Date: January 26, 2011

Topic: FDP Animal Care and Use Sub-Committee Minutes

Co-Chairs: Kay Carter-Corker, JR. Haywood, and Mary Ann Ottinger

Sub-Committee Projects

1. **Practical Guidance Project**—the goal of this project is to build a resource of information on the FDP site that would be available to members and provide accurate and clear information about processes and best approaches to meet the regulatory requirements without adding unnecessary administrative or PI burden. Nancy Ator will lead a workgroup to develop this project.
   1. Action Items:
      1. Request participation from a sub-group of volunteers to develop and expand practical guidance questions (see list below).
         1. What do you do in your protocol review process that makes it efficient, expedient, and compliant?
         2. What do you do in your institution that you consider a self imposed regulatory burden?
         3. What do you do in your institution in response to animal rights activists?
         4. How do you ensure sufficient training in your institutional animal care and use requirements and specific animal use procedures?
         5. How do you ensure animal study procedures are being done according to the approved protocol?
      2. Prepare short summary of the practical guidance project including management of information
         1. “Are these the right questions?”
         2. Add other questions
      3. Refine draft practical guidance questions and prepare to add to the web site
2. **Resource Web site**
   1. Identify useful items to put on the site such as eVent (Sandra Schneider will work with us on this project)
   2. Identify FAQ links (need additional volunteers to gather information from all the participants; Lauretta Gerrity and Sara Rockwell are volunteers to assist where needed)
      1. Use the list serve (names will be added from this meeting attendees also to see about resources and web links)
   3. Ask the Expert section (coordinate with the Human Subjects Subcommittee as they are doing a similar effort; Mary Ann and Kay will work with Lois Bracko and Jane McCutcheon to coordinate)
      1. Develop the process
      2. Identify who to monitor the questions
      3. Identify who to find the expert
      4. Identify who to provide the answer
      5. Format the Q&A
      6. Request pilot test the questions
      7. Identify links for FOIA guidance
3. **Discussion of a Potential Demonstration Project**
   1. Marti Dunne and Beth Israel have both suggested ways to streamline the paperwork required from the institution at the time of award. Marti suggested that we partner with the NIH to work out a model for a demonstration in which a certification could be administered by the home institution as an assurance to the agency that the compliance functions are appropriate and in place at that institution. A similar discussion will be initiated with OLAW by Kay Carter-Corker to see about coming to FDP and talking with the Animal Care Subcommittee regarding this approach. In discussion with Jean Feldman during our session, it is likely that NSF will need additional information and this approach may be difficult. Mary Ann Ottinger and Kay Carter-Corker will arrange for a follow up meeting with the NSF.
   2. JR Haywood has drafted an additional potential demonstration for consideration by the FDP Compliance Committee. The demonstration is aimed at a Just in Time type of process across agencies to streamline the time required for protocol approval at the time of award. In addition, there is a proposed removal of the Vertebrate Animals and Human Subjects sections of grants as this information is already provided in the respective assurances with the granting agencies.
   3. The intent of all these projects will be to reduce the burden to both the researchers and to the administrative units. This is an excellent opportunity to open the discussion with NIH, NSF, and OLAW to clarify these areas of additional burden. As we move forward with these projects, collaboration with the Human Subjects Subcommittee will help to coordinate our efforts for the FDP.
4. **Activities to support a demonstration project**
   1. Identify, quantify, and document specific areas of “burden”
      1. Develop a list of activities that institutions/researchers consider “burden”
      2. Create a data table that captures the following for selected Federal agencies:
         1. List of agencies that award grants
         2. Summary of information required by the Federal agency at the time of proposal submission (i.e. vertebrate animal section)
         3. Is this information redundant or in addition to the institution required information
         4. Is this information considered critical for assuring public/congressional trust
         5. Institution points of contact that need to receive notice of award
         6. Average time frame between submission of required paperwork and the Federal agency determines if an award will be issued