FACULTY COUNCIL
MINUTES
March 1, 2017

Attendees: Drs. Baron, Berin, Brodman, Butts, Choudhri, Doshi, Herrera, Howell, Kalir, Katz, Sim-Schluger, Miller, Poulikakos, Ramaswany, Shim-Chiang, Stone, Wang; Ms. Schneier

Guest: Dr. Glenn Martin

I.   Program for the Protection of Human Subjects

Guest: Glenn Martin, MD, Executive Director, Program for the Protection of Human Subjects (PPHS) and Senior Associate Dean for Human Subjects Research

Dr. Martin reported on:
- Which IRB reviews? We now have a single program for The Mount Sinai Hospital Mount Sinai West and Mount Sinai St. Luke's; Mount Sinai Downtown will eventually join. Sites wholly owned by Mount Sinai Health System use our PPHS, but Elmhurst and Queens faculty, if authorized, can use either ISMMS or BRANY. Outside entities are case-by-case. Multi-center, industry-sponsored studies may be allowed to use a commercial IRB, e.g., BRANY, provided there is an agreement between ISMMS and that IRB. The degree to which our faculty are involved in the project e.g., investigator or PI, also influences degree to which we want to have oversight. Level of project also matters, e.g., live patient vs. de-identified data.
- Ideate – All sites use IDEATE, the new processing platform for research. PPHS is costing out a migration strategy to bring more projects into IDEATE to ensure appropriate tracking, notification, reporting, etc. InfoEd is still in use, because not all elements of project processing have been incorporated into Ideate.
- Staffing – PPHS is almost fully staffed and stable, and staff are getting certified as IRB professionals.
- Process – Improvement efforts to accelerate processes include: improved questions for streamlined communication; pre-reviews to avoid project deferrals; asking questions before IRB meetings. Projects typically take 4-6 weeks start-to-finish; expedited projects are faster because Chair rather than full Board reviews.
- Federal Common Rule – These research regulations for federally funded programs were issued 1/18/17, but are on hold in new administration so that effective date will, at earliest, be 9/17.
- Multi-site projects – A single IRB must run multiple projects
- De-Identified Data – Checklist for de-identified data will guide you on whether a study qualifies as research and/or human subjects research. Federally funded studies may face additional restrictions. If you inadvertently identify someone from de-identified data, notify the IRB through call or email w/copy to Legal.

- Data Ownership – If using patient data from another faculty member, agree beforehand on its use.
- Subject Recruitment – Cold calling not permitted. Can work on other approaches, e.g., alerts to physicians, flyers in waiting rooms. Prospective subjects must be consented in advance of participation.
- PPHS Website – Good resource for information and guidance.

II.   Approval of Minutes

Upon motion duly made and seconded, the minutes of the January 3, 2017 Faculty Council meeting were unanimously approved.

III.   Committee Updates

- <u>Benefits:</u> Dr. Stone:
    - Introduced Daniel Katz, MD (Assistant Professor of Anesthesiology) is joining the Resources Committee to assist in benefits planning.
    - Reported that Ms. Maksoud will notify her when benefits planning meetings for 2018 are scheduled.
- <u>Professionalism Committee</u> – no cases
- <u>Faculty Disciplinary Tribunal</u> – no cases

IV.   Elections

Letters have been drafted to initiate the election process and will be distributed over next month.

V.   Invitations

- Academic IT – Mr. Paul Lawrence