

DRAFT MINUTES
HUMAN SUBJECTS POLICY BOARD

9:00 – 10:30 AM
January 18, 2008
142 Gerberding

Members Present

Cathryn Booth-LaForce
Steven Buck
Wylie Burke
Jeff Cheek (Chair)
Robert Crutchfield
Robert Mason
Deborah McCutchen
Pamela Mitchell
Karen Moe
Carl Rimmele
John Slattery
Clarence Spigner
David Takeuchi
Kenneth Thummel
Alan Wilensky.

Members Absent

Theresa Barker
Zane Brown
John Brunzell
Edmund Chaney
David Eaton
Donald Sherrard
Andrew Saxon
Gigi Streidel
Karen Thomas

Announcements

Jeff called the meeting at to order at 9:05 AM.

Approval of minutes from last meeting

The minutes from the Board meeting of 9/28/07 were approved. It was noted that if any future revisions are needed, these should be sent via email.

1. Brief updates from the Human Subjects Division by Director Karen Moe

Karen briefly reviewed some of the major changes currently underway in the Human Subjects Division (HSD):

- a) Accreditation - HSD office is in the process of seeking accreditation through the Association for the Accreditation of Human Research Programs (AAHRPP). Spurred by a mandate that all VA facilities must obtain accreditation for their human subjects' research programs and because HSD oversees research activities at the Seattle, Boise, and American Lake VA's, accreditation is a necessity. The accreditation application for the UW HSD office is due March 1, 2008 which is an extension from an earlier stated deadline. The extension was granted by AAHRPP due to the myriad changes that are taking place in the HSD office.
- b) DORA – The Database of Research Activities (DORA) will be implemented on February 4, 2008. This new database will provide a more efficient method of tracking submissions, greater depth at providing an overview of research activity, and an easier method of running reports to measure efficiency within the office.
- c) UW Tower – HSD will be moving to the UW Tower, probably in late April/early May, 2008. This move will provide the office with more space to grow in the future, a

- dedicated conference room for committee meetings, and additional office resources such as a training room and several conference areas.
- d) Public data sets – The new Public Data Set policy and procedure has been posted to the HSD website and is now officially implemented. Although the policy has been utilized in the HSD office for the past six months, due to web-related workload issues in the Office of Research, the documents were posted only recently. Researchers using public data sets listed in the document may either go ahead with research without HSD review or, if a determination letter is needed by their funding agency, HSD staff will provide this documentation.
 - e) Revised Modification Form – The office has experienced some difficulty in the formatting of the revised modification form, primarily in the unlocking and locking requirement when completing the document. As this mechanism has proven difficult for some researchers, the form is being converted to a standard Word format to circumvent this issue.
 - f) Committee V2 – Beginning January 16, Committee V2 is operating as the newest IRB for the Seattle, American Lake, and Boise VAs.
 - g) Confidentiality Agreement – The purpose of the Confidentiality Agreement is to satisfy a provision in WA State regulation RCW 42.48, which requires that all identifiable information obtained from State agencies without a subject’s consent is maintained according to outlined standards. This form has been revised to improve clarity and ease of use by researchers. A guidance document has also been posted, as it became clear during the form revision process that mis-understanding of this requirement was resulting in the submission and processing of many unnecessary Confidentiality Agreements.

2. Discussion: Consent forms in foreign languages: require certified translations?

At the previously-held IRB Chairs Luncheon, one topic of discussion was the requirement to approve a consent document that is in another language. Specifically, questions centered on how one may approve something that cannot be read/understood by the person approving it? The following discussion points were raised pertaining to foreign language consent forms:

- a) Several members indicated that documented translations would be helpful; however, this requirement may pose a cost burden to researchers.
- b) Members proposed that if the local (i.e., foreign) IRB accepted the study consent form, then the UW IRB should accept the consent form as well.
- c) There is no federal or institutional requirement that consent documents have certified translations. Rather, OHRP leaves it to the individual IRB to make this determination.
- d) Some IRB chairs are not comfortable with stamping the consent form as this implies approval.
- e) Stamping consent documents is an HSD policy. OHRP does not require that IRB’s stamp consent documents. HSD implements this policy to assist staff in determining the most recent version of the consent form. Whether or not a consent document is stamped, if the overall application is approved, OHRP considers the foreign consent document to be approved as well.
- f) Members were interested in developing an institutional policy by which the need for certified translations was contingent on level of risk to subjects and/or if the research did not have funding to cover translation costs. The IRB Committees should define the threshold according to risk.
- g) Members further discussed that a policy be developed to require certified translations but that the IRB can waive the requirement if 1) the study can be considered to be of low risk to subjects, 2) the researcher identifies the person who will translate the documents, 3) obtaining a certified translation would be cost prohibitive to the researcher, 4) a local IRB has approved the translated consent document for use in their community.

- h) It was opined that a potential problem for such a policy would be that the researcher would only know the IRB's determination after the study was reviewed. It would be beneficial to the researcher if this information was known prior to submission.
- a) One method discussed to rectify this issue would be to have a document that researchers could complete prior to submission. The document would provide assurance that the documents were translated correctly. Additionally, guidance would be provided to list the methods by which the IRB considers translations acceptable.
- j) A consensus was reached that "minimal risk" submissions would not require certified translations. However, greater-than-minimal-risk research and clinical trials research would require certified translations.
- k) The members requested that guidance be provided to IRB members on what documentation should be required when approving foreign language consent forms.
- l) It was mentioned that the new DORA database may be able to track studies that include foreign language consent documents.

