

**HUMAN SUBJECTS POLICY BOARD
MINUTES
9:00-10:30 a.m. February 9, 2007
142 Gerberding Hall**

Members Present

Cheek, Jeff, **Chair**
Booth-LaForce, Cathryn
Buck, Steven
Crutchfield, Robert
Eaton, Dave
Patricia Kuszler
McCutchen, Deborah
Mitchell, Pamela
Moe, Karen
Rimmele, Carl
Saxon, Andrew
Streidl, Gigi
Thummel, Kenneth
Wilensky, Alan
Zuiches, Carol

Members Absent

Barker, Theresa
Brown, Zane
Brunzell, John
Burke, Wylie
Chaney, Edmund
Handsfield, H. Hunter
Mason, Robert M.
Rein, Rebekah
Sherrard, Donald J.
Slattery, John
Takeuchi, David

Announcements and approval of minutes from December 4, 2006 meeting:

Jeff Cheek called the meeting to order at 9:05 a.m. He reminded the Board that all IRB chairs are members of the Board, and that other members represent key stakeholder groups, thus providing an appropriate cross-section of institutional representation to determine policy on human subjects research. He has met one-on-one with each IRB chair since the last meeting. Many members, particularly those from the VA, had indicated that they preferred morning meetings because of travel time, and Jeff noted that we will attempt to arrange future meetings accordingly (fortunately, the remaining two meetings of this academic year are on Friday mornings). Jeff urged the Board members to feel free to suggest agenda items for future meetings, as the Board represents the key forum by which stakeholders can address issues and policies regarding the UW human research protection programs.

The minutes from the December 4th meeting were approved and accepted.

Updates and process improvements:

Karen announced the addition of new staff at the Human Subjects Division: two in the Minimal Risk group and one administrator. The new administrator, Zan Manning, has experience as an ER nurse, as well as a law degree and a master's degree in bioethics. She will be primarily working with the biomedical IRBs. Karen was also happy to announce that they've hired a new Assistant Director for Operations, Shannon Sowards, who will start March 19. Shannon is from Los Angeles and has been the Director of IRBs at Children's Hospital (in LA). She also has research experience and a master's degree in psychology. Mark Hamblin will be the new co-chair of Committee D (with Margaret Neff), replacing Rebekah Rein, who will be chairing the new VA IRB.

Karen reported that Vice Provost Mary Lidstrom has been working on acquiring new space for the Human Subjects Division, perhaps at Safeco Towers, but if not at Safeco, in surge space that will be freed up after other units move to Safeco in another year or so. Dave Eaton remarked that one problem with Safeco is that, even though it's great space, there are too few conference or meeting spaces to guarantee confidentiality, which would be a problem for HSD. Karen agreed, and said it's more likely that HSD will end up elsewhere on campus.

Karen reported on the "not research" form, now called the "Biological Specimens Determination Form", that deals with use of biological specimens. The new form will be posted publicly and will be available for use by 3/1. She said that the office is working on new formatting for all their forms, which will be widely announced as they become available.

She also mentioned that the new HSD database is coming along. The only remaining development is to look at integrating several business processes among the three institutions sharing the database.

Update on accreditation process:

Accomplishments since the last Policy Board meeting include fixing the automatic email notice sent to researchers when annual status reports are due (which previously had a 5-10% failure rate); clarifying with staff when IRB applications can be closed (which previously had caused widespread confusion); and establishing a secure, confidential listserv around issues related to emergency medicine research (which is challenging to review due to conflicting regulations between FDA and OHRP); and transitioning to the use of flash drives for distribution of IRB applications to the reviewers (which greatly reduces the amount of paper used). The AG's office has offered an internship to HSD to provide advice on dealing with vulnerable populations. The intern will prepare a white paper as well as a Power Point presentation to use for training, and a checklist for use by the IRBs.

Discussion: Standard care risks and consent forms:

Jeff and Karen updated the Board on several IRB-approved protocols from the last few years that involved obtaining consent for research procedures apart from those associated with standard of care procedures. Karen Moe noted that with regard to informing subjects on the risks of participating in a research study vs. potential risks associated with standard of care procedures, there is no clear guidelines provided by federal authorities - it is up to each institution to define its own policy. One member inquired if OHRP expected researchers to require subjects to undergo a separate consent process for standard of care procedures and then again for participating in the research study. Board members also debated just how much detail should be provided to address incremental or theoretical risks, while also needing to keep consent forms as short as possible to ensure that subjects are not swamped with unnecessary or unhelpful verbiage. Jeff inquired of the Board if the UW needs a policy on how to provide guidance on the

adequacy of consent documents on a case-by-case basis; Karen said that OHRP is seeking to have research institutions act accordingly. Jeff closed the discussion by saying that if the Policy Board is comfortable with it, we will draft an IRB guidance form for the Board's review.

