Research Compliance Committee

Thursday May 14, 2009

Minutes

I. Discussion of Overall RCC Structure

Introduced overarching goal of Research Compliance Committee -

Introduced Mary Ann and JR as Co-chairs for Animal Care and Use Subcommittee.

II. Animal Care and Use Subcommittee - Mary Ann Ottinger and JR Haywood

Establishing a Strong Program with Components Interacting and Issues in Maintaining a Strong Program

Mary Ann chaired the IACUC for 5 years and wrote their first guide for campus. It was the letter of the law, what we had to do to comply. She finds that the university is very regulated and requires a whole office to ensure compliance and is looking at how best to distinguish what the letter of the law is versus what is a recommended "best practice".

Universities would benefit by looking for the lowest common denominator and determining where they go overboard with imposing unnecessary burdens.

Some ideas:

How do you establish a strong program? Break it down by component portions of program…role of vet, administration, IACUC and PI? How to mesh them where the PIs know what they are supposed to go?

Trying to hit a moving target. Things changing and don't know what's the letter of the law and with different interpretation. Everyone is trying to figure out how closely to adhere to it.

International responsibilities: what is our responsibility how do we deal with post approval monitoring and harmonize them?

Low hanging fruit – problem when agency contacts investigator …somehow assure the funding agency that no work will start until the regulatory approval s are in place but allow the money to flow so that the ground work can be laid. Is this a problem? Would your institution allow it?

Issues:

Hitting a Moving Target – Regulation by Policy and Guidance

Guide Harmonization – Including International Harmonization

Possible Demonstration Projects:

Post- Approval Monitoring – causes significant burden but not letter of the law.

Determining an institution's responsibility for subcontractors - This is really going to tax regulatory committees in terms of manpower and oversight.

Agency collaboration to create uniformity between agencies - Explore ways to work with agencies to resolve additional interpretive burdens- Example of monoclonal antibodies. The institution was informed by OLAW that university was responsible to include such antibodies under their assurance.

Institutional burdens – the IACUC and IRB and the administrative offices implementing the regulations have institutional burdens that weigh them down and cause delays, which indirectly affect faculty member's ability to do work. IACUC have to report to OLAW, do assurances, reporting to USDA, annual reports, etc…all burden to animal care. The faculty burden survey looked at individual burden – perhaps we need to look at institutional burdens? This could also include the types of protections a university must implement to protect against animal rights activists.

Award restrictions on no spending until protocol approval and activation - Extending the restrictions for use of animals that NIH follows only at the end of the year where they need to make the award, as standard operating procedures.

Elimination of individual certifications – replace grant and protocol specific certifications with an institutional affirmation that it is in accordance with the IRB/IACUC requirements and just a flow down term in our award. Prove to the government that the certifications are not required. The IRB and IACUC are very well imbedded so can eliminate the paperwork and last minute. Make part of cover sheet.

Elimination of congruency reviews -Now required to conduct a congruency review, they have to read grants and animal care protocol to make sure they agree. This requirement does not improve the protection of animals if the system is working properly.

III. Human Subjects Protection Subcommittee

a. Updates – GAO Testimony on Human Subjects Research

b. FWA/IAA discussion

c. Possible demonstration projects – will discuss during September meeting.

IV. Open

The consensus was that the federal requirements have escalated. There is a general interest in understanding what institutions use electronic, current databases for compliance. In particular, those systems that would allow an institution to keep current on the number and uses of the animals. Systems are not generally going to track the breeding the mice – when are they in a breeding colony versus an experimental tracks, how are you supposed to watch how many cages/number of mice. Electronic initiatives will be explored by the RCC, as real time tracking could be very helpful.