The meeting began with a discussion about reporting research issues to FUROC. There are efforts in the Human Research Protection Program (HRPP) and the Clinical Translational Science Institute (CTSI) to increase monitoring and the teams are working to improve communication between the two units. All CTSI monitoring reports (and all other monitoring reports) are sent to the IRB by the investigators. CTSI is designing a new quality assurance function to ensure this process and sustained adherence to protocols and GCP.

HRPP currently reports twice a year to the Office of General Counsel, the Office of Institutional Compliance and the federal Office of Human Research Protection. FUROC will receive those reports as well. Fairview Research has also just started getting the PAR reports.

Next steps: FUROC should have monthly reports of patient rights or safety issues, climate issues, and any complaints regarding these issues submitted through the University or Fairview. In absence of a meeting, reports should be sent to the co-chairs. It was also urged that the monitoring report for the implementation plan needs to completed ahead of the July deadline.

The second agenda item was an update on transferring management of clinical trials in Psychiatry to the CTSI. Dr. Schacker stated that CTSI has posted and is interviewing for both the manager and regulatory specialist positions. A CTSI project manager is working with Psychiatry faculty full-time in the interim. In addition, CTSI has developed new training which will be piloted in Psychiatry this summer. Work has begun on requiring all investigators to use Fairview IDS. The financial hub is in place and CTSI is encouraging investigators to use it, work has begun on using OnCore (the clinical trials management system) for all new trials in Psychiatry, and CTSI is developing a new quality assurance program with Dean Jackson.

Third, the Research Compliance Office brought a new policy regarding for-cause investigations to the committee for review. The policy is scheduled to be finalized in early June.

The committee also reviewed a new checklist created by the Department of Psychiatry and Fairview Behavior Health Services to improve communication and collaboration between researchers and clinical staff. The new process includes information pre-study, research updates throughout the study, and a report on outcomes. It requires signoffs by dyad leadership throughout the study to ensure adherence to the new practice.
The committee discussed the need for a climate assessment in the behavioral health unit. A smaller group including both the Department of Psychiatry and Fairview Research Services will develop a plan for this assessment.

A small group will also work on a plan to share more publicly the purpose and work of this committee.

Meetings will occur every other month. The next meeting is June 20, 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.