Meeting Synopsis:

1. Call to order
2. Approval of the minutes from October 8th
3. Records retention requirements for faculty – human subjects research
4. Post-awards, F&A and audit issues
5. Intellectual property and the role of FCR
6. Adjourn

1) Call to order

The meeting was called to order by Rosenfeld at 9:00 a.m.

2) Approval of the Minutes from October 8th

The minutes from October 8th approved as written.

3) Records retention requirements for faculty: human subjects research

Barbara Benson (Director for UW Records Management Services), Christene Taylor (UW Medicine Records Management Services) and Karen Moe (Director & Assistance Vice Provost for Research, Human Subjects Division) were in attendance to discuss changes to the university’s retention policy for records related to research.

Over the last several years there have been many changes to the amount of time to keep records when a research study closes. This is an instance of another change and Benson is asking the council to review the changes and provide concurrence to move forward. Benson clarified that these changes apply to clinical research tied to IRB-approved research, not towards non IRB-applied or animal research. Since the late 1990s UW has required a 30-year retention period for research records. Currently, UW is proposing to reduce the retention period to only 6 years. Benson explained the 30-year retention was initially agreed upon to protect UW from malpractice lawsuits. However, it has become apparent that this retention period is difficult to live with and sponsors do not support the cost of storing records once the study closes. Over the last few months Benson has been meeting with the Attorney’s General Office, Office of Risk Management, Office of Research and Human Subjects, and from looking at historical and current analysis of malpractice suits against the university it has become apparent that the original retention decisions greatly overstated the risks.

A question was raised asking if the changes impact electronic records. Benson clarified that state and federal regulations impact records regardless of its characteristics. For example, the regulations would impact paper records the same as electronic records, regardless of its format. A question was raised asking how the changes would impact relationships with commercial sponsors, such as pharmaceutical
companies. Benson explained that the retention periods, as required by government agencies, have shorter retention periods which tend to be 3-4 years. If the sponsor has a retention policy with a longer time period then the principle investigator (PI) would have to keep the records longer. Benson commented that anyone with a question about records retention can contact her office. Discussion ensued about long research trials and reporting back to federal agencies. Taylor explained that the trigger to begin records retention begins at the end of the research project, also called “close of study”. Benson explained that her office is working with schools and departments across campus to receive feedback on the proposed changes. The proposal will eventually be reviewed and approved by the state records committee but she is interested in receiving the council’s feedback prior to being sent to Olympia.

A question was raised asking where the policy exists. Benson stated the records retention policy resides within the UW General Records Retention Schedule. Moe explained that her office will be sending out information regarding the new policy in a newsletter and have information posted on their blog. Additionally, once her office implements an electronic submission/review process there will be information about the policy available for faculty. A suggestion was raised to add a link to the policy within the GIM.

A question was raised asking who is responsible for destroying the records once they are past the required retention period. If the records are electronic it is up to the individual PI to destroy the records. If the records are in paper form the PI would also have to manage the destruction of the records appropriately. However, if the paper records are stored at the Magnusson site Barb’s office will follow the normal procedures for destruction which includes sending notification to the PI in order to shred the record. Benson explained that her office will not destroy a record until they receive a signature from the PI.

Members expressed their support for the changes to the records retention policy.

4) Post-awards, F&A and audit issues

Susan Camber (Associate Vice President for Financial Management) was present to discuss recent developments surrounding the F&A (indirect cost) proposal. The proposal is submitted every 4-5 years as a multi-year proposal which includes a pure calculation of what it costs to conduct research at UW. Camber explained the second phase requires negotiation on the rate which is followed with UW submitting projections on changes down the road, such as new buildings being developed. Camber explained UW looks for anything built within the rate cycle and project out the cost during this phase. Camber noted the calculated rate is around 57% which is different than the past negotiated amount at 56%. Camber explained that recently some institutions only received a phone call during this phase which is different compared to a typical site visit where representatives visit an institution to review the consistency in what the university initially reports and determine how much is actually being allocated for research.

