

MINUTES
HUMAN SUBJECTS POLICY BOARD
9:00 – 10:30 AM
March 20, 2009
Gerberding 142

Members Present

Cheek, Jeff, **Chair**
Brown, Zane
Buck, Steven
Burke, Wylie
Chronister, Lynne
Crutchfield, Robert
Mason, Robert
Moe, Karen
Rimmele, Carl
Saxon, Andrew
Sherrard, Donald
Spigner, Clarence
Takeuchi, David
Thomas, Karen
Thummel, Ken
Turns, Jennifer
White, Emily
Wilensky, Alan

Members Absent

Barker, Theresa
Burns, Stephen
Brunzell, John Steven
Hamblin, Mark
Karpen, Richard
McCutchen, Deborah
Mitchell, Pamela
Neff, Margaret
Rein, Rebekah
Slattery, John
Spieker, Susan

Guests

Shannon Sowards

Welcome:

Jeff called the meeting to order at 9:04 a.m.

Approval of minutes from meetings of 1/16/09 (Jeff Cheek)

The Board accepted the minutes of the 1/16/09 meeting as submitted.

Data encryption requirements (e.g. for laptops) resources available to subjects impacted by data theft. (Zane Brown)

Board member Zane Brown introduced the general problem of how to protect sensitive data related to subject privacy where subject data is stored by researchers on laptops. Other institutions are coming up with requirements for data security. He reported one particular case in which an investigator maintained a large database on a laptop. Someone broke into the investigator's car, and took the laptop; nothing else was stolen, suggesting that thieves were interested in the laptop and/or content stored within. The IRB discussed this security breach and requested that HSPB discuss whether PIs should be required to encrypt confidential data stored on a laptop or other mobile media device. Consents in general describe that identifiable research data has to be under lock and key and describes how data is stored, which does not include provisions for electronic data susceptible to theft. Should data only be entered in a work station located in a locked room accessible to project staff? If data is allowed to be entered and transported on a laptop, should the institution insist that everything entered in the laptop be encrypted as a safety measure?

The trade off for allowing researchers to use laptops to store research subject data is that although this may enable researchers to have freedom so they can do analyses anywhere they need to, it potentially puts the subjects and the institution at risk. The Board noted that this overall concern regarding security also applies to data stored on a zip drive or disc. Zane reported that IRB Committee A reviewed other security breach incidents that have occurred throughout the Puget Sound area that involved major banks, institutions, and HMOs in which there have been loss of laptops with data. One Committee member suggested that if the Board decides that encryption is an appropriate requirement to impose on investigators, then the definition and minimal level of encryption must be made very clear since many people don't know what this means. The Board discussed that encryption can range from being very simple to very complex and if it were to be complex, this can cause problems as well. The Board determined that someone from industry should weigh in as to what is a usable encryption. Jeff suggested that the IT folks at the UW be consulted since encryption could also impose hardware requirements.

One Board member suggested that any new policy should describe what are considered high risk factors for having research data stolen. Karen Moe stated that she has consulted with Kirk Bailey, UW Chief Information Security Officer about data that are most vulnerable to use for identity theft or financial manipulation. Kirk's office and the Office of Research Information Services (ORIS) can provide guidance about encryption. However, the Board agreed that encryption could make collecting and analyzing research data much harder for researchers.

The Board discussed potential consequences to researchers and to the public when data is stolen. If PHI is stolen, HIPAA applies. In addition, the federal stimulus package contains several additions to HIPAA regulations that will impose additional disclosure requirements of data breaches.

Should researchers disclose in the consent form where data is actually being stored? Such full disclosure may make PIs more careful with individual data and where it is stored. In contrast, other Board members suggested that researchers only be required to confirm that research data is encrypted. Jeff requested that Board members consider minimum compliance requirements for minimizing this type of security breach so that researchers know what they are required to do.

The Board agreed to the following:

- Further input is needed from appropriate offices regarding security measures and implementation;
- Any future guidance from HSD and the IRB should accurately reflect concerns held by researchers and the public;
- It is unrealistic for researchers to not use laptops for research;
- HSD should investigate methods for encryption and educate people about requirements;
- HSD should research and suggest security solutions that minimize risk to subjects but that do not inhibit people's work.
- There are different levels of risk depending on what type of information is collected;
- An escalation policy regarding encryption should be based on the risk associated to and with the data.

Karen offered to discuss these issues with Kirk Bailey and to identify graded strategies and to identify low cost encryption methods easily available. She offered to circulate a polished version of her discussions with Kirk in advance of the next HSPB meeting. Jeff and Karen encouraged Board members to go to their faculty to invite further input on how to further protect research data.

HSD “metrics dashboard” on the Web (Karen Moe)

Karen announced that HSD’s performance metrics were recently published on the HSD website (<http://www.washington.edu/research/hsd/metrics.php>). Karen distributed hard copies of the report of “Key Performance Metrics for the IRB Review Process” for the period from July 1, 2008 to December 31, 2008. Karen reviewed some aspects of the report, which provides an overview of the IRB review process and defines the metrics. Specific turnaround times were cited: for example, full IRB reviews took a median average of 48 business days; for items that received conditional approval, the median was 24 days. For minimal risk and exempt applications, the median averages to approve minimal risk applications were 15 business days and 3 business days, respectively.

Karen reported that these numbers represent a dramatic improvement in turnaround time for all these categories over the last four years. The report contains comparisons with 2004 data where the median turn around time for approving minimal risk applications was 37 days with a range of 1 to over 300 days, contrasted to the reports median turnaround time of 15 days. The HSD staff deserves credit for the improvement to turnaround time. Data from 2004 shows that turnaround times for exempt applications used to be a median approval time of 7 business days with a range of 1-110 business days. This has also been improved to a turnaround time of 3 business days.

