Research Policy Committee
Minutes
1/19/18
Fleming 4006
2:30 pm

Members present: Yu-Su Chen, Kate Eaton, Whit Froehlich, Jessie Lee, Peter Lenk, Sari Malek, Sandy Momper, Adam VanDeusen
Guests: Bill Greer, AVP for Research, Animal Program Compliance; Lauren Danridge, Assistant Director, Quality Assurance, Animal Care and Use Office

I. Discussion with Bill Greer: AVP for Animal Compliance Oversight
   a. The 21st Century Cures Act (2016) was designed to (among other things) decrease regulatory burden in order to hasten approval of drugs and devices for medical use. Dr. Greer cited the FDP project study (the 42% study) as one impetus for the Act, and stated that there will be a comment period as to how the act should be implemented. This will allow comment as to how regulations slow research progress. Good PBS report is here
   b. The Act was discussed in the context of Dr. Greer's plans to (among other things) start to shift regulatory burden from the PI to the service unit (in this case, the animal compliance office).
   c. Updates from the animal compliance office included:
      i. UM was granted full AAALAC accreditation in 2017.
      ii. There was some discussion of the regulatory administrative structure at UM. Compliance overall is under the VP for Research Policy and Compliance (Mike Imperiale), the Assistant VP for Regulatory and Compliance Oversight (Lois Brako), and Bill Greer (Animal Compliance). No one seemed to know who handles IRB.
      iii. The animal compliance office has established a PI advocate committee made up of PI's from units that depend on animal research. The goal of the committee is to collect data on regulatory burden. Noel Ramsey is a potential faculty advocate/contact for regulatory burden issues.
      iv. A new Q/A team directed by Lauren Danridge was formed to work directly to discover and minimize burden and transfer burden to service units. Their job is to talk with PIs, collect data and look for common themes.
      v. Bill shared some history that has led to animal welfare regulations
   d. Discussion centered on plans for minimizing burden. These include:
      i. Decrease redundancy by coordinating activities of animal, biohazard, and controlled substance regulators.
      ii. Simplify policies and regulations: UM regulations often surpass those of external regulatory agencies
      iii. Switch burdens to service units by, for example, offering boilerplate text or offering suggested terminology for protocols.

iv. Inconsistencies between state, USDA, DEA, and other external agencies remain a challenge. UM can attempt to make policies that comply with all agencies and may be able to assist investigators with issues regarding government regulations.
v. A number of non-UM organizations are working to ease governmental regulatory burden, including the Council on Government Relations, The National Science Board, FASEB, National Association for Biomedical Research, the American Association of Medical Colleges, and others. A recent report (2017) is here.

II. Next meetings:
a. Feb 28: 3 pm Volker Sick, AVP Natural Sciences and Engineering: Engineering research initiatives
b. March 23: Daryl Weinert (Research and Sponsored Projects)
c. April 25:
i. Mike Imperiale: Research Policy and Compliance
ii. Mark Burns: Mcubed
d. May 11: Karl Jepsen (Lab research Safety Initiative)

III. Minutes of 11/15/17 and 12/20/17 were approved.

IV. The meeting ended at 4:10 pm.