1. **Call to Order and Approval of Agenda**

Council Chair Ron Stenkamp called the meeting to order at 9:02 a.m.

2. **Approve minutes from March 14, 2012 FCR meeting**

Minutes from the March 14, 2012, FCR meeting were approved without amendments.

3. **Requests for Information and Updates**
   a. *Draft policy for use of the University of Washington Institutional Review Board (IRB) – Karen Moe*
   
   Director of the UW Human Subjects Division Karen Moe introduced herself. She requested councilmembers to provide feedback on a draft of the revised UW IRB eligibility determinations. New research taking place at UW Affiliates such as Children’s Hospital brought up the question of whether such organizations are eligible to use the UW IRB. The complication was noted that some salaried individuals do not run funding for research through the University, and concerns were that individuals benefiting by the IRB may not be contributing to overhead funding, and additionally, the University has no control over compliance for such individuals. Also, a written policy did not exist to determine eligibility to use the UW IRB. Mary Lidstrom was approached by Moe to better understand the system, and the policy was drafted. The approach taken was to err on the side of being inclusive, rather than restrictive. This drafted policy has been presented to other groups, such as the Assistant Deans and Associate Deans of Research.

   Moe provided Criteria:
   - Engagement: UW needs to be engaged in the research
   - Lead researcher on UW IRB application: Needs to be UW salaried faculty member, salaried appointment as a resident, fellow, post-doc, trainee or student, or is a matriculated UW student with a faculty advisor. Some affected groups which should be exceptions were discussed.
   - Reason for doing the research: Part of responsibilities and expectations within the mission of UW.
   - Institutional conflict of interest: No institutional conflict in respect to the research, or if there is conflict of interest, the management plan does not require use of an external IRB to manage this conflict.
Scenarios were then presented by council members to understand whether they would be excluded or allowed to use UW IRB. One scenario was a faculty member who had 90% of their salary paid by the Department of Veteran’s Affairs. This is permitted through language in the draft: “Because of the close relationship between the UW and the VAPSHC, UW faculty members whose primary paid employment is at the VAPSHC are eligible to serve as the lead researcher on the UW IRB application.” Students at other schools doing research with UW faculty were noted to be eligible, as long as they are UW students. Discussion followed on what options would be available for faculty if a project is split between two different IRBs. This would be determined by the Principal Investigator within the project. In such cases, it was clarified that the two institutions would need to work together on this matter. Moe clarified that eligibility is more in respect to the faculty appointment, and whether or not salaries are received from UW was a secondary issue. Another scenario was with the Pacific Northwest National Library, where they have dual appointments; even as an employee with PNNL, they have a special affiliation with UW and work here.

Moe emphasized that the main intent of this policy is to not provide IRB resources to researchers who are clearly employees of another institution. Should the research by either student or PI be part of the University of Washington, then they would be eligible to use the IRB. In the case of subcontracts where grants are coming from another organization, this would require further discussion to determine if they can use the UW IRB. She requested for Council members to inform her of any other scenarios in which UW researchers would be negatively affected by such a policy.

b. Update on PHS regulations on financial conflicts of interest – Jeff Cheek
Associate Vice Provost for Research Compliance and Operations Jeff Cheek was introduced to the Council. He is providing an update on the changes to UW policy on financial conflicts of interest (FCOI), which are coming due to changes mandated by the Public Health Service (PHS). These changes will have increase administrative burden on individual researchers and the institution. Cheek informed that his office is struggling to inform UW personnel of these changes before they take effect in August 2012 and develop a system to monitor compliance.

Cheek reviews around 200 potential conflicts of interest annually and assembles management plans together to address potential biases. He proceeded to discuss what constitutes a FCOI:

- Outside salary, honoraria, consulting fees
- Compensation for speaking engagements
- Stock, stock options, other ownership interests
- Intellectual property rights (patents, licenses)
- Imputed interests (spouse, etc.)

Current policy on FCOI applies to all research, even if it is not sponsored. The University is overcautious even in the appearance of conflict. Intellectual Property and ownership within startups can also be considered a FCOI. This is to prevent bias in research, harm to human subjects, and misuse of university resources, which could lead to a violation the State Ethics Act. Currently FCOI only applies to Conduct of Research, specific to the research project.
Such disclosures are identified either when there an IRB application is submitted, or a technology license transfer entered by the Center for Commercialization. Cheek provided an example of a researcher working on a clinical trial; should the research hold any financial interest with the sponsor, a management plan must be put into place. If requiring human subjects review, the researcher is compensated less than $5,000 annually, this would not require disclosure. Previous thresholds were set at $10,000 or 5% ownership in the equity. Cheek noted that the National Science Foundation definition would not change, but the PHS definition will. Key changes in the PHS rules are as follows:

- **a)** Lowers the minimum threshold from $10,000 to $5,000 for disclosure of compensation for services or equity interest in a publicly traded company, with a $0 threshold for disclosure of equity in a non-publicly traded company.
- **b)** Requires investigators to disclose all significant financial interests related to their institutional responsibilities (rather than only those related to the PHS-funded research). Teaching versus research implies different levels of disclosures.
- **c)** Increases the institution’s responsibilities regarding identifying significant financial interests related to PHS-funded research; managing financial conflicts of interests; federal reporting requirements, and ensuring sub-recipient compliance.
- **d)** Requires public transparency of FCOI management plans by either publicly accessible website or written response to any requestor within 5 business days of request for institution’s financial conflict of interest policies and certain information regarding any key personnel whose significant financial interests are related to PHS-funded research.

