Meeting Synopsis:

1) Call to Order and Approval of Agenda
2) Approve minutes from November 14th FCR meeting
3) Announcements
4) Requests for Information and Updates
   a. Post-Approval Monitoring Program by Human Subjects
   b. Impact of Sound Transit Tunnel below Campus
5) Adjournment

1. Call to Order and Approval of Agenda
The meeting was called to order by Chair Gerald Miller at 9:03 a.m. He introduced Lynette Arias, the new director of the Office of Sponsored Programs.

2. Approve minutes from November 14th FCR meeting
Minutes from the November 14th FCR meeting were approved without corrections.

3. Announcements
Miller provided updates on two committees dealing with intellectual property issues. IPMAC, the Intellectual Property Management Advisory Committee is charged by President Michael Young. The Special Committee on Intellectual Property and Commercialization was created by the Faculty Senate. As FCR Chair, Miller is an ex-officio member for both groups. Both are in discussion on the “Request for Approval of Outside Professional Work for Compensation” form.

SCIPC reviewed an updated draft of this form, considered such revisions an improvement over the current form, and suggested no assignment language of intellectual property rights to be included in this form. The rationale for this was due to the difficulty to assign rights on an invention prior to its creation. IPMAC has had much discussion on revision of this form, is investigating best practices at other institutions, however no decision has been made. Miller noted that both committees are concerned with protecting faculty rights, and the University in such discussions. Changes will be made to policy, but Miller was uncertain of impacts to faculty across campus.

4. Requests for Information and Updates
   a. Post-Approval Monitoring Program by Human Subjects

Wendy Brown, a Post Approval Monitor in Human Subjects was introduced. She described a new program within Human Subjects which is close to launch. Called the “Post Approval Verification and Education Program (PAVE), this is intended to verify that human subjects research is being conducted in compliance with all research regulations and according to IRB approved study plan.
Beyond this, this program offers investigators the tools to address any identified gaps, and assist with needs for systemic education and clarification. Brown also emphasized the opportunity to highlight best practices within current research projects.

Non-compliance tracking at the University has been occurring for the past five years. Following an internal audit in 2011, the lack of post approval monitoring was noted to be a high risk finding, and the implementation of this program will allow the University to be consistent with similar programs at peer institutions. Compliance monitoring could occur within all active UW Institutional Review Board (IRB) approved studies, and any UW study approved by another IRB on behalf of the UW IRB.

The first year of this program will focus on investigator-initiated studies using an investigational drug or device, which present the highest risk. Studies will also be evaluated for a PAVE visit at the request of a UW IRB. In the future, this program will select such studies by UW IRB requests, and be guided by compliance data and regulatory issues, occurring after IRB approval.

Topics reviewed within this evaluation are:
- Recruiting, screening, eligibility
- Consent
- HIPAA Authorization
- Study procedures conducted as approved
- Data security and protections
- Tracking of IRB approval dates and requirements
- Oversight of the study by the Lead Researcher
- Other aspects of the study as appropriate

Questions were posed on what happens should there be findings which should have been reported to the IRB but were not. In this case, Brown will work with the researcher, alerting them of their responsibilities, and guiding them. Any findings resulting from a PAVE review would be communicated first through a draft report, to the lead researcher who will have an opportunity for comments or input prior to the report being finalized. Final reports will be sent to the lead researcher, IRB, Human Subjects Division Director, the Institutional Official and other UW offices as appropriate.

An evaluation of the each PAVE review will consist of an anonymous survey via Catalyst sent to researchers following the IRB review of the final PAVE report. Input will also be sought from IRB members, and annual metrics will be gathered to improve the program. Each study evaluation is expected to take around one week to perform, a similar timeframe to peer efforts.

Discussion followed how research programs of the highest risk will be determined; this was described to be an investigator who has dual responsibilities as the sponsor or holder of the investigational device exemption (IDE), or investigational new drug application (IND) and fulfilling the responsibilities as the lead researcher of the study. This differs from the Institutional Animal Care and Use Committee (IACUC) protocols, which mandate annual or biannual reviews by investigators, but Brown noted a lack of resources to take such an approach. Reports will be
produced for every project evaluated, and those selected for evaluation will be required to undergo it, however flexibility may be given on the timing of such an evaluation. Concern was expressed on how faculty would feel about undergoing such reviews and how this would be mandated. Initial evaluations were in part voluntary.

