Brent Stewart called the meeting to order at 8:10 AM.

Meeting Synopsis:
1. Agenda and minutes approved (Camber and Zuiches submitted corrections at the end of the meeting)
2. Overview of Office of Research changes and plans for Human Subjects Division organizational improvements (Lidstrom/Discussion)
3. Export Control Policy (Zuiches)
4. Faculty Effort Certification and response to Draft DHHS OIG Research Compliance Guidance (Camber/Discussion)

1. Announcements, Agenda, Minutes
Agenda approved.
Minutes approved.

19 January, 16 February and 7 March are the winter quarter 2006 meeting dates, Stewart announced. The meeting time will be 9:30-11:00 AM in Mary Gates Hall, Room 420.

Stewart welcomed Nanette Welton, the new ALUW representative, and Mary Lidstrom, Professor of Chemical Engineering, who began her post as Vice Provost for Research on 15 November.

2. Requests for Information and Updates
a. Office of Research and Human Subjects Division (M. Lidstrom)
Lidstrom provided a brief update on the Office of Research, and requested 10 minutes at a future meeting, to give a “state of UW research” update. UW is moving to a more distributed team model, with three or four part-time Associate Vice Provost appointees. Her plan is to achieve broader representation of research at UW within the Office of Research. Mac Parks will be conducting a special project in winter quarter, looking at commercial IRBs (i.e., Western IRB) and evaluating potential relationships between UW and such entities. Then he will be on administrative leave for one year, and ultimately return to his academic department.

David Eaton (Associate Vice Provost for Research and Professor, Environmental and Occupational Health Sciences) will be working primarily within the Office of Research with External Relations, interfacing with Barbara Perry and other contacts, serving as a key liaison. His research experience includes serving as head of a Center. Lidstrom will bring an org chart and provide information on the rest of the team when she returns to another FCR meeting. She hopes to achieve a more active, client-oriented model within the Office of Research.

The Human Subjects Division workload has exploded in recent years. This is the result of both increased volume of research, and increased regulatory burden. It’s been very difficult for the Human Subjects Division to keep pace. Concurrent with these increases, central administration hadn’t invested sufficient additional resources to cover the demand, nor did they invest adequately in a management structure within HSD. When Provost Wise arrived in August 2005, she assessed the need and set in motion some changes. Funds were appropriated to address both the workload and management issues.

Goals for HSD are threefold: protect participants, meet regulations, and serve researchers. HSD has been so overwhelmed that the service mission to researchers has faltered.
Provost Wise developed a list of recommendations, which Lidstrom will share at a future meeting. Lidstrom is developing a plan to address these. Lidstrom has been meeting with Associate Deans, and has learned that a large backlog exists with Humanities and Social Science applications. HSD received an NIH grant to develop the UWISE on-line system; this has been halted early in the deployment process because staff had to shift attention to responding to finds from the Office for Human Research Protection (OHRP) from February 2005. UWISE development and rollout will be resumed.

Research compliance and risk management needs to be elevated within UW’s leadership. A full time Associate Vice Provost for Research, Compliance position has been created. The purpose of the position will be to provide coordination and leadership. Focus will need to be on HSD, but Animal Subjects and Environmental Health will also be included. Lidstrom hopes to have the position filled by early April.

Lidstrom has just posted an Assistant Director position to handle daily operations in HSD. She hopes to have this position filled in six weeks. A couple of promising candidates have already been identified. Two support positions, Compliance Analysts, will provide additional support. Karen Moe will then be able to focus on process improvement, which was the original intent of her appointment before UW’s focus was redirected to responding to last years OHRP findings.

UW has decided to move forward and seek accreditation of the HSD. This goal creates a timeline, which will help UW achieve the process improvements we seek. Moe will lead this initiative.

A pre-review process will be established within HSD, so that protocols can be returned prior to committee review, thus more efficiently addressing basic errors. Offering workshops for incoming graduate students, particularly in the Humanities, is another potential project. Within six months, Lidstrom expects to see significant changes in HSD, but cautioned FCR that her goal of service to researchers might require additional time to achieve.

HSD has also received approval to hire a half-time trainer to provide education. This position’s initial focus will be on the training needs of IRB members and incoming staff. HSD needs to improve its consistency of approach among individuals who come on board at different points in time. Shifts in regulations have made it difficult to keep everyone current.

