Chair Cathryn Booth-LaForce called the meeting to order at 10:32 AM.

**Meeting Synopsis:**
1. Call to Order and Approval of Agenda
2. Introductory Comments
3. Approve minutes from 8 June 2007 FCR meeting
4. Announcements
5. Volunteers
   - Classified, Proprietary, & Restricted (CPR) Research Subcommittee
6. Requests for Information and Updates
   - Update – Office of Research (Mary Lidstrom, Vice Provost for Research, Office of Research)
7. New Business
   - Initiating clinical studies and faculty burden issue (John Slattery, Vice Dean, Research and Graduate Education, School of Medicine)
8. Discussion
   - Issues for the 2007-2008 academic year
9. Adjournment

1. Call to order and approval of agenda
Cathryn Booth-LaForce opened the meeting at 10:32 AM by asking for the approval of the agenda.
Agenda approved.

2. **Introductory Comments**

Cathryn welcomed everyone to the new academic year and read the Charge for the Faculty Council on Research.

The Faculty Council on Research (FCR) is one of twelve advisory bodies to the Faculty Senate and is responsible to the Senate Executive Committee (*University Handbook Vol. 2, Part 4, Chapter 42, Sec. 42-31*). The FCR serves as the deliberative and advisory board for all matters of University policy relating to research and is the primary forum for faculty-administrative interaction in determining that policy (*University Handbook Vol. 2, Part 4, Chapter 42, Secs. 42-31 and 42-37*). One of our weightier responsibilities deals with Classified, Proprietary and Restricted Research (*University Handbook Vol. 4 Part II: University Research, Chapter 1: Classified and Proprietary Research*). The FCR does not have general oversight responsibility for the University policy on the protection of human subjects, which is the responsibility of the Research Advisory Board (*University Handbook Vol. 4, Part 2, Chapter 2, Sec. 7*).

3. **Approval of minutes from the 8 June 2007 FCR meeting**

The minutes of the June 8th meeting were approved.

4. **Announcements**

Cathryn asked if anyone had any announcements or comments. There were none.

5. **Volunteers**

Cathryn asked the council members if anyone would be willing to volunteer their services on the Classified, Proprietary, and Restricted Research Subcommittee. Ronald Stenkamp volunteered to join the other subcommittee members; Dan Vogt and Gerald Miller. Cathryn thanked Ron for volunteering. Dan Vogt will continue to be Chair of this group.

6. **Request for Information and Updates**

- Update: Office of Research (Mary Lidstrom, Vice Provost for Research, Office of Research)

Mary Lidstrom distributed a handout to the council members updating activities for the Office of Research over the past year. A lot has been happening over the past year. The Office of Research’s overarching goal is to support the research effort broadly across the institution. The strategies used were:

- Focus on people (Faculty, staff and students)
- Focus on partnering to achieve common goals
Over the past year many improvements have been made in a number of categories:

- Communication and training
- Process improvement, including electronic systems
- Policy development
- Organizational restructuring
- Support and recognition for researchers

There have been challenges and opportunities for growth:

- Grants.gov transition for submission of proposals
- Transition to an electronic business system in both OSP (Fall 06) and HSD (Fall 07)
- Turnover of Directors in OSP and HSD
- Upcoming move to the UW Towers
- Ever-increasing workload
- Decreased availability of research funds
- Increasing competition with other universities and states

Progress has been made in areas of communication and training.

- Improving web sites
- Developing training materials and workshops
  (i.e., Grants. Gov and HSD training for behavioral sciences)

Some accomplishments in organizational restructuring are:

- Hired Debbie Flores as Director of Operations and a consultant (Cheryl Hawley)
- Launching iSTAR (improved service to Advance Research)
- Our Goals:
  - improve customer satisfaction and process partner relationships
  - improve the working climate in the Office of Research
  - improve employee morale and job satisfaction
  - improve operational and organizational effectiveness

- Restructuring in OSP
  - It was announced that Carol Zuiches was moving to a policy-development role in the Office of Research. However, since that announcement was made, Carol has accepted a position at the University of Chicago; her last day in the Office is December 12th.
  - New Director Search underway; the focus is on business management and the target change is November 2007 but may be as late as the first of the year.

