



**MINUTES  
HUMAN SUBJECTS POLICY BOARD**

**9:00 – 10:30 AM  
September 28, 2007  
142 Gerberding**

Members Present

Cheek, Jeff, **Chair**  
Booth-LaForce, Cathryn  
Buck, Steven  
Burke, Wiley  
Eaton, David  
Mason, Robert  
McCutchen, Deborah  
Mitchell, Pamela  
Moe, Karen  
Saxon, Andrew  
Slattery, John  
Streidl, Gigi

Members Absent

Barker, Theresa  
Brown, Zane  
Brunzell, John  
Chaney, Edmund  
Crutchfield, Robert  
Kuszler, Patricia  
Rein, Rebekah  
Rimmele, Carl  
Sherrard, Donald J.  
Takeuchi, David  
Thummell, Kenneth  
Wilensky, Alan  
Zuiches, Carol

Announcements

Jeff called the meeting to order at 9:00 a.m. There were no announcements.

Approval of minutes from meetings of 5/25/07 (Jeff Cheek)

The Board accepted the 5/25/07 minutes with minor corrections.

Follow up on previous 5/25/07 Policy Board meeting agenda items (Karen Moe)

Karen provided follow-up on previous agenda items from the 5/25/07 Policy Board meeting.

First follow-up item: Public Data Sets

Karen summarized the Board decisions from the 5/25/07 meeting about research using public data sets, which will be implemented by mid-October 2007. The Board had no changes to what was agreed upon (e.g., public data sets that did not contain identifying information were not considered to be human subjects research.) The Board had agreed upon the list of what those specific data sets are. The policy, procedures, instructions, verification for researchers, and the list of public dataset will all be posted.

Second follow-up item: Audio taping in exempt research:

Karen Moe summarized that Board decisions. She reported that after the 5/28/07 Policy Board meeting, there was a working group composed of three faculty members and a HSD staff member that dealt with the list of concerns. Using the recommendations of that group, a HSD team is revising the exemption form. The group is also examining, revising, and documenting unwritten policy and procedures related to the review of exemptions. One board member asked whether departmental review of exempt research was sufficient review such that HSD review was not required. Karen responded that she would like to see the review of exempt research continue to be conducted by HSD office because departmental chairs have not been provided adequate education about the

criteria and categories of exemptions. The Board discussed the implications and meaning of requiring the chair's signature on exempt applications going to the Human Subjects Division. The discussion also focused on the turn-around time of exempt applications.

**Progress update and discussion of current initiatives at HSD (Karen Moe)**

There are five current initiatives at the Human Subjects Division: a) HSD/IRB process improvement, b) accreditation, c) regulatory compliance of researchers and of the IRB, d) information and assistance to researchers, and e) coordination with other UW compliance offices. Her overall approach to current initiatives has been to look at root causes of problems in HSD when developing solutions.

**A) Specific HSD/IRB process improvements:**

The goal of the process improvement project is efficiency, transparency, and consistency.

1) New database for HSD

The database is being developed by a consortium consisting of Fred Hutchinson Cancer Research Center, Children's Regional Medical Center, Swedish Medical Center, Benaroya Research Institute at Virginia Mason, and the University of Washington. The new database will allow the office to track each part or process of IRB review, provide reports to other UW offices, and track all studies funded by a particular center grant. It will also serve as the foundation for a future electronic application submission system. None of these things are possible in HSD's current database.

One board member wanted reconciliation between subject enrollment tracking by the IRB versus the Clinical Research Budget & Billing office (CRBB). Another request was to have the Human Subjects Division office post goals of turn around time. Jeff pointed out that HSD did post information about an expected summer slow down. He added that posting specific turn-around time definitely a HSD goal. The Board discussed the impact of publicly posted turn-around times and the best way to present information.

2) HSD management team:

The HSD management team is finally complete with the recent addition of Wendy Brown, Assistant Director of Quality and Compliance.

3) Dual review by biomedical and behavioral IRB committees:

Some IRB applications have been reviewed by both a biomedical and a behavioral IRB committee. This process was examined and subsequently eliminated as unnecessary and inefficient.

4) HSD's general email address ([hsdinfo@u.washington.edu](mailto:hsdinfo@u.washington.edu)):

Researchers and research staff use this address to pose questions to HSD about IRB review. Karen examined the process used for answering these questions, and the turn-around time. As of Monday 10/1/07, this email address monitored and triaged/answered by a different process and by more experienced and knowledgeable HSD staff.

5) HSD quality assurance projects:

Several quality assurance projects are being currently conducted, to ensure that HSD and IRB processes are compliant with federal regulations. Two examples are: IRB meeting minutes, and the granting of waivers of subjects consent.