It was suggested that Cheek’s office draft a flowchart in order to better present the new policy on disclosure to researchers. Cheek noted that although the specifics of changes are not yet defined, communication to affected parties can already begin. Faculty members were concerned that the policy point stating “that all investigators must disclose their significant financial interests related to their institutional responsibilities,” would signify that new rules would apply to all researchers. Lidstrom responded that the burden falls on PHS funded research. She emphasized that the only new PHS requirement which will be applied to the whole University is the reduction of the threshold for FCOI from $10,000 to $5,000. Members voiced lack of clarity in faculty responsibilities, depending on the type of funding, and their department.

Cheek then noted the two changes which will impact all UW investigators:

- **a)** All UW investigators that have financial interests related to their research will be subject to the lower threshold of FCOI for disclosure requirements, regardless of sponsor (i.e., there will be a single standard to define FCOI)
- **b)** Office of Research Information Services (ORIS) is developing an electronic disclosure process that will replace the current paper-based procedure, which will reduce the administrative burden for faculty disclosing FCOI related to research projects.

The mandatory certification regarding FCOI will be required to be completed by all PHS funded “investigators,” estimated to be 7,000 individuals at UW, who must complete a mandatory training by August 2012 before spending new PHS funds. Discussion followed on who is considered an investigator, particularly in light of the lack of clarity whether Graduate Students would be considered as such. It was explained that the intent is to
identify any potential researcher with a financial interest who could independently alter the design of the research. Debate continued on who are considered investigators. Lidstrom noted that peer universities are working on excluding students from such restriction. The responsibility of designation of investigators falls to each Principal Investigator, which must comply with certification. A suggestion followed that everyone working on a project be certified. Though anyone can take the certification, Office of Sponsored Programs (OSP) is required to not establish a budget until everyone who has been designated as investigators has been trained, and concern was raised that broadening the individuals requiring training would hold up budgets.

Further discussion on the training followed. Questions will be developed by NIH, will be online and shouldn’t take more than 15-20 minutes. Impact on affiliate organizations such as the Fred Hutchinson Cancer Research Center and Children’s Hospital will be attempted to be mitigated. The Office of Sponsored Programs will have the ability to track these certifications following the trainings. Such trainings will be valid for four years.

Another major change which Cheek noted to be particularly burdensome is the requirement of disclosure of any reimbursed travel from outside sources. Such payment from non-profits, foundations and national associations must also be disclosed; exemptions include PHS and other academic institutions. UW will be required to review these case by case, around 10,000 disclosures reviewed annually. This information will be submitted via a web-based form, linking to the state’s database. It was unclear if institutional responsibilities extended beyond research and potentially may affect other UW organizations, such as I-TECH. It was clarified that National Science Foundation researchers wouldn’t fall into this category, solely PHS investigators. Should a pharmaceutical company provide a gift to the University for travel costs of researchers, this would not be required to be submitted.

Cheek emphasized that the highest impact of these changes falls on PHS funded investigators at UW. He noted that his group will need support from UW PIs and department administrators in spreading awareness and getting investigators certified. This process will begin in June, for completion in August. Questions followed on tracking mechanisms, noting that there is a need centrally track new personnel added to ongoing PHS funded projects. There will not be an annual reminder to recertify new personnel in multi-year projects; if a financial interest exceeds the threshold, investigators will need to declare potential financial conflicts of interest at that point. Council members pointed out that this training could be added to Responsible Conduct of Research (RCR) training already in place. Ideally this curriculum would be embedded in the RCR training. However there is no funding to do so.

Cheek thanked the Council and requested to return, provide further updates, and get feedback.

4. Old/New Business

- Two APL restricted research contracts – Dan Vogt, Restricted Research Subcommittee

   Daniel Vogt introduced two restricted Applied Physics Laboratory (APL) projects to be approved by the Council. The subcommittee did not feel there were any significant issues with either of these two contracts.

   The first contract considered was “2012 ONR Joint Active/Passive Sonar Review.” Mandex is funding APL to hold a security conference on campus for discussing and peer reviewing classified data and classified research. This contract was noted to have no effect on publications nor foreign nationals working on this project. Vogt
suggested that FCR approve this item. Questions were asked on the details of this conference, and it was noted that this conference has taken place multiple times at the University of Washington. There was a motion to approve this at FCR and send it to OSP.

“2012 ONR Joint Active/Passive Sonar Review” was approved unanimously.

The second contract considered was another ONR funded project, “The impact of submarine depth, speed sonar systems on Arctic sea-ice draft measurements,” through the APL. This is a proposed contract to take classified data which has already been collected regarding thickness of Artic Sea ice. The hope is to transform the data into declassified research, providing access for scientists interested in researching climate change. Discussion followed on the political nature of such information. The subcommittee’s charge is to investigate the impacts to research, or students' ability to publish, and that this was not included in this charge. The nature of the classified data was attributed to security concerns of exposing submarine locations and times, as submarines measure this ice. This data will be removed from the dataset. Concern would rise if subjective criteria would be applied to the dataset, however it was considered that this data would be evaluated objectively. Peer review could mitigate any such this risk, and it is more likely ONR will restrict the data. There was a motion to approve this at FCR and send it to OSP.

“The impact of submarine depth, speed sonar systems on Arctic sea-ice draft measurements” was approved unanimously.

5. Adjournment
Meeting was adjourned at 10:29 a.m. by Ron Stenkamp.

Minutes by Jay Freistadt, Faculty Council Support Analyst. jayf@u.washington.edu

Present: Faculty: Stenkamp (Chair), Rosenfeld, Miller, Haselkorn, Slattery, Vogt
President’s Designee: Lidstrom
Ex Officio Rep: Spelman, Gruhn
Guests: Susan Camber, Lynne Chronister, Karen Moe, Jeff Cheek

Absent: Faculty: Spieker, Roesler
Ex Officio Rep: Fridley, James, Nolan, Pantazis