

RAC Minutes 04/08/2010

Meeting called to order 12:03 by Kenneth Fahnestock for Vanessa Foreman

**Susan Buskirk and Susan Hines – *Human Research Protections Office (HRPO)***

Susan Buskirk, MS – Assistant Dean Human Research Integrity and Compliance

Discussed the UMB Human Research Protections Program (HRPP) covering the mission and specific components of this program. The UMB Institutional Official (IO) is Dr. Bruce Jarrell. This responsibility was delegated from President Ramsay through the Dean of the School of Medicine.

Federal-wide Assurance (FWA) is a very important area of compliance. The UMB IO has signed an assurance with the DHHS that we will comply with the terms of the Assurance for all human subject research conducted at this institution. Failure to comply with these terms can result in serious compliance issues that can have operational and financial impact for individual investigators and for the institution as a whole.

The University received accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in December 2005 and was re-accredited in December 2008.

The Human Research Protection Office (HRPO) includes support of Institutional Review Board (IRB), Embryonic Stem Cell Research Oversight (ESCRO) and Conflict of Interest (COI) committees.

The IRB is lead by Dr. Robert Edelman and consists of 5 vice chairs.

Susan Buskirk covered a number of milestones for the HRPO and HRPP over the period 2003 to present.

There are 3 levels of protection for research participants. They are 1) regulatory oversight, 2) IRB and 3) Informed Consent. Discussion covered the independence and authority of the IRB as well as the progression of the turn around of IRB protocols over the past 6 years.

Susan Buskirk covered the requirements and responsibilities of being a PI on this campus. There are required training courses covering HIPAA and HS protection training that are required to be engaged in HS research.

Discussion covered the various definitions of research and human subjects as defined by a number of government publications.

Discussion covered the IRB review process which included the comprehensive institutional collaborative evaluation of research on-line (CICERO), definitions of minimal and greater than minimal risk and full & expedited protocol review. The types of IRB submissions were covered.

Discussion covered the IRB process as applied to NIH sponsored research and Industry sponsored applications. The fees charged for all industry supported IRB review was discussed with an increase proposed for July 1. More details to follow when final decision is made.

Susan Hines, MS, CRNP, Director, Human Research Protections Program, indicated that there were plans to establish a new faculty orientation to help provide training in areas of IRB and HS research compliance.

### **Questions:**

Are there plans to allow CICERO access at the Administrator level in the future? Further discussion of this will occur to see what can be done to allow access to the protocol data much like for IACUC protocols for Pre and Post research grant proposal issues.

Who does the data belong to? Data belongs to the University. Original data of all types are required to remain with the University. Discussion should happen between PI's and the HRPP offices to make arrangements to copy and take data with departing faculty.

Full PowerPoint presentation attached!

### **Dennis Paffrath - Office of Research & Development**

There is a new process for handling foreign outgoing subcontracts. Export control issues must be handled first before the subcontract group can move forward with outgoing subcontract documentation.

Dawn Wilkins will be leaving for a challenging new opportunity. Jim Rose has left the University.

Dennis announced that his area will be now known as Sponsored Programs Administration (SPA)

### **Lynn McGinley – Assistant Vice President**

Lynn announced her newly acquired title on the campus and that her office will now be called Sponsored Projects Accounting and Compliance.

Question: What is happening with the RAC Mentoring Committee? Discussion will be held with Karen Sack to determine what will happen with the RAC mentoring meetings.

Meeting Adjourned!