



OFFICE OF RESEARCH

**MINUTES  
HUMAN SUBJECTS POLICY BOARD  
9:00 – 10:30 AM  
January 16, 2009  
Gerberding 142**

Members Present

Cheek, Jeff, **Chair**  
Barker, Theresa  
Buck, Steven  
Burns, Stephen  
Brown, Zane  
Chronister, Lynne  
Crutchfield, Robert  
Karpen, Richard  
Mason, Robert  
McCutchen, Deborah  
Mitchell, Pamela  
Moe, Karen  
Rein, Rebekah  
Rimmele, Carl  
Saxon, Andrew  
Spigner, Clarence  
Thomas, Karen  
Thummel, Ken  
Turns, Jennifer  
White, Emily  
Wilensky, Alan

Members Absent

Brunzell, John  
Burke, Wylie  
Hamblin, Mark  
Neff, Margaret  
Sherrard, Donald  
Slattery, John  
Spieker, Susan  
Takeuchi, David

Guests

Shannon Swards

Welcome:

Jeff called the meeting to order at 9:07 a.m.

Approval of minutes from meetings of 11/21/08 (Jeff Cheek)

The Board accepted the minutes of the 11/21/08 meeting as submitted.

Continued discussion on research in humanities and social sciences - when is IRB review required?  
(Karen Moe)

The HSD office is continuing with their broad educational objective to educate campus on IRB compliance requirements. From the HSD standpoint, the objective is more of an outreach issue to

promote awareness of what constitutes “human subjects research” and when IRB review is required. Efforts also include identifying what educational materials are in place and what materials might need to be developed to convey whether IRB approval is required. Some of the boundaries for when IRB review is required are not always clear, but identifying these boundaries will assist in developing resources.

#### Performance metrics and forthcoming HSD “dashboard” (Karen Moe)

Karen referred to three handouts distributed at the meeting. These handouts are a response to a long-awaited request from campus stakeholders asking for information on turnaround times. One objective, which is closely tied to the Office of Research’s (OR) iSTAR initiative, is for HSD to create a dashboard which will include published performance metrics that can be made available to the public. Karen reminded the Board that this has been a multi-year effort which has included cleaning up the HSD database and developing queries from the database to provide responses. Karen invited Board members to provide input on how best to use the information presented via the dashboard. In the last 4-6 months, solid metrics have been developed and this meeting is the first-time the metrics are being presented. Karen next reviewed the metrics table provided on one of the handouts.

Some results HSD has identified from this first set of metrics are the following:

1. Mapping of a business process: HSD has identified approximately 19 discrete steps in the review process. The numbered items in the metrics report represent review activities, separated by events (e.g. IRB meetings). This information will allow HSD to calculate metrics which will identify bottlenecks and suggest areas for improvement.
2. Limitations to metrics analyses: Due to some programming limitations in the database, not all review process steps can be automatically analyzed. HSD is currently working around this challenge through manual input into the analysis.
3. Development of reports: A variety of metrics for different parts of the review process are used internally:
  - a. Tracking within the HSD office. HSD staff are given reports monthly or weekly that include the following:
    - i. New IRB submissions received but that have not received IRB approval.
    - ii. Report of items that have not received responses from PI.
    - iii. Report showing inconsistent or incomplete data entry.
  - b. Metrics to identify areas for process improvements.

While reviewing HSD processes, we discovered there are highly variable steps in the process that contributes to turnaround time. One example is the initial intake process of IRB applications. This includes date stamping applications when they first arrive, data entry, limited screening, and assigning the application to the appropriate IRB staff or IRB Committee. HSD is working with initial intake staff to identify and address the factors that contribute to variability in this process.

Some Board members provided input on strategies to improve review processes which included the following:

1. Send poorly written IRB applications back to the applicant. Encourage the applicant to work with colleagues familiar with the IRB process. This may reduce HSD staff and IRB Committee time required to review the application.
2. Have HSD staff work with PIs to revise applications before the application is presented to full IRB Committees. This will potentially reduce the number of times the application goes back to full Committee.
3. Publicize the information that HSD staff are available for consultation.

Karen stated that another important factor is the clarity of the HSD forms. Jeff noted that, in general, people on the front line doing research are at the forefront of the UW's human research protection program (HRPP), and thus we seek to provide them with the information and business practices to facilitate compliance with UW policy and federal regulations. We want to identify how to promote good business practices to facilitate the overall UW HRPP. Although certain individuals submitting to the IRB are challenged with unique situations, such as time pressures and lack of experience with the IRB, the metrics will assist HSD in focusing what effort should be made and developing concrete solutions.

Karen stated the metrics will also be useful for compliance and auditing purposes, and for identifying research trends. For example, reports identifying international research issues specific to certain countries facilitates operations with IRBs in that country. One Board member asked if it might be foreseeable that other campus departments can use the database for specific queries. Karen reported that this request is already under consideration, but due to confidentiality issues there may be challenges. In the meantime, the overall metrics will be made available to campus. Karen described the information that would be made available, which includes the following:

- 1 Dashboard: HSD will start by posting basic metrics on its website. Further developments and metrics will follow the dashboard model developed by the Financial Management Office. Their dashboard tracks historical data over time, is easy to read, uses a consistent format which includes graphs with numbers and definitions, and provides brief analyses of what has occurred within each reporting period. Jeff informed the Board that though Financial Management's model is a good example to follow, there will be some differences because HSD does not have the dedicated resources required to produce a complete dashboard of this type, and because Financial Management utilizes dynamic data whereas HSD must take snap shots of data that are retrospective as opposed to "real time".
- 2 Preliminary basic turnaround times and definitions, including a measure of average, variability, and total range.

