Council of Principal Investigators (CPI)
Meeting Minutes

Thursday, November 17, 2022
4:00 p.m. – 5:30 p.m., Microsoft Teams

Members in attendance:	Jean Bopassa, Gregory Collins, Lynette Daws, Katherine Dodanville, Asma Khan, David Libich, Daniel Lodge, Georgia McCann, Susannah Nicholson, Marzieh Salehi, Casey Straud, Susan Weintraub and Tara Karns-Wright
Members Absent:	Armen Akopian, and Darpan Pate
Guests:	Meredith Zozus, Ph.D. (Professor, Division Chief, Clinical Research Informatics) Kim Summers, Pharm.D. (Assistant Vice President for Research)

Discussion: Data Access Policy (Dr. Meredith Zozus)
Dr. Zozus presented the Data Access Policy developed over the last three years. There are three categories for access of patient data: (1) clinicians and employees using data for treatment, payment and operations (TPO); (2) human subject research; (3) others outside these existing groups. Only item 3 requires data governance approval. A data governance group [Data Acquisition, Access, Use and Release (DAUR)] was assembled to provide a streamlined evaluation process. In the last two and a half years, approximately 30 projects have been found to need approval. The HOP was updated to clarify the process:

- HOP 5.8.22 Data Protection – the types of requests that require data governance evaluation were specified.
- HOP 5.8.4 Access Management – aligns institutional policy with current types of research data access and limitations on bulk data access for research use.

The HOP policies related to the patient data governance process that were not updated include:

- HOP 5.8.21 Data Classification
- HOP 5.8.22 Data Protection
- HOP 5.8.4 Access Management
- HOP 2.2.1 Records Management

There is a two-stage governance process for DAUR requests.

1. DAUR requests are first reviewed by the CISIL committee (Compliance, Information Security, IRB and Legal) to assist the requester to develop an approach that is compliant with relevant laws, regulations, UT HOPs, and other requirements. A risk assessment is then conducted.
2. DAUR requests are reviewed by the Patient Data Governance. Possible decisions at this stage include approval, rejection, or delay to seek additional information.

Once approved, the PI can proceed with their IRB submission. A link will be added to the Office of the Vice President for Research website that will have comprehensive information about the data access policy. Turnaround time of a decision is normally one month, depending on the steps needed for evaluation.

Dr. Libich suggested that the pre-award staff of the HSC schools be made aware of the steps needed for the evaluation process so that sufficient time is allocated prior to proposal

submission deadlines. Dr. Zozus said that she would contact the appropriate individuals in the pre-award group. She also said that another possibly would be to add a research forum (town hall) presented through the IRB.

An internal data use agreement needs to be completed to verify that the requester is aware of their obligations for receiving patient data since identified data carries additional responsibilities under HIPAA. There are several ways to access patient data, including self-service and fee-based analyst assisted. The route used depends on the familiarity of the requestor with generating queries for the data warehouse. Inquire through Dr. Zozus' for further information.

CPI Business

- The September and October minutes will be sent via email for approval.
- Update from the Research Compliance Subcommittee (Visiting Scientist Policy). Dr. Wright reported that most of the meeting focused on the new NIH requirement for a data management and sharing plan. Additional information is needed from NIH in order to provide recommendations for new NIH grant application. Revision of the visiting scientist policy is still being considered.
- Update from the Data Management Working Group. Dr. Weintraub reported that the group is meeting weekly. They are assembling information locally and from other universities with the goal of having templates and guidance for PI's to use directly in their proposals.
- Brain Health Building and Parking Structure Construction. Dr. Libich updated that the main concern is that there will vibration from drilling for the new pillars for the parking structure which is near the Barshop building. Researchers at the Barshop are concerned about their animal colonies due to the stress the noise/vibration might cause. Dr. Libich will share the PowerPoint slides that were that presented at the meeting if anyone wants additional information.
- Upcoming CPI meetings. Suggestions include: Dr. Hromas (or possibly in the spring as a follow-up to his recent forum); Dr. Bhat as the LSOM interim Vice Dean for Research; Raymundo Rivera (Facilities).

No additional new business was introduced, and the meeting was adjourned at 5:30 p.m.