Karen requested feedback from Board members. One current technical limitation is that real time data can’t be captured at present, so our web developers advised HSD to put a static document on the web to update periodically. Karen asked Board members to provide input on whether this report is the best way to present data. She further explained that the report also is attempting to convey that the IRB review process is not a simple process, but one that has multiple factors influencing total turnaround time. Board members complimented Karen on a well-developed report. Several members were in favor of inserting an overall summary of the data up front and recommended that the report be posted more frequently than on a quarterly basis. Karen explained that at HSD would be challenged to post any more frequently right now, but it may be possible to revisit posting more frequently by the end of year. The report will be modified each quarter to add more detailed metrics for each process. Jeff reminded the Committee that this initial metrics report doesn’t simply reflect a cumulative collection of data, but is also a means of establishing baseline data.

Several Board members suggested that the metrics page be referenced throughout the IRB forms and throughout the HSD website so users are informed for what to expect. One Board member pointed out from the PI’s perspective, what matters is when the approval letter is received from the IRB, but what is not currently captured in the current report is the time IRB staff need to write the letter. Karen reported that this is a mistake that will be corrected. She reported that turnaround time does include time required to notify the PI, but HSD staff have to manually record this in the database. Karen stated that she would correct the report to reflect this.

Other new information provided included two handouts that have been recently developed, including a new item called the “IRB Pocket Guide”: one for IRB members only and one intended primarily for

researchers. The researcher's Pocket Guide is not meant to be a comprehensive listing of IRB requirements, but rather to summarize what the IRB is looking for and what criteria are used to approve a research study. The backside of the Pocket Guide describes the researcher's responsibilities which the IRB office wants to publicize widely. Karen invited feedback from the Board members.

ARRA aka "Recovery Act" or "stimulus package"- HSD's contingency plans (Karen Moe)

Karen and Jeff explained that there is a double-edge sword related to the stimulus package. Although there is promise of significant new funding, research administrative offices will experience a consequent significant increase in workload. In addition, the UW will be challenged to meet new required reporting criteria (e.g., job creation, economic development).

Karen provided an update on how the stimulus package will impact the UW:

- 1) Lynne Chronister and Tami Sadusky led the effort to develop the website focused on ARRA. Users can search for this web page from the UW home page, and there is a link to ARRA located on the HSD web site.
- 2) HSD's challenge is to get PIs approval as soon as possible. HSD has already received IRB applications from PIs who are receiving federal stimulus funding
- 3) Researchers need to contact HSD right away when they know they have been, or will be, awarded stimulus funds. HSD will pre-assign the application to an IRB or to a minimal risk reviewer who will work closely to meet time requirements for a particular grant.
- 4) For the IRBs, HSD will focus on increasing flexibility. For example, this may include scheduling special ad hoc meetings or holding meetings via phone conference call, which is allowed by regulations.
- 5) HSD is aware of special circumstances related to research funded by the stimulus package and has discussed fast track options that still comply with regulations.
- 6) Other methods to achieve a quick turnaround time for this research include proactive consultation with PIs to confirm their applications are correct, meeting with coordinators to revise applications, and having PIs and coordinators attend IRB meetings or be available by phone.
- 7) All these are options that IRB staff and members are being encouraged to adopt as necessary, depending on the PI's situation and funding agency requirements.
- 8) Assigning priority to review applications funded by the stimulus package will mean other applications will take longer to be reviewed.
- 9) The time requirements for research receiving stimulus funds is so short that HSD is expecting hastily completed IRB apps. Thus, more modifications will likely be associated to these applications.
- 10) Funding from the stimulus package is expected to last for two years. In most cases, IRB applications stay open longer than funding is active, with an average lifetime of 3 years.

Legal advice on RCW 70.02 – impact on research using biological specimens (Karen Moe)

State Law RCW 70.02 (Uniform Health Care and Information Act) can be interpreting to imply that any biological specimen material containing human DNA is theoretically "identifiable". This exceeds federal regulations, since research with biological specimens that are de-identified doesn't usually require IRB review. Karen is working with one of the UW's Assistant Attorney Generals to clarify the interpretation and application of this state law to biological specimens.

Request for Board input on HSD's FY 2010 goals (Board Members)

Karen reported that the i-Star initiative in the Office of Research (OR) requires each unit in OR to develop strategic and specific goals. For example, HSD established annual goals that are set each fiscal year, where input from staff, members, campus, and board is solicited. This input assists HSD in establishing goals for the next year.

Karen provided a handout that outlines the strategic goals of OR and HSD. She mentioned that two annual goals from the current year will likely continue for next year as well: reduction of turnaround time for full IRB applications and exempt applications. Other efforts that will continue include working with other campus offices to streamline the start up process of clinical trials, increasing the HSD staff rewards and recognition program, and continuing education for staff. Additional written policies and procedures will be developed, along with revisions to forms and filing system.

Karen solicited input from Board members. Their ideas included:

- Develop some type of compensation or recognition for community members who serve as IRB members.
- Develop metrics to identify how many applications UW HSD analyzes versus other IRB offices throughout the nation as a means to analyze and compare the workload of HSD and the IRBs.
- Review other business models to increase efficiency of staff work.
- Provide completed model IRB applications, and post them for researchers as a guide.
- Set up a system for identifying and retaining consultants to IRB.
- Formulate questions for consultants to consider during their review to assist them in reviewing IRB applications with more efficiency.

Updates from HSD / Board Members and future agenda items Board Members - Update on Certificates of Confidentiality? (Board Members)

Karen updated the Committee that she consulted with the Attorney General's Office regarding a successful challenge of a certificate of confidentiality in a criminal court case. In general, judges will be responsive to defendants who state that they need access to research data in order to respond to accusations.

Submitted by Kim Blakemore