University of Washington
Faculty Council on Research
Wednesday, October 12, 2011, 8:30 a.m.
142 Gerberding Hall

Meeting agenda:

1. Call to Order and Approval of Agenda
2. Approve minutes from May, 2011 FCR meeting
3. Announcements
4. Old / New Business
   A. Request for approval of a restricted research contract
5. Requests for Information and Updates
   A. Update on challenges and opportunities for UW Research this year – Mary Lidstrom
   B. Update on Office of Sponsored Programs – Lynne Chronister
   C. Revision of federal human subjects regulations – Karen Moe
6. Adjournment

1. Call to Order
Chair Stenkamp called the meeting to order at 8:33 a.m.

2. Approve minutes from May, 2011 FCR meeting
No revisions were suggested for the minutes from the May 2001 FCR meeting.

3. Announcements
Chair Stenkamp requested that current members consider recommendations for serving on FCR, as this year there will be some turnover in membership.

4. New business:
Dan Vogt provided a brief overview of a restricted research project started in July, which is a feasibility study of mid-infrared electro-optic polymers and biotronics for Air Force research laboratories for $90,000, ending in December. Vogt provided the standard list of 6 questions that the Subcommittee on Restricted Research requested from Primary Investigator Dr. Jen, and had responses to all questions. After reviewing the paperwork, the subcommittee found this project is similar to past requests that were approved by FCR; it unanimously proposed FCR approval for this project as no students will be involved, and the only restrictions for the postdoc or principal investigator would be obtaining Air Force approval prior to publication. A question was posed whether intellectual property was owned by the Air Force or the University of Washington. Clarification was provided that if data was originally the Air Force’s property, then it will remains theirs; if data is from the University of Washington, it is its property; if jointly developed there is joint ownership. Another question was if a time frame was provided for the Air Force to review the project, it was between 30 to 60 days maximum, as dictated by the University of Washington.

Vote was called and 8 members approved the measure, without opposition. Approved.

5. Updates
   A. Update on challenges and opportunities for UW Research this year – Mary Lidstrom

Mary Lidstrom, Vice Provost for Research, highlighted a list of forthcoming issues that would be relevant to FCR’s charge to monitor:
- **Fostering Collaboration for the 21st Century:** These are guidelines for deans and associate deans in establishing centers and institutes (“organized research units”) developed by Dave Eden and Jerry Baldasty from the Sustainable Academic Business Plan initiative. A draft of these guidelines is almost finalized and will be presented to the Faculty Council on Research.

- **National Institute of Health (NIH) Conflict of Interest Training:** New deadlines and training, which will be discussed shortly by Lynne Chronister. This currently only affects departments with NIH funding, but eventually will affect everyone on campus.

- **Policy and Effects of Activity Based Budgeting (ABB) model:** Lidstrom believes that of all the issues, this is potentially the most pressing. She will discuss the impact of this policy during the next meeting.

- **Security and Privacy Policies:** Formalizing current internal processes regarding restricted research when there are questions of the content, not dealing with the role of FCR.

Lidstrom provided a brief overview of research at the University of Washington in 2011, this has been a record year for research funding: we received $1.5 billion. There is a large amount of American Recovery and Reinvestment Act (ARRA) funds remaining, and more is to come. Lidstrom expects funding to decrease next year, but when evaluating the funding base, which increased a great deal over last year, the University of Washington is doing a great job of competing. UW's market share in federal funds has been increasing, and even if federal funding does not increase over the next few years, the University of Washington will probably continue to do well in funding due to its faculty. There was a brief discussion of the difficulties to make a comparison in funding with other universities.

