University of Washington
Faculty Council on Research

The Faculty Council on Research met on Friday, May 6, 2005, at 8:00 a.m., in Mary Gates Hall 420. Chair Brent Stewart called the meeting to order at 8:00 a.m.

Synopsis:
1. Comments, announcements, agenda, minutes
2. Discussion
   a. Human Subjects Division update on HSD improvements and recent OHRP findings – Helen McGough, Director, HSD and Prof. Karen Moe, Asst. Director, HSD.
3. Requests for Information and Updates
   a. Mac Parks – update regarding FCR/SEC approved FCR-related changes to the Handbook

Comments, Announcements, Agenda, Minutes
The agenda was approved. The minutes of the last meeting were approved.

FCR is losing Stewart Tolnay, Ross Heath and Mehmet Sarikaya at the end of this academic year. New members will include Richard Wright (Linguistics), Mark Haselkorn (Technical Communication), and David Fluharty (Marine Affairs). Brent Stewart thanked the retiring members for their excellent service, and will invite the new members to attend the June FCR meeting.

Mac Parks told the Council that SB5811 (aka HB1806), referred to in the March minutes, passed the state legislature. This change in the ethics laws gives the UW some added flexibility in the Tech Transfer area.

Ross Heath announced that the siting report for the proposed Level 3 Regional Biocontainment Lab is expected to be submitted to President Emmert on May 17. Emmert has asked for general comments, with a list of pros and cons, addressing three options: RBL on-campus, RBL off-campus, and "no change." Comments are still being gathered from the general public. Even if the project is approved, there is a funding shortfall of 30-40 million dollars with no obvious source of funds identified.

Barbara Perry, UW Director of Federal Relations, invited FCR members to a brownbag roundtable discussion Friday, May 13, 193 Gerberding Hall, from 2:00-4:00 p.m. She and her Washington D.C. staff are eager to hear what's on the minds of UW researchers, and to learn what they can do to be more helpful to the UW research community.

Stewart reported that UW President Mark Emmert met with John H. Marburger, III, Director of the Office of Science and Technology Policy, in the White House.

Stewart announced that comments on the Department of Commerce rulemaking letter are due back by May 27. Carol Zuiches is the lead on this, but all members are urged to review and comment on the revisions.

Human Subjects Division Update, and Office of Human Research Protections audit findings
Helen McGough, Director of the Human Subjects Division (HSD) of the Office of Sponsored Programs, and Karen Moe, Assistant Director HSD, visited FCR to talk about improvements at HSD and the recent publicity around the audit findings of the Federal Office of Human Research Protections (OHRP).

McGough said that OHRP made a 2.5 day site visit to HSD in late February 2005, their twelfth visit since 1999, and conducted an audit of about 100 files. OHRP followed this up with a letter dated April 5, 2005, in which they cited seven findings and seven concerns.
On April 17, while HSD was developing their response to the audit letter, OHRP published the letter on their Website. The letter, which contained redacted portions and was not accompanied by a UW response, was viewed by the Tacoma News Tribune, who published it on April 19. The negative publicity blindsided and embarrassed President Emmert, Senator Patty Murray, and Representative Norm Dicks.

McGough provided copies to FCR members of the un-redacted OHRP letter and the UW response, both of which are posted on the OSP Website. McGough assured FCR members that no human subjects were put at risk in connection with the findings, which involved documentation inadequacies in minutes, required regulatory findings, and other paperwork. She characterized the OHRP findings as "a regulatory bureaucratic documentation of issues."

Stewart Tolnay commented that the things OHPR objected to are things that have been put in place to assist researchers – he is concerned that complying with the audit findings will cause the HSD process to become as slow as it once was, which is not acceptable. McGough agreed that the changes, which require more extensive reviews for minor changes in proposals, will slow down the review process. She is setting up a system that she hopes will triage the reviews into areas of low, medium and high concern so HSD can deal with each level according to its importance. She is working on the application form so the review committee gets the information it needs, but this will also slow HSD down. It may be possible to institute more review boards (IRBs), but this would take additional funding.