Discussion: Undergraduate research:

Karen Moe led a discussion on who can be the Principal Investigator (PI) on a human subjects research project or application. She detailed the current University policy, and asked the Board members to discuss who is ultimately responsible for oversight of human subjects research conducted by students? Should we continue to allow students to be PIs? Should we restrict the circumstances when students can be PIs? Should we add additional training requirements, (e.g., one-on-one sessions with HSD staff)? One Board member said that we need to make a distinction between the capabilities and responsibilities of graduate vs. undergraduate students. One member asked whether undergrads are required to do human subjects research training – under current UW policy, only PIs receiving NIH funding are required to take training in human subjects protection. Another member noted that if faculty were to assume principal responsibility for oversight of all undergraduate research, the faculty may not be able to allow undergraduates to pursue certain projects, given the ratio of student projects to faculty members. Another Board member suggested that if they make the faculty member the PI on the human subjects application, the research might not be as instructional for the student.

Jeff noted that the main issue at hand is the varying degree of engagement by faculty overseeing student-initiated research. Board members' thoughts on how best to address this issue were diverse. One member noted that merely changing who is the PI on the human subjects application won't address the issue of mentor engagement. Another member was completely in favor of changing the current policy, thus requiring the faculty member to be the PI on the application, especially if the research is not minimal risk. There was general consensus that oversight undergraduate-led human subjects research is an extremely difficult issue because many students are not diligent in compliance with institutional policies and federal regulations. The range of engagement in faculty oversight of graduate research is part of a larger issue and perhaps best addressed by the Dean of the Graduate School, among others. Adopting the National Science Foundation's policy was also suggested, which stipulates that both the student and the faculty member are co-PIs and both share equal responsibility for oversight of research.

Jeff concluded the discussion by noting that the administration is not seeking to impose additional controls in place unnecessarily, but there are institutional risks and potential liabilities if we don't address the issue. Karen said she would research the policies of other institutions and create a summary document to distribute for a future Board meeting.

Discussion: Genetics advisory group:

Jeff reported that, during his interviews with current IRB chairs, one recurring theme was that the IRBs need assistance evaluating applications requiring specialized expertise, such as medical genetics. Ideally, IRB staff would like to have access to a pool of researchers willing to answer questions from IRBs. It was also suggested that the pool of experts should be familiar with IRB procedures and federal regulations, but one Board member said that requiring such knowledge of

a medical genetics expert may limit the recruitment pool unnecessarily. Jeff said they need to determine the range of issues and questions that arise during IRBs evaluations, prioritize what needs to be addressed immediately vs. long-term, and then decide on the next steps. He encouraged the IRBs to identify questions and issues they would like to have addressed.

Future agenda items:

When Jeff asked for suggestions of future agenda items, one Board member mentioned following up on the issue of exempting from IRB review some research using publicly-available social science databases

The meeting adjourned at 10:35 a.m. The next Human Subjects Policy Board meeting will be April 13, 2007, 9:00-10:30, in room 142 Gerberding.

DISCUSSION: Who can be the PI on a Human Subjects application?

Current policy

Any faculty member, staff, or student (including classified staff and undergraduate student)

Problems

- Lack of training, experience, knowledge in
 - Research
 - Human subjects issues
 - Other research compliance issues
- Non-compliance
- Risk to students (impact on educational progress, such as dissertation completion)
- Risk to subjects
- Risk to the institution

Possibilities

1. Leave the policy unchanged.
2. Restrict the PI role to a smaller group of roles
3. Restrictions on circumstances under which students can be the PI
 - Type of research (subject matter, risk level, funding, etc.)
 - Level of IRB review required
4. Additional requirements for student PIs
 - Training/education
 - One-on-one advance meeting with HSD staff
5. Additional requirements for faculty advisor
 - Training/education
 - One-on-one advance meeting with HSD staff and with student
 - Written agreement between advisor and student re: responsibilities, expectations
 - Written statement of advisor responsibilities (from HSD)