Lidstrom introduced guest Fiona Wills from the Center for Commercialization, and provided background on the Request for Approval of Outside Professional Work for Compensation,” ([http://www.washington.edu/admin/acadpers/forms/approval_compensation.docx](http://www.washington.edu/admin/acadpers/forms/approval_compensation.docx)) which is the form that faculty need to fill out to get approval for compensation outside the university. Wills explained that the Stanford v. Roche ([www.supremecourt.gov/opinions/10pdf/09-1159.pdf](http://www.supremecourt.gov/opinions/10pdf/09-1159.pdf)) case elucidated the fact that the assignment language within University of Washington policy was substandard, and language, not policy, was changed in order to ensure the university is not at a disadvantage when compared to other universities. Wills provided a handout with explanation of the impacts of this change and assured that this change did not take away any further intellectual property. She recommended that investigators participating in their own startups become aware of potential liability and fill out form 1460. She emphasized that it is in the investigator’s best interest to get advice and know what policies to follow. Lidstrom alerted that there is greatly heightened concern regarding this issue by the federal legislators and stated that the University of Washington does a great job in managing conflicts of interest for faculty members and making faculty aware of policies in place. Questions arose regarding the scenarios where filling out such a document was necessary, and Wills clarified that these forms would need to be filled out for each year and each job, generally any role outside of regular work.

**B. Update on Office of Sponsored Programs - Lynne Chronister**

**General OSP Update**

Lynne Chronister presented the current scenario for the Office of Sponsored Programs (OSP)[Appendix A]. She discussed challenges faced due to the current budget situation, as colleges and departments have reduced their grants support significantly. Lawsuits and additional federal regulations are increasing the workload at OSP, and one member of her team has retired after managing subcontracts for over 25 years. After OSP brought up many different policy changes last year, these are coming into effect presently, some of which are:

- Changes in facility and administrative rates and the policy itself;
- Reduction of paperwork burden, Facilities and Administrative cost waivers;
- Grants Information Memoranda (GIM) 13: Increased rate on clinical trials to 27%, which were below market value;
- GIM 34: Policy regarding Gifts and Grants, which required a better distinction of whether to approach OSP or Advancement;
- GMI 38: Reduced responsibility: Earlier policy was not compatible with university systems, so it was adapted to work with our systems;
- GIM 39: Closeout policy: Policy to hold funding for research reports which are more than 90 days delinquent. 30 reports to the government were sent out recently. Important for faculty to not have delinquent reports, as some organizations will restrict funding to the entire university if reports are late.

Chronister also highlighted changes within OSP’s processes and training. Prior to the changes, faculty members could not see what was in their OSP file; now faculty and their administrators can access their own SPAERC files, only compliance is kept confidential. NIH is allowing individuals to file “snap proposals,” and OSP is investigating ways to lighten this administrative burden to faculty. OSP has already convened two new faculty orientations, and has a series on brownbag lunches. Their orientation material is available online via webcast (http://uofw.adobeconnect.com/brownbag/). These orientations are important as departments are cutting down on administrative staff, and many faculty members are submitting their own forms. Chronister briefly discussed the state of contracts at the University of Washington. There was an increasing amount of bad debt, reaching $600,000, due to confusion in the difference between a contract and a grant.

**NIH Conflict of Interest Training**

Chronister provided an overview of the impact of the new NIH Conflict of Interest policy (http://grants.nih.gov/grants/policy/COI/). Compliance with the new policy will be mandatory by August 24, 2012. This is a huge undertaking to create a program for training and tracking, considering the short timeline and no extra funding provided for this work. She commented that OSP is still determining whether to use online training which would dovetail with the System to Administer Grants Electronically (SAGE), providing awards after training had been performed. Chronister justified the need to triage training between only NIH grants initially, as working with individual departments would be too big of a task. Lidstrom recommended that the University of Washington invest in training all awards, while this is currently solely a requirement of the U.S. Department of Health and Human Services, other agencies are following suit. There was brief discussion regarding the clarity of who make up “investigators” and thus require training, and Lidstrom recommended that anyone who could be considered a principal investigator has training.

Some of the policy shifts within these regulations were discussed, lowering the threshold for reporting Significant Financial Interests from $10,000 to $5,000, disclosure of travel reimbursement related to private contracts, and public disclosure regarding senior personnel. A comparison between 1995 Regulations and the 2011 Final Rule can be found online at: [http://grants.nih.gov/grants/policy/COI/summary_of_major_changes.doc](http://grants.nih.gov/grants/policy/COI/summary_of_major_changes.doc). Additional questions followed, in regards to the additional administrative burden on faculty, and the ability to track costs related to these regulations. The Council on Governmental Relations (COGR) is to report back what the cost is to the University, and Lidstrom mentioned costs may be reduced through national regulatory relief. Questions were raised regarding the enforcement of this policy, but Lidstrom assured that compliance would be strictly enforced.

