

**MINUTES  
HUMAN SUBJECTS POLICY BOARD  
9:00 – 10:30 AM  
May 15, 2009  
Gerberding 142**

Members Present

Barker, Theresa  
Cheek, Jeff, **Chair**  
Brown, Zane  
Buck, Steven  
Brunzell, John Steven  
Chronister, Lynne  
McCutchen, Deborah  
Mitchell, Pamela  
Moe, Karen  
Rimmele, Carl  
Saxon, Andrew  
Slattery, John  
Thomas, Karen  
Turns, Jennifer  
White, Emily  
Wilensky, Alan

Members Absent

Burke, Wylie  
Burns, Stephen  
Crutchfield, Robert  
Hamblin, Mark  
Karpen, Richard  
Mason, Robert  
Neff, Margaret  
Rein, Rebekah  
Sherrard, Donald  
Spieker, Susan  
Spigner, Clarence  
Takeuchi, David  
Thummel, Ken

Welcome:

Jeff called the meeting to order at 9:02 a.m.

Approval of minutes from meetings of 3/20/09 (Jeff Cheek)

The Board accepted the minutes of the 3/20/09 meeting as submitted.

Encryption of identifiable research data (Karen Moe)

Karen reminded board members that this is a follow-up to discussion held at the March in particular to theft of any type of media where sensitive information is stored. At the March meeting, the board thought it would be better to research what other portable media options are available for storing research data instead of restricting researchers from using portable media options completely. After researching what options are available, the following summary of research options and considerations were presented to board members:

- Certain types of research data should be encrypted.
- There is no satisfactory conclusion on criteria for encryption, but identifying that not all data needs encryption is good starting place.
- There are encryption methods for free available to researchers on campus.
- The main problem related to encrypted data is the being able to de-encrypt the data, which is a challenge for researchers.
- IRBs should require encryption of data when they think it's appropriate.
- Graduate students or inexperienced researchers who may need advice on what encryption methods to use should contact the Human Subjects Division (HSD) for assistance.
- In the interim, Karen will work the HSD staff to identify encryption methods that are easy to use. The methods will be formalized and written criteria for IRBs to consider when reviewing issue will be developed.

Karen invited members to provide input on whether encryption rules should be consistent throughout schools or should encryption requirements be left up to the discretion of the IRB. Several board members voted to leave encryption requirements up to the discretion of the IRB since the IRB has a better sense of what the data represents. Other members indicated that one challenge with leaving encryption requirements up to the discretion of the IRB is inconsistency between IRBs: the same PIs may have several projects reviewed by separate IRB Committees leading to potential inconsistency of requirements. One board member recommended that some kind of definition that is not IRB specific, be developed to assist in project categorization so that PIs who have a study reviewed by one IRB Committee can have a reasonable expectation that their study will be dealt with using a minimum of standard rules. This may also assist another IRB in their review as well as give researchers knowledge on what to expect when submitting an application.

The board discussed that researchers should be encouraged to code any data stored on laptops so that if the laptops are stolen, the person who stole the laptop can't figure out who the data belongs to. Additionally, researchers shouldn't have to encrypt as long as they code the data so that no one can be identified.

**Action Items:**

- Allow IRBs to assess encryption recommendations and requirements on a case-by-case basis;
- Develop a checklist of scenarios where encryption might be recommended as a resource for IRB Committees and researchers.

VA separation status and UW IRB operations after separation (Karen Moe)

Karen announced that the formal separation between the UW IRB office and the VA IRB office will occur July 1, 2009. The IRBs at the VA will become VA IRBs exclusively. The HSD is working on procedures to make the separation as easy as possible for researchers. A town hall meeting will be held at the VA that will be televised to inform the public and to address questions.

Karen informed the Committee that given the tight timeline for separation, not much time can be spent on efficiency and ease of forms/procedures. HSD and the VA will go with a dual review process, and HSD will help coordinate. During the coming year, HSD will obtain input from researchers and make the process more friendly.

Preview of next HSD metrics report (Karen Moe)

HSD is continuing to refine the metrics that are being reported on the HSD website.. Karen introduced a draft of the next quarterly metrics report which will be posted in June.

HSD is also now providing an **internal** metrics report with the staff and chairs of each IRB Committee.

**Action Items:**

- Provide metrics on type of PI for deferred applications.

Formation of a new IRB at UW (Karen Moe)

Karen reported that due to the increase in IRB applications anticipated from projects supported by the American Recovery and Reinvestment Act (ARRA), the Provost's Office provided temporary funds to hire two additional staff to support a new IRB Committee. In addition, about 300 studies that were formerly reviewed by the VA IRBs must now be reviewed by other UW IRB committees. The new IRB will be a hybrid IRB that reviews studies containing both social/behavioral and biomedical components. The Committee may be ready by July 1.

**Action Item:** John Slattery will negotiate with Department Chairs to identify appropriate faculty nominees to serve as IRB members.

#### Conclusion of OHRP review of UW emergency medicine studies (Karen Moe)

Karen informed the board that the federal Office of Human Research Protections (OHRP) recently concluded their review of two UW studies involving special waiver of consents for research conducted “in the field” where medics cannot obtain consent from research subjects. .

#### Adverse event reporting

One board member asked what should be reported to the IRB as an adverse event and what should PI report on renewal as adverse events? The board discussed the current definitions used by HSD, as well as the IRB’s role in reviewing adverse events. . Karen clarified the distinction between an adverse event and an “unanticipated problem” as defined by federal regulatory agencies.

The Board recommended that the IRB Status Report form be modified so that PIs are asked to describe adverse events that occurred throughout the lifetime of the research study, categorized by relatedness. This will assist the IRBs in identifying patterns, especially for research studies that don’t have Data Safety Monitoring Boards (DSMBs).

Karen reported that HSD is overhauling all “problem reporting” procedures and forms. Karen reminded the Board that the Serious Adverse Event form was recently revised to clarify what “related” means in response to several questions.

#### Board membership and process for next year (Board Members)

Jeff updated the Board that they will be contacted over the summer to set up the next bimonthly meetings, to discuss membership next year, and to get thoughts on changes or if things working well.

Jeff invited members to provide input on groups from campus from whom the board needs representation. Some members have reflected that their presence on the board represents past representation on campus which may no longer reflect current stakeholder needs.

Members recommended that an individual representing ITHS, be included.

The members discussed and recommended that issues arising within a IRB Committee should be shared with the other IRB Committees, to assist with predictability and harmonization.

#### **Action Items:**

- Contact ITHS to obtain nominations for potential board members.
- Develop process to share relevant information between IRB Committees.