

MINUTES
HUMAN SUBJECTS POLICY BOARD
9:00 – 10:30 AM
April 13, 2007
Gerberding 142

Members Present

Cheek, Jeff (Chair)
Booth-LaForce, Cathryn
Brown, Zane A.
Buck, Steven
Burke, Wylie
Kuszler, Patricia
Mason, Robert M.
McCutcheon, Deborah
Moe, Karen
Saxon, Andrew
Sherrard, Donald J.
Slattery, John T.
Streidl, Gigi
Takeuchi, David
Thummel, Kenneth
Wilensky, Alan J.
Zuiches, Carol

Members Absent

Barker, Theresa
Brunzell, John
Chaney, Edmund F
Crutchfield, Robert
Eaton, David
Hamblin, Mark
Lidstrom, Mary
Mitchell, Pamela
Neff, Margaret
Rein, Rebekah
Rimmele, Carl
Sherrard, Donald J.
Thomas, Karen

Announcements and Introductions

(Jeff Cheek, Karen Moe)

Jeff called the meeting to order promptly at 9:00 a.m.

Karen introduced Shannon Sowards, the new Assistant Director of Operations for the Human Subjects Division. Karen also introduced Arna Elezovic, Administrator at HSD, attending the Board meeting to take minutes.

Jeff announced that Cynthia Wythe is no longer working for the Office of Research. He requested that the Board forward all correspondence and issues to him directly until a replacement for Cynthia is hired. Jeff announced that there were a couple of general issues which required feedback from the Board.

Jeff provided an update about the HSD staff concern about the IRBs' need for additional genetics expertise. Jeff asked the Board for the names of UW faculty or professional staff who might be willing to be a member of a genetics consultant pool for the IRBs.

Jeff began a discussion about the increasing difficulty of recruiting faculty members for service on the IRBs. He plans to contact department chairs to bring the matter to their attention. In the ensuing discussion, one Board member stated that the current IRBs are not getting adequate representation from across campus. Another member described the lack of support for IRB service within the Colleges of Arts and Sciences because of faculty workload. Currently, IRB service is not associated with any release from teaching or other service obligations. The Board member felt that IRB recruitment efforts were not going to be very successful until there was some commitment from the university administration to support faculty in IRB service. Another Board member

suggested that the number of IRB applications should be correlated to the number of faculty persons provided by the department for IRB service, and that the Departments which submit the most number of applications (e.g., the “heavy” users) should supply a senior faculty member for IRB service. The rationale for requesting senior faculty members to serve on the IRB was the impact of the required time commitment on junior faculty members’ need to focus on research and teaching in support of tenure and promotion. The Board member acknowledged that this kind of decision would affect the entire University and should come from the Provost. Other Board members agreed that senior faculty would be valuable for particular issues but also stated that serving on an IRB is a good experience for many junior faculty members, especially if they are allowed to rotate through. Finally, it was suggested that a description of the expected and realistic workload of IRB members be developed, and then examined in terms of impact on recruitment.

Updates: Policy about standard care risks and Biological Specimens Form (Karen Moe)

Karen provided an update to the Board on the successful resolution of an inquiry from the Office of Human Research Protections (OHRP). The resolution incorporating the feedback of OHRP into a revised written policy about when standard care risks should be described in consent forms. The policy will be implemented and posted on HSD’s web site within a few weeks.

Karen also informed the Board that the new Biological Specimens Determination Form has been released and is now posted for use on the HSD website. She thanked the Board for their patience in the process of incorporating all of their concerns. This form will make the issue of research involving biological specimens much easier for researchers. One Board member asked if this new Determination Form replaces the category of exempt research. Karen responded that the form does not replace the exemption form, but is rather a “registration” of research that does not require IRB review but may need certification thereof.

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

Karen facilitated a discussion of planned emergency medicine research and the regulatory basis for waiving informed consent in this type of research. In particular, she raised the issue of whether the waiver should include access to medical records associated with the initial hospitalization after the emergency intervention. Medical records access is a necessary part of safety and data monitoring of emergency medicine research. It is also essential for determining the safety and efficacy of the emergency intervention being tested. Karen described some guidance from FDA which appears to support medical records access under these conditions without consent. She therefore proposed that UW policy state that the emergency medicine exception to consent include access to medical records. This “records access” would not extend beyond the subject’s discharge from the hospital. One Board member asked if this policy would allow medical records access to extend to all institutions where the subject stays if it pertains to the intervention. Karen said yes it would. She added that this draft policy is based on input from the chairs and staff of the biomedical IRBs.

Karen raised another issue in this type of research, which is the potential enrollment of a subject in multiple emergency medicine studies. Because some of these studies target the same populations and geographic locations, the IRBs are concerned about the possibility and impact of subject enrollment in multiple studies. Board members discussed whether it was reasonable and feasible to limit enrollment to only one emergency medicine study. The Board recommended development of a policy that allowed for a case-by-case decision by IRBs. The Board also recommended that the IRBs include emergency medicine researchers and emergency responder personnel in the discussion underlying this policy development. One Board member asked about item #3 on the proposed policy, which is the exclusion of minors; the Board member expressed concern about this exclusion from emergency medicine research. Karen responded that this has been the *de facto* policy for HSD for years, and also to there are specific regulatory criteria that must be met to involve minors in research. The Board recommended that the IRB consider revising this part of the policy to allow a case-by-case decision on this issue.