Lidstrom is re-instituting the Human Subjects Policy Board (HSPB), which had been dormant. She wants to develop an iterative policy model, given the frequency of regulatory changes inherent in human subjects work. She noted that the HSD staff appears to be energized about these changes. They want to provide better service.

HSD will now report directly to the Vice Provost for Research, rather than through the Office of Sponsored Programs. This leads to minor support changes, as there was some integration between the two staffs. Space is an issue; interim additional space will be in the Gerberding basement. They may identify a small satellite elsewhere on campus, to avoid moving all of HSD to a new location. Zuiches noted that a satellite location has been a solution in the past, and that those affected liked the space and the satellite experience.

Stewart noted that UW administers nearly $1 billion in research and felt that some of the changes experienced by researchers are based on new interpretation of regulations, rather than on regulatory changes themselves. Lidstrom will look at membership on the HSPB, to ensure that adequate knowledge of researchers’ experience is represented. She also endorsed the need to benchmark whether we’re interpreting policy and regulations in a manner consistent with the rest of the science community. Morrison suggested that training include departmentally based staff who can then contribute to the pre-review model. Lidstrom noted the Provost’s belief that institutions sometimes have special opportunities—a moment in time—to effect significant positive change. Lidstrom hopes this will be the case for HSD. Stewart referenced Paul Hopkins’
report that addresses ORIS’ role and services. The report said that ORIS needed more guidance, and that they
tended to move in directions not well-aligned with the rest of the institution. The committee briefly discussed
the centralized C&C model and options to this model.

Regarding the Associate Vice Provost for Research, Compliance search process, Lidstrom is willing to
include a representative of the FCR in the application screening process. Also, she intends to convene a broad
interview team.

Stewart asked whether accreditation will reduce Federal scrutiny. Lidstrom thought not, given the size of our
research enterprise. Zuiches added that despite the federal government’s statement that they won’t require
accreditation, pursuing accreditation will set a standard that stabilizes UW’s approach and assures procedures
are in place. Dworkin noted that accreditation will also enable structured self-analysis.

Welton noted that UWISE was advertised as a service improvement and efficiency boost for faculty, but some
colleagues have found it to be slower and more frustrating. Lidstrom agreed that more faculty input is
necessary as they proceed. Not very much usability testing has occurred during the development of some
campus systems. Discussion addressed the expertise of the Technical Communications department as a
resource.

b. Export Control Policy (Zuiches)
Zuiches circulated a letter from Lidstrom to UW faculty, reiterating the significance and seriousness of Export
Control laws which govern strategically significant technologies. The letter is posted on the OSP website.
Zuiches recapped the historic status of export controls. Universities enjoy the benefits of fundamental
research exclusion if they comply with regulations. As a result, university publications are not restricted, and
there are no restrictions on foreign nationals’ involvement in research activities. These exclusions and
allowances date back to the 1980s. Zuiches would like to update the committee on recent developments. The
federal Department of Commerce seeks to undermine these exclusions via new rulemaking. This would
change the definition of “use”, to include operating and maintenance of affected technologies. Such activities
would now require a license for any individual foreign national. For example, some mass spectrometers are
included. Per the new proposed rules, access would be defined by your country of birth. UW’s foreign
graduate student numbers are a much lower volume than many of our peer institutions, thus other institutions
would be very significantly affected by such changes. And industry-focused organizations have been
similarly concerned. Congress received over 300 responses from academia and industry objecting to aspects
of the proposed rules. A revised Federal proposal will probably be published in January.

Soon after this was published, the Department of Defense proposed some changes to their rules, and the same
community responded with negative input. DOD has deferred a decision pending the outcome of the
Commerce proposal.

Zuiches has formed a committee, including Purchasing, faculty representatives, Tech Transfer, the Security
Office of APL, staff from the Office of Sponsored Programs, Environmental Health and Safety, and Theresa
Richmond from the Attorney General’s office. Several people attended an NCURA conference on this topic,
and found the networking with other universities to be quite helpful. The Department of Technical
Communications is building a training module for the OSP website. Will expand training to assist the Travel
Office, Graduate School, and Libraries.

A small number of countries (Cuba, Syria, Liberia, Sudan, Libya, Iran, and North Korea) are embargoed, and
all activities involving them must be licensed. This means that faculty traveling to these locations cannot
transport data. They should also not leave behind their laptops when they return to the US. Zuiches noted
that faculty who violate these rules are at risk of personal fines and jail time, as is stated in the Lidstrom
memo. UW is likely to contract with a company which is positioning itself to provide a matrix of countries and associated regulated technologies.