Camber reported that UW is undergoing an NSF data analytics audit in which the agency reviews 3 years’ worth of data and look for trends that may be of concern. For example, the study will cover a selected sample of supplies and equipment to determine their purchase date. Camber explained that in some cases equipment is purchased near the end, or after, the grant expires without a good explanation of how it benefits the grant. Camber noted that there are instances in which faculty are going to a program officer to obtain permission for expenditure which is not appropriate for cost-related items.
Instead, faculty must go to a financial grants officer at their agency to obtain the proper permission. Concern was raised that faculty do not know who the appropriate people are to grant permissions. Camber’s office works closely with staff about getting the word out stressing the importance of approaching a financial grants officer. Concern was raised that it is difficult to receive detailed information on the current rules and there is no reliable place to check. Camber explained that Ted Mordhorst trains on compliance and is constantly working with faculty. Camber commented that after an internal audit there have been concerns raised, such as late purchases of equipment, questionable spending on events attached to grants, administrative and clerical salaries that are not allowed, per diem exceptions without clear documentation, and issue surrounding cost transfers. Discussion ensued about faculty are found to be out of compliance. Camber explained that the PI is responsible for paying back the money which if often in consultation with their department or college, such as transferring funding to other sources. Camber clarified this is not an institutional issue and has only arisen a few times in the past.

Camber reported on the HIM/HHS cash payment and close-out process. NIH and HHS came out with a ruling that all draws would be handled on a grant-by-grant basis. A question was raised asking about the reason for the rule changes. This came as a result of a report on the close-out process at HHS conducted by the General Accounting Office. The report found that they still had open accounts from many years ago which prompted the agency to clamp down on the process. Discussion ensued. Concern was raised about the impacts on principal investigators, administrators and active projects. Members discussed their personal experiences working with federal agencies.

Camber reported the combined federal circulars are still changing and she will provide an update at a later time.

5) Intellectual property and the role of FCR

Jerry Miller (past chair of FCR) and Fred Holt (Director for Strategic Initiatives for UW Center for Commercialization – C4C) were present to discuss intellectual property (IP) at the university and the role of FCR.

Shen reported on the role of the Special Committee on Intellectual Property & Commercialization (SCIPC) which is charged with reviewing all UW policies and practices related to faculty intellectual property, including its management and commercialization. Last year SCIPC worked with present assignment language in the Outside Work Form along with prepackaged IP agreements in order for faculty to engage with companies on outside projects. Members discussed the need to change EO 36. Shen explained that SCIPC is one of many stakeholder groups that will be involved with the changes since the policy has university-wide implications.

Miller reported on the history of IP discussions at the university, including the formation of SCIPC, the president’s Intellectual Property Management Advisory Committee (IPMAC), and the Outside Work Form. Discussion moved to open access and past work between FCR and the Faculty Council on University Libraries (FCUL) to provide suggestions on how the university should address the issue.

Holt provided a summary of how FCR, IPMAC and SCIPC will be able to address additional issues including changes to the state ethics act, developing policy that accurately reflects how IP is actually created at the university, and how intellectual property impacts online courses and software.
Miller reported that IPMAC will work in several stages to revise EO 36, including information gathering at public hearings, analyzing perceived information, and reviewing results of current IP policy which may need to be amended. IPMAC will also focus on new issues that have emerged since its last revision, including software, online courses, teaching materials, student work, and IP created outside the university. Members discussed issues and concerns that FCR should address. A comment was raised that FCR should provide input on classified research that requires restrictions and stipulations for publications based on contracts with outside entities. Concern was also raised that faculty are not being properly advised on the implications of signing contracts that may remove their IP rights. Holt explained that C4C assists faculty with navigating contracts when working with companies outside UW. Members discussed how the new policy should accurately reflect how work is currently conducted at the university in order to effectively address IP rights for faculty.

A comment was raised stressing the need for FCR to work closely with SCIPC and IPMAC as changes to university IP policy as discussed.

6) Adjourn

The meeting was adjourned by Rosenfeld at 10:30 a.m.

Minutes by Grayson Court, council support analyst. gcourt@uw.edu

Present: Faculty: Mike Rosenfeld (chair), Cecilia Aragon, Mark Haselkorn, Gina-Anne Levow, Todd Scheuer, Juliet Shields, Tueng Shen, Daniel Vogt
Ex-Officio Reps: Dianna Louden, Tom Gebert, Steve Carlin
Guests: Karen Moe, Barbara Benson, Christene Taylor, Susan Camber, Fred Holt, Jerry Miller

Absent: Faculty: Norm Beauchamp, Benjamin Marwick, John Slattery
President’s Designee: Mary Lidstrom
Ex-Officio Reps: JoAnne Taricani