Karen invited Board members to take the metrics provided so far and to review these with others on campus and to provide input on other ideas.

One member suggested that it might be useful to have a flow chart to show PIs the different steps of the review process, including minimal risk reviews. This may give researchers an idea of what happens to proposals and the status. Karen stated that one HSD objective is to educate researchers about what part of the review process the HSD and IRB controls versus what part of the review process PIs can control. The overall turnaround time number is important, but researchers could find it valuable to know where in the process that their participation is critical.

Karen reported that the initial analysis has revealed better turnaround times than were expected. This demonstrates the positive impact of changes in UW IRB business practices, additional resources, and other improvements. The IRB Chairs also deserve credit for this positive trend. The Board discussed types of improvements that might occur in addition to reductions of average turn-around time. One improvement would be to reduce the variability of turnaround. Another type of improvement is not related to overall turn around time, but with the number of times any single application may go back and forth between researcher and the IRB. This leads to another benefit of the metrics in that we can identify specific departments that might be having challenges with IRB applications in general. We can then approach the Department Chair asking if HSD can present at a department meeting.

One member asked if there will be an on-line tracking system in the future that PIs can access. Karen reported that this is part of an ongoing multi-year effort called the Research Roadmap Initiative. This initiative will create a portal for PIs, which will eventually include a database that will identify the status of applications in each office. Finally, Karen reported that the first HSD Performance Metrics Report will be published by the end of February, followed by quarterly updates.

#### Update on VA status: audit, restrictions, separation from UW IRB (Karen Moe)

Karen summarized previous discussions regarding the audit of the Seattle VA. The Western region of the VA Office of Research Oversight conducted an audit of the human research protection program at the VA Puget Sound Health Care System (informally called the Seattle VA). The audit team imposed restrictions on the Seattle VA human research program, which included re-reviewing every active human research study. The UW IRB committees at the VA started re-reviewing studies on December 15, 2008. Approximately 20% of the studies have undergone re-review. The estimate for when all studies will be re-reviewed is approximately two months. To date, the re-reviews have not identified any problems that impact the risk or welfare of subjects.

There continues to be challenges in working with the ORO audit team. The UW IRB is seeking to have some restrictions reduced first, than the next step will involve tackling the requirement of separating the Seattle VA from the UW IRB, which will probably occur by June 2009.

#### Implementation details of compensation initiative for service on social / behavioral IRBs (Jeff Cheek)

Jeff reminded Board members that he requested their assistance in spreading the word about the compensation initiative, and that the problem being addressed is the need for greater disciplinary expertise on the UW IRBs. The question is how will we encourage greater faculty participation and provide an appropriate inducement. Due to workload and disciplinary requirements, the initial target audience is faculty primarily on upper campus and in the social/behavioral sciences.

The strategy is to provide compensation to the academic unit for the faculty member's time, which could include either course buy-outs or some other incentive to encourage their scholarly activity. This is not a "quid pro quo" compensation directly to the faculty member for IRB service. Jeff provided a handout describing the status of this project. He requested that Board members please communicate to faculty members that this mechanism will be in place sometime in the Spring quarter this year. A written communication will be developed and published as policy.

Karen explained that the initial funds to support this initiative are from temporary funds from the Vice Provost for Research.

One Board member asked for some follow-up on tracking attendance of new IRB members recruited through the compensation initiative. Jeff reported that this objective will not be pursued at present, since current IRB members donate their time voluntarily and we want to start out with a "good faith" perspective. Right now we are relying on clear communication about expectations and commitment so that newly-recruited IRB members will meet obligations. We will assume that meeting the necessary commitment will not be a problem, but we will also make clear what the expectations are.

One Board member who serves as an IRB Chair stated that most IRB members who serve as reviewers are given applications a week in advance; therefore they have to be in attendance at the IRB meeting. Karen reported that there have been relatively few problems with attendance among current members. One member provide an idea for how to recoup money to be used for the compensation initiative, suggesting that research projects funded by sponsors that do not pay full indirects be assessed a 10% fee for IRB service as a direct cost. Karen reported that at present HSD has relatively few studies involving such sponsors (e.g. private foundations). Lynne suggested that since this is not included in the budget per current UW policy, it could be done in the future. The Board agreed that this issue is more appropriately addressed by the Research Advisory Board and should initially be discussed in that venue.

Karen described that UW HSD does reviews as a courtesy for other institutions, such as the Puget Sound Blood Center. It may be necessary to change this policy.

The Board discussed that the timing of providing compensation might vary based on the needs of individual Departments.

Jeff described the process someone would need to follow if interested in participating in the compensation plan. Potential members are asked to contact Karen or any HSD manager regarding to issue compensation to respective Departments.

#### Request for Board input during next meeting on HSD's FY10 goals (Karen Moe)

Karen reported that HSD is establishing an annual goal identification process in association with the iSTAR process improvement effort in OR. Karen will invite Board members to provide input at the next HSPB meeting.

Updates from the Board and future agenda items (Board Members)

Jeff and Karen invited Board members to provide ideas for future agendas. One Board member asked that the next agenda include discussion of data encryption issues since other Universities have standard procedures for determining to what degree data encryption should occur.

Karen updated the Committee that there has been a successful court challenge to a federal Certificate of Confidentiality. She is obtaining advice from the Attorney General's Office.

Submitted by Kim Blakemore