A Frequently Asked Questions form will be provided to address common questions and will be posted on the HSD website. Discussion followed on how broadly PAVE reports may be distributed to disseminate best practices. Not enough resources are available to attend such high demand, if many researchers request evaluations.

The Council debated the impact on minimal risk studies, and the amendment of research protocols. Brown noted that UW Human Subjects is awaiting finalization of changes within federal Human Subjects regulations to understand implications towards minimal risk studies. It was suggested by one member of the committee to speed up the regulatory procedures for minimal risk studies.

In the consequences of non-compliance, the researcher will be advised by the PAVE Monitor to contact the IRB and report of elements outside of those approved. Ultimate responsibility is left to the IRB to follow up with researchers on projects. Brown thanked the Council for its suggestions.

b. Impact of Sound Transit Tunnel below Campus

V’Ella Warren, Senior Vice President and Treasurer, Board of Regents at the University of Washington (UW) introduced Richard Chapman, Associate Vice President of UW Capitol Projects. This presentation was to outline the efforts to mitigate potential impacts, temporary and perpetual, of the Sound Transit Light Rail tunnel under the University District.

Chapman described the current construction on the Link Light Rail, which will bring the train to the Husky Stadium by 2016. Presently, focus is both on the boring to occur beneath campus, and regular light rail operations under campus over the next 100 years. He demonstrated the trajectory of the route, with estimated daily passenger boarding’s reaching 62,000 by 2030. In 2007, the trajectory had been altered, however the only potential change in impacts were noted on the Burke Museum, which was not perceived to pose any issues. The main impacts of the construction and ongoing transit would be felt by areas with electron microscopes. The UW Board of Regents will be requested to approve an additional agreement on the space between 15th Ave NE and the University Tower on January 10th. Tunneling under campus is only expected to take 6 months, during 2016, and with construction equipment located near the UW Tower.

Chapman described his involvement in negotiation with Sound Transit on a Master Implementation Agreement in 2007, which came forth from monthly discussions within an Advisory Committee, discussing technical matters such as electromagnetic interference thresholds. Impacts of long-term operation of the train under campus were considered in three categories: a) magnetic fields of, b) the moving mass of the train in the earth’s magnetic field; and c) construction. Sound Transit is obligated to use state of the art mitigation techniques such as “floating slabs” which protect against
vibration/electromagnetic interference, ultra-straight rail, quadrupole technology, and speed control. A liquidated damage clause serves to ensure that Sound Transit carefully protects this area.

A map was displayed showing 26 buildings where scientific research occurs. In 2006, these buildings were delineated as “off limits” to be impacted by magnetic fields, both in construction and regular train operations. Prior to the beginning of services, testing will be performed, and the train cannot operate should “off-limits buildings” be impacted. Construction vibration has no set levels, and UW has agreed to tolerate impacts to the extent that they fall within predictions. Lessons were learned by Sound Transit through construction in the Montlake area, which will be applied to this construction. Currently, UW is designing a real-time monitoring program on vibration and electromagnetic interference for Sound Transit, which could also be used to verify if train operations impacted research. Should vibrations be found to exceed predictions, Sound Transit must pay to mitigate these effects. For any effects unable to be further mitigated, research projects will be relocated, as this is more cost-effective than changing the train’s trajectory.

Chapman emphasized the constant communication between UW and Sound Transit, at both an executive and technical level. Warren noted that UW is fortunate to have such a tight collaboration with Sound Transit. Questions followed on why such a route was chosen, through campus, rather than north of campus. This was agreed upon by the Regents, weighing both ridership and impact. Faculty and staff of the College of Engineering were encouraged to interact with Capital Projects to ensure that all current issues are understood. Planning and Budgeting office may also assist in departmental strategizing of where to locate labs, in light of the construction and operation of the light rail. Questions were requested to be directed to V’Ella Warren or Richard Chapman.

5. Adjournment
Meeting was adjourned at 10:35 a.m. by Chair Miller.

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

Present: Faculty: Miller (Chair), Vogt, Aragon, Rosenfeld, Scheuer, Roesler, Beauchamp
Ex Officio Rep: Yin (GPSS), Nolan, Kiehl Sundt (ASUW)
Guests: Lynette Arias, Sue Camber, Wendy Brown, V’Ella Warren, Richard Chapman, Andrew Cassillas

Absent: Faculty: Slattery
President’s Designee: Lidstrom
Ex Officio Rep: Fridley, James