During a wide-ranging discussion, the following questions were raised:

- What can be done so that simple, even innocuous, studies do not need such a long review process?
- Do HSD staff understand what the various projects are about, so they can review them properly?
- Does the electronic system actually speed the process – some researchers question whether it saves them any time.
- Why does it appear that there is no long-range pre-planning for the staff needed for core research compliance issues? If trends indicate that research grants will double in a specific time period, why isn't the infrastructure added to handle the workload when it arrives? Other institutions around the country seem to be ahead of the UW in their planning for additional research efforts.
- Has anyone investigated how well UW researchers are being served by HSD?
- Should there be a cultural shift in the interactions between HSD and researchers, from a "policing" mindset to a culture that asks "how can we work together to make sure these things are done right?"
- Why it should be the case that, in any collaborative group that includes other institutions, a UW researcher's application is invariably the last one approved, while researchers at other institutions are able to meet with their Human Subjects people and come to some agreement? This has been one researcher's experience and she strongly reinforced the call to look at the culture that exists between HSD and UW researchers.

McGough responded that she believes the application form is part of the problem – she is trying to standardize the pre-review so the IRBs can work effectively. She also thinks the electronic management system will speed up parts of the process. McGough pointed out that even apparently "innocuous projects" require the same documentation and review as do risky projects.

Kiyak suggested that McGough ask for more staff – if the staff do the pre-review, fifty percent of the delays will disappear. McGough has some temporary staff and applied for more permanent staff, but will not know until July whether the request is approved. She asked FCR to support her request with the Provost. About one-third of all research projects need Human Subjects review, so the workload is heavy.
Sam Dworkin asserted that his thirty-year career as a researcher has given him great respect for the job HSD does. He agrees that FCR should support McGough's request, and asked what form she would like that support to take. Should FCR draft a letter of support, or sign onto McGough's request for more staff?

Mac Parks commented that one cannot assume that, as Federal grant monies increase, increases in infrastructure support are proportionally funded. The leadership is always forced into an allocation of inadequate dollars. Whether the UW does its costing well or badly is a fair topic for discussion, Parks added. Bob Franzia concluded that we should focus on increasing the true rate of cost recovery.

Karen Moe reported that HSD has implemented some beneficial changes. A minimal risk administrator has been hired and the contract for Western IRB has been negotiated. All of HSD is now housed in the same place, which makes working together much easier. Beta testing of UWISE was completed at the end of March and the system will be deployed in April. Moe is writing new policies and procedures for the division, with a special focus on the results of the audit and addressing OHRP requirements. HSD has a new Website that will be rolled out June 1, after comments and testing from 25-50 people on campus. A lot has been done, but there is more to do, Moe added.

Heath said that there should be some flexibility in next year's budget. But despite the level of funding, the goal for HSD is not doing more and more of the same thing but finding ways to do the job better so costs don't grow. Perhaps an ad hoc subcommittee from FCR could be formed to bring new eyes to the problem and help HSD get rid of some of the bottlenecks.

Parks advised that research funding priorities will be a subject for discussion at the next RAB and FCR meetings.

Stewart asked whether FCR members would like to form an HSD Subcommittee to work with McGough. Kiyak and Booth-LaForce volunteered to serve on such a subcommittee. Others are welcome to join.

It was also decided that FCR will send a letter to the Provost supporting HSD projects, but will do that after looking at the Office of Research information on budget requests from all OR units. Mac Parks will provide this information, so that the requests and letter of support from FCR can go to the Provost in one package.

**Approved Changes to the University Handbook**

Two changes supported by FCR, one on HSD and one on Proprietary and Classified Research, are making their way into the University Handbook. The changes were wrongly routed to the Senate legislative process and were delayed, but will appear by Executive Order as soon as the Order is signed.

The meeting was adjourned at 9:32 a.m. *Minutes by Linda Fullerton, Recorder.*