Zuiches noted that the Department of Treasury focuses on services and money flows pertaining to Export Control laws, and includes oversight of distance learning programs in their scope. Affected foreign nationals can’t enroll in regulated distance learning programs.

Shipping to foreign countries, collaborating with foreign countries, working with foreign nationals, working with proprietary information (this is not protected under fundamental research exclusion): these are reasons to consult with OSP. Recently, it took 6 months to obtain a license for a money transfer to Sudan for research purposes.

Earth and Space Science must be very attentive to these regulations, as they work with satellites. These fall under ITAR. Every talk they give must be considered in light of export control regulations. Haselkorn noted the appointment of a Vice Provost for Global Affairs and suggested that UW should have a broader group engaged in these issues. Lidstrom will be talking to Susan Jeffords soon, and will cover this topic.

Zuiches noted that COGR has been very active on this issue. AAU has also been an active participant. Every university is working on this issue. Industry associations are also pushing back on the federal government.

c. Faculty Effort Certification and Response to Draft DHHS OIG Research Compliance Guidance (Camber)

In 2003, DHHS’ Office of Inspector General announced they were working on compliance guidance for universities. Universities objected, but in September 2005 OIG issued draft compliance guidance. The date for responses has been extended to 30 January 2006. OIG’s purpose: to strongly recommend that universities have compliance programs. They recommend only one model program, which doesn’t fit all universities, and their general approach is overly prescriptive. They’ve emphasized three risk areas, including effort reporting. UW is very concerned about their approach. For example, the language pertaining to effort reporting is moving from tolerance of a certain amount of estimation, to an expectation of accuracy and attention to detail. Universities and major organizations are responding with written objections. Part of the argument against this guidance is that OIG is adding requirements on effort that go beyond those stated in OMB Circulars A-21 and A-110, and that their initiative is not coordinated across all federal agencies. Camber is responding on behalf of UW, and welcomes FCR’s input. Stewart will circulate a four-page document from Camber following this meeting. The AG’s office has provided some written feedback to Camber. She’ll be seeking input from other campus groups, and will finalize her comments to OIG by the end of January. She will circulate a draft to FCR. Circular A-21 was intended as the single source of guidance, but over time other governmental entities are stepping in and adding to the regulatory content.

Stewart asked if faculty effort reporting would work better if faculty committed to a fixed number of hours committed to individual grants and obligations. Camber noted that effort reporting has been based on percentages for over thirty years, and that we should think very carefully about changing to hourly reporting. How would faculty document hourly time commitments? How would faculty address fluctuations in their schedule from week to week or month to month? Franz suggested that UW establish a metric that communicates explicitly the number of hours expected of faculty. Camber noted that the federal government doesn’t want to be funding grants and contracts that cover your 40 hours, so that they’re paying your full salary, when you are working an additional 20 hours on other activities in support of the University mission. Dworkin suggested that identifying a base number is the lesser evil. Camber suggested that universities should argue that productivity should be measured on whether the science was done. She noted, however, that institutions which have paid fines for inadequate effort reporting have not been criticized for failing to complete the science—productivity is not considered by the federal government in setting standards for faculty effort reporting.
3. Upcoming Issues for Winter Quarter Meetings
This was not discussed due to lack of time, but is planned to be addressed at the next meeting.

4. New Business
   a. Request from the Chair of the Faculty Senate to Examine Outside Compensation and Forms 1460 and 1461 in light of new FEC Rules
      This was not discussed due to lack of time, but is planned to be addressed at the next meeting.

The meeting was adjourned at 9:30 AM. Minutes by Kathy Bracy, Director of Finance and Administration, Office of Research and Graduate Education, School of Medicine. Minutes approved by FCR on 19 January 2006.

Present:  Faculty members: Booth-LaForce, Fluharty, Franza, Haselkorn, Haeseleer, Morrison, Rasmussen and Stewart  
Ex officio members: Ashby-Larrabee, Crown, Dworkin and Lidstrom

Absent: Faculty members Benner, Kiyak, Kumar, Miller, Vogt and Wright  
Ex-officio members: Barker, Lowell, Slattery and Welton

Guests: Carol Zuiches, Assistant Vice Provost for Research, Office of Sponsored Programs  
Susan Camber, Assistant Vice President, Research Accounting and Analysis