3. Discussion: When is it Quality Improvement vs. Research?

- a. The discussion began with a description of the New York Times article regarding OHRP's decision that implementation of a checklist designed to prevent certain hospital infections by Johns Hopkins and a Michigan health care system was research. The agency issued notice to the researchers that by introducing a checklist and tracking the results without written, informed consent from each patient and health-care provider, they had violated human subjects regulations.
- b. It was stated that HSD recently reviewed a similar application from a UW researcher in which the QA/QI project was determined to be human subjects' research. The study intended to record sensitive information about health-care provider practices without their written consent. Although identifiers were to be maintained for a limited time, the state public records law would make such identifiable information potentially disclosable and thereby could place health-care providers' reputations at stake. This issue highlighted the importance of IRB review for such projects as the investigators could have placed the providers at risk if review did not occur.
- c. It was discussed that there is ambiguity between what is considered to be human subjects' research and what is considered to be Quality Assurance/Quality Improvement (QA/QI). The following items outline this discussion:
 - 1) The article's interpretation that OHRP's sole decision was based on not obtaining written consent from patients and medical providers was incorrect. Rather, the focus should have been on the basis of what is QA/QI and what is research.
 - 2) If a QA/QI project is considered to be research, then the issue for IRBs and researchers to consider is whether a waiver of consent should be granted. Focus should be on safety and practicability issues.
 - 3) It was mentioned that when "systems" are being investigated, the systems involve individuals but the focus is not on them. Would this be considered human subjects' research?

Example: One example: many organizations routinely have their employees complete checklists in which the individuals are identified (e.g., Airlines having pilots complete checklists to measure Q/A). Also, why is it that a journalist can publish identifiable information and a researcher cannot? What about marketing research?
 - 4) Although many individuals do not have an understanding of the difference between QA/QI and research, other individuals undertake investigations under the auspice of QA/QI to avoid IRB review.

- 5) Many UW Departments see human subjects review as a “throttle” as to what research can be done at what speed. Explaining the reason why it is important to adhere to federal regulations concerning human subjects’ review would be helpful to researchers in understanding this rationale and process. Specifically, HSD not only enforces the federal regulations but acts as an advocate for researchers, as an intermediary between them and the federal regulations. What is needed is a less burdensome system to make this happen.
- 6) A thoughtful interpretation should be provided indicating that IRBs are granted discretion in making these determinations. This communication is important and should be provided as “friendly” guidance to clear up current misinformation.
- 7) It would be helpful if guidance were created to assist individuals in making this determination a priori. Development of this guidance should include individuals from UWMC that regularly conduct QA/QI.
- 8) Should publication of results be a criterion for determining of whether a specific activity is human subjects’ research? It was mentioned that many QA/QI projects are published and therefore this would not be an adequate criterion. Guidance should instead be focused on the intent of the investigation. Mainly, is the intent of the investigation to contribute to generalizable information? OHRP provides limited information on the definition of what can be considered “generalizable”. Again, it is often left to the discretion of the IRB.
- 9) IRB members may promulgate the burden of regulatory guidance by taking a more conservative approach.
- 10) It was discussed that whether the determination about whether QA/QI investigations are research with human subjects should be made by one person in HSD. It was explained that this is already the current process within HSD. Furthermore, HSD staff wrestles in making these determinations on a daily basis.
- 11) OHRP will be publishing guidance in the near future concerning QA/QI determinations; however, this decision may still involve many subjective determinations.
- 12) The greatest difficulty will be in developing clear guidance. It was mentioned that this topic is to be addressed at an upcoming CTSA conference. Dr. Moe also indicated that she was part of a public policy working group for PRIM&R to address this issue. (PRIM&R is a national organization of professionals working in human subjects compliance areas.)
- 13) It would be helpful to inform researchers that even if an investigation is considered to be human subjects’ research, waivers of consent are still feasible and this could be accomplished with a relatively quick turn-around of their application.

4. Discussion: HIPAA: unintended consequences for research and clinical care (moderated by Jeff Cheek-proxy for Don Sherrard)

- a. The discussion opened with information pertaining to U.S. Senate Bill 1814, the Health Information Privacy and Security Act (HIPSA), currently under consideration by the Committee on Health, Education, Labor, and Pensions. HIPSA would broaden the application of HIPAA regulations to govern all those that use private health information (PHI) rather than only HIPAA-covered entities.
- b. It was requested the Board members speak with their colleagues about HIPSA to determine what impact it might have on them.

5. New business

A proposed new state law regarding disclosure of financial interest by members of UW IRBs and the Policy Board was briefly described by Jeff Cheek, and discussed by Board members.

The policy would require all IRB members, including some HSD staff, to disclose personal financial information to State authorities. Jeff will keep the Board informed. UPDATE:

6. Adjournment

Jeff Cheek adjourned the meeting at 10:25 AM.

Minutes submitted by: Shannon Sowards