight Board and Fairview Research Administration. After incorporating the initial feedback, they are now consulting it with additional stakeholders, including clinical staff and research participants. Phase 3 will be approval by VP Herman and HRPP Director Debbie Dykhuis. After approval, the Bill of Rights can be made into a poster and the pamphlet will be available to be handed out to everyone but required by some studies depending on risk. They are hoping to have final approval by the end of November.

Feedback from the group focused on the tone of the materials and the absence of any information about the benefits of research. Several members commented that positive language about the fact that participation in research leads to advances in health care, and that this is an opportunity that doesn’t exist everywhere, would be helpful.

The second topic of this meeting was an update from the Department of Psychiatry. Dr. Vinogradov and Dr. Lim discussed first that the department is regularly engaging in discussions of research processes and ethics. There is a research council that meets weekly to consider strategies for faculty and who consult with faculty as requested. The department also has a monthly faculty meeting devoted to research. Work with the CTSI monitors is going very well and is seen as helpful to ensuring compliance and improving practices. The department has made many changes, including implementation of the checklist with Fairview, a new policy on therapeutic misconception, and a consent form to be approached about research at the outpatient clinic. They have also partnered with the Center for Bioethics and CTSI to develop a new course on informed consent, which is rolling out to research staff in the department this November and then to faculty. Ultimately this course will be available University-wide.

There was also discussion of the IRB’s new policy and education around capacity to consent and the new tools that are used for assessment.

The group discussed that at this point there is some confusion and possibility redundancy with all the new policies and processes between HRPP, CTSI and Fairview. In a few months, the department will
likely have a better sense of where we could streamline and make some improvements. It will be helpful for investigators and regulators to have more coordination and clarity.

The group indicated an interest in reviewing the monitoring plan with all the units involved at the next meeting.

Meetings occur every other month. The next meeting is December 21, 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 site’s email address: advancehrp@umn.edu.