**C. Revision of federal human subjects regulations – Karen Moe**

Karen Moe from the Human Subjects Division summarized upcoming revisions for Federal Human Subjects regulations, first providing a background on the formation of these revisions and discussing the extent of modifications. These changes are significant, but feelings are that only half of the revisions are confirmed with many still uncertain; the burden of addressing these changes would fall mostly on the institution rather than Primary Investigators. Currently COGR is preparing a response for the university. Moe’s office is also drafting a response, and she requested additional comments from members of FCR prior to the comment period ending on October 26, after revisions were proposed at the end of July. There is an intention to implement these changes prior to January 2013, after another 90 day comment period.
Moe described that consent forms would be limited to three pages, and there would be an increase in both the amount and type of research that can qualify as exempt or expedited research and tightening of regulations. This type of research is either minimal or low risk and would only need to be reviewed once, requiring additional reviews only should the protocol change. Moe summarized the willingness for this change due to reduction of regulatory burden on researchers, while controlling identity of the data rather than risk: if sensitive data were released it could cause financial, legal or personal damages to subjects. Data would have more stringent standards to protect for individuals’ identities, similar to the Health Insurance Portability and Accountability Act (HIPAA). This change is contentious because these are very extensive regulations and as these standards were created for the medical field, it is difficult to say how it will impact other areas of research to assess psychological, financial and social risks. Additionally there is a proposal to extend federal guidelines to all research performed at our institution.

Moe also discussed a proposition of a “central institutional review board” for multi-site research rather than using individual institutional review boards (IRBs) at each site. This would be an impact of the shift towards exempt or expedited research, and larger research organizations, such as University of Washington, may be better prepared than smaller institutions in this area. There are very few rules about how to implement such a policy: who would make the choice and what criteria it would be chosen by. Moe had already been approached by a team of researchers requesting to know if UW would be willing to serve as a central IRB. Discussion followed, raising issues of whether it would be cost effective for the University of Washington to take on such a role, competition with private companies, and the challenges within the current legacy systems at the University of Washington for review.

Moe expressed interest to potentially return to FCR to discuss this sometime in the spring after revisions had been made, to inform of changes made on subject compensation program (treatment and compensation for those injured in research) and changes from ICD9 to ICD10 coding. Draft feedback would be greatly appreciated, taking into consideration the tight deadline; Moe would send this to Chair Stenkamp and the council.

6. Adjournment
The meeting was adjourned at 10:03 a.m.
LOOKING FORWARD: 2011/2012

UW Policy Implementation
- GIM 13: Facility and Administrative Rates
- GIM 34: Gifts and Grants
- GIM 38: Reduced Responsibility
- GIM 39: Closeout

More Learning Opportunities
- Faculty Orientation: Kickoff and Brown Bag Sessions
- Comprehensive Research Administration Learning Program

Challenges
- #1 Reduced Grants Management Staffing with Increased Proposal Submissions
- #2 More changes in Federal regulations

Streamlining Processes
- Access to OSP SPAERC files (Read Only)
- Looking at SNAP submission for PI's
- Some budget set up delays as a result of the new Federal IRB policy

CONTRACTS GONE WILD!
AGENDA
1. What is a Grant/Contract/Gift? Do I Care?
2. Reviewing the Contract
3. Some Pitfalls
4. Scary Case Studies
5. Suggestions and Best Practices

New Federal Rules: COI
• $5000 threshold for disclosure for payment of service and equity interest
• All SFI related to institutional responsibility (not just research)
• Disclosure of Travel reimbursement related to privately sponsored project
• Public disclosure of FCOI’s held by senior/key personnel.
• Each investigator must complete training prior to engaging in PHS research. Renew every four years.