- Restructuring in HSD
  - Karen Moe is Director
  - Hired two new Assistant Directors
The Office of Human Subjects has had many successes to-date. The “Minimal Risk” review team is now larger and re-organized, which improves the turn-around time and a better match between reviewers and topics. Many new processes have been developed. Specimen research does not need to be reviewed, which will help reduce the workload for many researchers and the workload for HSD staff and the IRB. There is also improved communication with researchers about changes in forms, policy and process improvement through our new electronic newsletter to researchers. The required application copies has been reduced from 9 to 3 which has helped reduced work and cost for researchers and increased efficiency in HSD processing. There is a rapid response system for numerous materials requiring HSD management sign-off, which creates a significantly faster turn-around and no lost materials.

There are many efforts currently underway in the Human Subjects Division such as forms revision with better questions and better applications, which makes for a shorter review letter and shorter turn-around time. Policies and procedures and guidance required for accreditation application (March 2008) have been expanded. The current focus is identifying what research does and does not require IRB review, exemption policies, and public data sets. Guidance through active input from Human Subjects Policy Board and small working groups of HSD staff and researchers have helped to expand new policies and procedures and better guidance. Also the web-based submission and review system which was developed through a local consortium (Fred Hutch Children’s, Benaroya, UW) will result in common application forms (should be completed around 4th quarter, 2008). These “Smart forms” will have questions tailored to research topics and methods. The paper absence will help reduce HSD processing and improve efficiency.

There has also been much progress in the Office of Sponsored Programs (OSP):

- Transitioned to an electronic management system
- Hired a consultant, carried out training and management, identified front desk as key issue
- Developed flow charts for industrial sponsored research agreements
- Working with the Clinical Research Budget and Billing (CRBB) support office and Oncology on oncology clinical trials
- Developed a process to handle early grants well before the deadline

SAGE (System to Administer Grants Electronically) has had many successes to date:

- Electronic upload and routing of all applications has eliminated walking all over campus and eliminated the load on the email system
- Capability of copying existing eGC1 has reduced data entry for renewal and resubmissions by 40%
- With the 250 word limit removed, there is no need to write two versions of abstract
- SAGE was built out of OSP system, which consolidates institutional data into a single system of record, reduces redundant data entry, foundation built for further expansion of SAGE and has an auto-generation of 10 standard communications.
SAGE has several efforts currently underway. With the development of 424 R&R and NIH specific forms first; we were able to develop and start a system-2-System with Grants.gov in June 2007 and plan to pilot submission rounds to start February 2008. A user task group was formed in April 2007 and with the completion of the prototype and requirements; we can now start on Phase I focus on UW standard budget preparation with the development of a detailed budget module to begin in October 2007. Also in October 2007, the technical design will be started for a pre to Post-award hand-off. This electronic system is being developed in Grant and Contract Accounting and will capture and hand-off the notice to establish award and requirements and prototype screened approvals. By working with an outside consultant, we have redesigned SAGE 2.0 for improved high-level navigation, integration of search, new task-list features and email notifications, and have improved the visual design and ease of use.

The Office of Research still has many challenges and issues to face. Some of the issues are:

- Turnaround times for all processes still unacceptable, but many have improved
- Transparency of policies and information still largely lacking
- Mechanisms to gather input are not in place
- Communication to the community still poor

Through iSTAR these issues should improve.

Other issues and challenges through new initiatives are:

- The coordination with other units both on and off campus needs major efforts
- Electronic systems needed in many areas
- Barriers exist to interdisciplinary research
- Need tools and expertise for mega projects
- Leadership training and support needed

Also, with the support of e-science infrastructure and through e-science initiatives this area should improve.

At the end of Mary Lidstrom’s update of the Office of Research, Cathryn asked the Council members if they had any hot buttons that they wanted to ask about. David Fluharty asked about limited submissions since Mary had not mentioned them.

Mary explained the process involved in limited submissions to council members. The limited submissions are coordinated out of the Office of Research and we have a review committee that selects what proposals are selected for submission. This review committee is headed by David Eaton, Associated Vice Provost, in the Office of Research and consists of Associate Deans from around campus. Also, Peggy Fanning organizes limited submissions by establishing a due date to the Office of Research and getting the information out to appropriate areas on campus. We have also created a new web site of limited submissions under faculty funding opportunities on the Office of Research web page.

Grants and Contract Accounting was also discussed. Mary Lidstrom acknowledged that there have been a lot of complaints regarding Grants and Contract Accounting. There
has been a huge increase in workload without a corresponding increase in the staff to handle it. Mary said she has been working with Sue Camber and V’Ella Warren to help resolve these issues.

