

**Human Subjects Policy Board
Minutes
9:30-10:30 a.m.
May 25, 2007
EE1 Conference Room 303**

Members Present

Cheek, Jeff, **Chair**
Barker, Theresa
Booth-LaForce, Cathryn
Brown, Zane
Buck, Steven
Crutchfield, Robert
Mason, Robert
Mitchell, Pamela
Moe, Karen
Rein, Rebekah
Saxon, Andrew
Slattery, John
Streidl, Gigi
Zuiches, Carol

Members Absent

Burke, Wiley
Brunzell, John
Chaney, Edmund
Eaton, Dave
Kuszler, Patricia
McCutchen, Deborah
Rimmele, Carl
Sherrard, Donald J.
Takeuchi, David
Thummel, Kenneth
Wilensky, Alan

Announcements and introductions (Jeff Cheek)

Jeff called the meeting to order at 9:05 a.m. Jeff thanked the members for their commitment to the work of the Board this academic year. He introduced Lois Lussier, newly appointed interim assistant to Jeff and the Office of Research. Lois has replaced Cynthia Wythe in the Office of Research and can be reached at Cynthia's old phone number.

Approval of minutes from 2/9/07 and 4/13/07 (Jeff Cheek)

Jeff asked the Board to approve the minutes of the 2/9/07 and 4/13/07 meetings. Minutes were emailed to members earlier in the week. Minutes were approved by Board members in attendance without exceptions or additions.

Update: Initiative to recruit genetics expertise to assist IRB reviews (Jeff Cheek)

Jeff opened the discussion on the HSD initiative to recruit additional expertise to assist with IRB reviews of genetic research studies. Board members discussed the challenges that face potential candidates, which include an already over-booked calendar, and the requirements to publish and to teach an ever increasing number of students. Jeff said that a later agenda item would offer an opportunity to discuss these challenges more thoroughly, and requested that Board members personally contact investigators they deem appropriate for participating in this effort.

Update: policy and procedure on research using public data sets (Karen Moe)

At the April 13, 2007 Board meeting, it was proposed that HSD develop a policy that allows research involving specific publicly available databases and/or data sets to be conducted without IRB review and approval, similar to that enacted at the University of Michigan. Karen provided an update on her contact with colleagues at U of M as to how they handle requests from funding agencies that require certification that a proposed research activity does not involve human subjects. The researcher provides the IRB office with a detailed memo describing the research; the office reviews the memo and then provides a response memo for the researcher to send to the funding agency. Karen proposed developing a checklist for researchers to provide to HSD for this purpose, as it would be easier for investigators to submit and much quicker for HSD to review. After discussion of how the UW should implement this policy, the Board agreed that HSD staff should draft a policy and procedure for review by the Board over the summer, which would specify (1) that research using “approved” public data sets would not require HSD review unless required by the sponsor; (2) how existing datasets would be added to the “approved” list for exemption from HSD approval (via nomination to the Office of Research and vetting by the Policy Board), and (3) use of a checklist that researchers may use to request institutional verification if required by a sponsor.

Update: Emergency medicine research and waiver of consent (Karen Moe)

Jeff then asked Karen Moe to brief the Board on the latest information on policies regarding emergency medicine research and waiver of consent. Per the Board’s recommendation at the last meeting, Karen has revised the draft policy to allow the IRB to approve concurrent emergency medicine studies if the IRB is satisfied that there is no additional risk to subjects and that the logistics of doing multiple studies have been adequately planned and described.

Update: Audio taping and exempt research (Karen Moe)

Karen continued with a presentation on the new sub-committee that has been formed to determine when audio taping may be used in research exempt from IRB review or that is subject to Minimal Risk review. The sub-committee is led by Tanya Mathews from HSD, with participation by Steve Buck, Deb McCutchen and Jennifer Turns (COE, Technical Communication). The group will meet on May 22nd and June 5th. Their recommendations will be sent to Karen Moe and to Jeff Cheek for review. The resulting draft policy will be routed to the Board by email.

Revising HSD policies in Faculty Handbook (Jeff Cheek)

It was noted that the HSD policies in the Faculty Handbook need to be updated. Jeff relayed instructions he received from Gerry Philipsen, Secretary of the Faculty Senate. Briefly, all of the text of Volume IV, Part II, Chapter 2 of the Handbook consists of Executive Orders, which are issued by the President. Secretary Philipsen recommended that UW Administration should issue an order to amend the Handbook as desired. In his experience, such an order is usually reviewed by the relevant Faculty Council, which in this case would be the Faculty Council on Research (FCR). However, it would also be appropriate to have the Chair of the Faculty Senate weigh in on this matter as well, as the Chair is involved in determining the Council to which a matter should be referred. Since the FCR will not meet again until Fall 2007, Jeff will pursue this approach with Cathryn Booth LaForce, FCR Chair, at that time.

Continuing Discussion: IRB member recruitment (Board Members)

Jeff re-opened the discussion from the previous Board meeting regarding recruiting additional members for UW IRBs. Board members articulated the challenges facing overly committed faculty—the very people that would be most useful as new IRB reviewers. However, Board members did feel that a more aggressive approach needed to be taken by the UW to recruit and retain IRB members. It would be helpful to broadly communicate the importance of the work of the IRBs to the livelihood and overall success of the University’s research enterprise. In addition, members felt that participants could be reminded that they would benefit professionally from learning more about the IRB application process. However, the Board did recognize the problems that some departments have with the recent increase in number of students per class and the other faculty commitments that go along with increased class size. In addition, the Board understood that some departments simply lack the funding to assist faculty to perform IRB service (e.g., teaching buyouts). It was noted that the key priority of faculty continues to be scholarly publications and teaching: even when IRB participation is considered to meet the academic service requirement for faculty promotion and tenure, it trails scholarship and teaching in priority for merit evaluation.

Jeff acknowledged the importance of the Board’s input on this issue and suggested that perhaps both long and short term strategic remedies need to be pursued. There was broad agreement by the Board that this was the right approach. Short-term suggestions included seeking means to reduce the overall workload on IRB members; consider the use of Research Cost Recovery (RCR) monies to provide release time for IRB service, and increasing central UW administration’s role in IRB member recruitment. Long-term strategies included devising means to compensate IRB members for service; identifying specific areas of expertise needed on IRBs and targeting recruitment accordingly, and devising incentives to individuals and departments to encourage participation in IRBs.

Request: Board input into HSPB role and procedures for next year (Board Members)

Jeff then asked the Board how they wanted the Board meetings and procedures structured for the 07-08 academic year. The Board felt that meeting every other month worked well and that Friday mornings were best. In addition, the Board felt that information could be shared with them at anytime when they needed to weigh in on a decision (e.g., circulating draft policies via email).

Future agenda items (Board Members)

Members requested future agenda items include a discussion on how to better communicate information to researchers on campus. Karen Moe told that Board that HSD has a developed an e-newsletter that will be published widely on a monthly basis beginning next week. Other items suggested for future meetings included accreditation issues, multi-center studies and clinical trials, and further discussion on the success of new IRB recruitment strategies.