Karen concluded by stated that draft policy and other documents on emergency medicine research will be posted for feedback to the HSD accreditation website.

Discussion: Use of public data sets not Human Subjects Research? (David Takeuchi; Bob Mason)

Jeff presented the background for this agenda item, which consisted of two policies from peer institutions (University of Michigan and University of Wisconsin). A white paper was also presented by two Board members similar to the policies from these two peer institutions, which described the circumstances under which the use of public data sets are not considered human subjects research and therefore do not have to go through IRB review.

It was proposed that the IRB develop a similar policy that allows research involving specific publicly available databases and/or data sets to be conducted without IRB review and approval. It was noted that this proposal is also consistent with new NIH guidelines.

Karen pointed out that the UW Office of Sponsored Programs (OSP) and some funding agencies often require certification that a proposed research activity does not involve human subjects. She presented a draft form that could be easily filled out by researchers in order to obtain a "Notice of Determination" which would provide the certification needed to OSP and funding agencies. Some Board members expressed concern about requiring a new form of all researchers simply because a subset of researchers might require a certification for funding agencies. It was agreed that Karen will call the IRBs of the two peer institutions with this policy to find out how they address this certification requirement issue. The Board decided that it might be most appropriate to establish two paths for researchers who use publicly available databases: either researchers "register" their research with the IRB and receive a certification notice (if required by the sponsor or other entity), or they do not need to go through the IRB at all (e.g. for investigators conducting unsponsored research). The Board concluded that the onus of this decision would be on the researchers.

The Board then discussed how to determine whether a database is "publicly available". It was pointed out that many databases or data sets have data use agreements. The Board decided that such agreements or the need to obtain permission to access a database did not necessarily preclude a database from being considered public. Many publicly available datasets have restricted sub-data sets. It was agreed that a "Public Dataset Policy" would not apply to those data sets which are restricted or have personal identifiers. Karen agreed to draft a procedure for nominating and reviewing datasets for addition to the list of publicly available datasets.

Audio-taping: automatic disqualification for exemption? (Karen Moe via faculty request)

This issue was raised at request of faculty and by the HSD staff minimal risk group. Historically HSD policy has been that audio tapes are considered identifiable and therefore research involving audio tapes has not qualified for exemption category #2. Karen also noted that the historic and unwritten policy of HSD has generally been more conservative than the regulatory description of exemption category #2. The regulatory description allows certain types of research to qualify for exemption as long as it is not identifiable *and* sensitive. Karen asked the Board to consider whether HSD policy should be revised to allow exempt research to include the use audio tapes, at least under some conditions.

The Board discussed how research intent and the recorded audio tape content would affect whether or not audio tape content should be considered "identifiable". The Board suggested for the formation of a working group (including researchers and HSD staff) to examine the old policy and to establish specific criteria for what is "identifiable" and under what circumstances research involving audio tapes might qualify for exemption category #2. The Board was unanimous in its agreement for changing the current policy (e.g. from all audio tapes are considered "identifiable") to a more accurate description of "identifiable" that is based on the intent of the research and the content of the audio recordings.

New appeals policy - HSD policies in Faculty Handbook (Karen Moe; Jeff Cheek)

Outdated and inaccurate HSD policies are still listed in the University Faculty Handbook. One important example is the IRB appeals policy. The version in the Handbook was found to be noncompliant with federal regulations during the 2005 audit of the UW IRB by the federal Office of Human Research Protections. HSD has since changed its policy to be in compliance with federal human subjects regulations. However, the old policy is still listed in the Handbook, and it needs to be removed or revised. It was also pointed out that many policies and procedures are being revised or written for the UW's IRB accreditation project, which would require numerous removals or revisions to the Human Subjects section of the Handbook.

The Policy Board discussed the general need to be able to quickly update IRB policies and procedures in the Handbook as federal regulations are revised or implemented differently. The Board discussed whether it would be advisable to simply remove all of the policies pertaining to the Human Subjects Division from the handbook. A Board member volunteered to consult with the Executive Committee of the Faculty Senate about how best to address this issue.

Faculty input on HSD policies & procedures (Board Members)

The Board began a discussion about mechanisms for faculty input to IRB policies and processes. Jeff noted that everyone on the Policy Board is an investigator and/or represents faculty who do human subjects research and could therefore be a contact point for providing input to the IRB. It was suggested that additional efforts be made to inform the University community about the Policy Board and its members, perhaps through the College councils as well as the Faculty Senate, in addition to the already-posted roster on the Office of Research website.

The Board concluded with a brief discussion about types of research for which IRB policies and procedures should be developed (i.e., databases, international studies and applying US standards to research conducted abroad, semi-public databases like blogs) The Board recommended formation of small working groups of Board members and IRB/HSD members to identify issues and suggest or help draft policies.

The meeting ended at 10:50 a.m.
Minutes recorded by Arna Elezovic.