Cathryn wanted to know if it would help if the members of the Faculty Council on Research write letters regarding these problems. Mary thought that would be a good idea. Mary and Cathryn plan to get together to work on the text.

Cathryn thanked Mary for her update over the past year on the Office of Research.

7. New business

- Initiating Clinical Studies and faculty burden issues

John Slattery, Vice Dean, Research and Graduate Education, School of Medicine, came to talk about initiating clinical trials and the faculty burden issues that are involved. The 2007 definition of a clinical trial is: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

There are so many problems with clinical trials that many researchers don't even want to get started. The International Committee of Medical Journal Editors (ICMJE) announced that in order for clinical trial results to be considered for publication in journals that adhere to ICMJE standards, all clinical trials that start recruiting on or after July 1, 2005, must be registered with a public registry before enrollment of the first patient.

In June 2007, the ICMJE re-evaluated its original policy and published an editorial, "Clinical Trial Registration: Looking Back and Moving Ahead." The editorial presents a revised “clinical trial” definition and describes registries currently acceptable to the ICMJE. The editorial also discusses the movement toward possible registration of trial results. The Committee’s purpose is to promote the public good by ensuring that everyone can find key information about every clinical trial whose principal aim is to shape medical decision-making, and to foster conditions in which decisions about care rest on all of the evidence, not just the trials that authors decided to report and that journal editors decided to publish.

The goal of the Clinical Research Budget and Billing Support Office (CRBB) is to achieve a system, which delivers the right bill for the right amount to the right payer at the right time. However, there are so many restrictions for General Clinical Research Center (GCRC) and Medicare. The GCRC is funded by NIH to provide facilities and resources for peer-reviewed clinical studies. The GCRC helps investigators conduct research with human subjects under the highest standards of safety.

The process of setting up a clinical trial, with the registration with the CRBB which can take months, the problems with billing Medicare and other restrictions, and the turn-around time before you can even see a patient, sometimes seems mind-boggling. There are about twelve separate offices, four different organizations where you need to get approval. Setting up a clinical trial could take as long as six months from start to finish. Then pricing is another problem involving budget review, and Oncology is separate from the IRB review. We need to identify what can be paralleled, for example, the review of
OSP with the CRBB. There are also two software issues; study manager and study enrollment. There are so many steps to take, a researcher needs to know what to do and in what order. By hiring a UW Clinical Coordinator, we may be able to increase productivity and get through this process in three months instead of six. The UW is a teaching hospital not a research hospital.

This is an important growth area and our mission is critical.

Cathryn thanked John for his presentation initiating clinical trials and burdens on researchers.

8. Discussion

- Issues for the 2007-2008 academic year

Gerald Miller asked about the Royalty Research Fund (RRF). He wanted to know the purpose of the RRF and what they are doing. Is it mainly for young researchers over established researchers - just what is the purpose?

Mary Lidstrom said that they review the RRF every five years and it is time to do another review. The review might be put on hold for another year. As far as who gets funded, about two thirds are assistant professors and about twenty percent of the applications get funded. There are two philosophies: 1) take a little bit of money and spread it out to RRF preproposals, or 2) give money to larger groups. The current policy is to spread it out more like seed money and hope that it opens more doors for funding possibilities.

One of the problems in RRF is getting stronger reviewers to write the reviews. The reviewers are volunteers and maybe sometimes not the strongest in the field of the particular area they are reviewing. We don’t want to send the proposals out to outside reviewers and give away some of our research ideas, plus it is hard enough to find volunteers.

Mary said that Provost Wise was extending the Bridge Program for another 2 years. The bridge program has more emphasis on junior faculty who have brand new directions and/or new ideas.

David Fluharty has three items that he would like the FCR to look at: 1) the Homeland Security issue was asking if the UW researchers were finding that they may lose access to their own data on the federal website due to new security issues; 2) the effect of proposals for a College of the Environment on research at the UW; and, 3) the status of the APL issues that we discussed last Spring.

9. Adjournment

Meeting adjourned at 11:58 AM. Minutes by Peggy Fanning.

Present: Faculty members: Booth-LaForce, Fluharty, Miller, Schwartz, Stenkamp, Vogt, and Wright

President's designee: Lidstrom
Other ex officio members: Russell
Absent:
Faculty members: Haselkorn, Khagram, and Wright
Ex-officio members: Allen, Harrington,

Guests: Peggy Fanning, Susanne Redaje, and John Slattery