6) HSD Minimal Risk Group:

All of the HSD staff for this group have been hired and trained. HSD management has reassigned workloads, and the Assistant Director of Operations is working with this group to examine processes and policies. A “roving” staff person will join the group in December to help with the expected winter quarter surge in IRB applications.

7) Research funding by the Department Of Navy (DON):

The University of Washington receives significant research funding from the DON. DON recently mandated that IRB apply some additional steps and criteria when reviewing DON human subjects research. HSD has developed an application supplement and a written procedure document to meet this requirement, and to guide researchers and the IRB.

In additional discussion, the Board discussed the large Clinical & Translational Science grant just awarded to the University. The Board hoped the CTSA infra-structure would improve cooperation among the IRBs of the four institutions participating in the grant and among compliance offices within the UW. The Board then asked about the IRB’s use of outside consultants. Karen stated that this is being addressed in several ways. (1) HSD has started a pilot project using video-conferencing to coordinate reviews with IRBs in other countries. (2) HSD management and staff are recruiting groups of consultants to tap for reviews involving specific issues (e.g., genetics, online forums). (3) The UW Attorney General’s office has been consulted more frequently (e.g., intellectual property, response to requests for research data). (4) A new program of intense 1-2 hour focused education sessions for HSD staff on specific research topics has been started (e.g., Dr. Ann Collier’s presentation on HIV/AIDS research).

B) Accreditation

Karen informed the Policy Board that she had negotiated with the accrediting organization (Association for the Accreditation of Human Research Protection Programs; AAHRPP) for a delay in the application due date. The due date is now March 1, 2008. Karen reminded the Board of the federal requirement to have all Veterans Affairs IRBs accredited. The UW IRB is the IRB of record for the Seattle and Boise VAs.

AAHRPP will want to meet with UW Policy Board as a group and/or with individual Board members, during its accreditation site visit (likely to be May, 2008). Karen will provide preparation materials to the board members.

C) Researcher compliance issues

Karen reported that HSD has been handling significantly more researcher noncompliance cases than in the past. This is undoubtedly due in part to the establishment of better reporting and managing procedures. Karen reported that the Dean of Graduate school will soon implement a new policy requiring all graduate students and their advisors to sign a form prior to beginning their thesis or dissertation work, stating that they are aware of Human Subjects and IACUC requirements. This policy should help reduce one major source of noncompliance (students conducting research without IRB approval). It will also emphasize the responsibility of advisors and departments in helping to appropriately advise students about the responsible conduct of research.

Karen informed the Board about her work with the Office of Financial Management in identifying and reducing confidentiality issues and tax reporting issues related to paying subjects. Together, the two offices are increasing education and guidance efforts to researchers and departments about these issues.

D) Information and assistance to researchers

Karen reported that Sharon Elsayed, HSD Assistant Director of Education & Communication, is developing several specific education modules for researchers. There will also be a major upgrade to the HSD website.

#### E) Coordination with other UW compliance offices

Karen reported that HSD (and OR) is working with other offices to making it easier for researchers to interact with all UW compliance offices. For example, Karen has been working closely with the Radiation Safety Committee to help implement a recent regulatory clarification about which types of radiation risks need to be described in research consent forms. This clarification means that a significant number of studies will no longer require Radiation Safety approval.

#### OR's Improving Service to Advance Research (iSTAR) initiative (Jeff Cheek)

Jeff described one of the first of two initiatives coming from Mary Lidstrom's office, both of which will involve OSP and HSD in some way. The "Improving Service to Advance Research" initiative is to look at process improvement but across all of the units within OR. The goals are to improve professional service, partner relationships, make units within OR better places to work, improve staff morale, and increase organization effectiveness.

#### OR's Responsible Conduct of Research Initiative (RCoR) (Jeff Cheek)

Jeff described this work, which was initiated by Mary Lidstrom working with a group of senior compliance administrators. The goal is to make a comprehensive assessment of research compliance offices, how the units interact with each other, describe the responsibilities of each, and determine what kind of information is provided to researchers. The end goal is to develop a more integrated and efficient approach to training in the responsible conduct of research. The Board discussed who should be involved in this effort, including at least one faculty member from the Department of Medical History & Ethics.

#### New business and future agenda items (Board Members)

The Board suggested the following items for future meeting agendas:

- How to provide information to researchers in an effective manner. One idea was to provide pop up menus of providing instructions to researcher in any future online IRB submission process.
- Effective recruiting of IRB members. One difficulty is in providing potential members with "course release" time. The Board felt that the discussion should involve what expectations were of what it means to be faculty.
- Integration of the CTSA scientific review process and the IRB review process.

The meeting was concluded at 10:30 a.m.

Minutes recorded by Arna S. Elezovic.