



**MINUTES  
HUMAN SUBJECTS POLICY BOARD  
9:00 – 10:30 AM  
March 21, 2008  
142 Gerberding**

Members Present

Cheek, Jeff, **Chair**  
Booth-LaForce, Cathryn  
Brown, Zane  
Brunzell, John  
Burke, Wiley  
Crutchfield, Robert  
Mason, Robert  
McCutchen, Deborah  
Rimmele, Carl  
Moe, Karen  
Saxon, Andrew  
Slattery, John  
Spigner, Clarence  
Streidl, Gigi  
Takeuchi, David  
Thummell, Kenneth  
Wilensky, Alan

Members Absent

Barker, Theresa  
Buck, Steven  
Chaney, Edmund  
Eaton, David  
Mitchell, Pamela  
Sherrard, Donald J.

Visitors present:

Shannon Seward, HSD Assistant Director for Operations

**Announcements**

Jeff called the meeting to order at 9:00 a.m. He introduced new Office of Research Compliance Analyst, Kim Blakemore. He briefly described that she would initially be involved in coordinating the Embryonic Stem Cell Research Oversight (ESCRO) Committee. She will also record minutes for the HSPB meetings.

**Approval of minutes from meetings of 1/18/08 (Jeff Cheek)**

The Board accepted the 1/18/08 minutes as submitted.

**Two policy proposals from the Human Subjects Division (Karen Moe)**

Proposal 1: Retain reviews of research involving human embryonic stem cells (hESC), gene transfers or gene therapy within UW IRB as opposed to outsourcing review to Western IRB (WIRB):

Karen described that currently WIRB reviews all industry sponsored protocols for the UW. However, there are research studies involving or that will involve hESC and gene therapy that require rigorous coordination and communication between institutional oversight offices since

these types of research studies are subject to additional regulations. Although WIRB serves an essential function for improving the timeliness of IRB review in general, it does not provide the service of ensuring compliance within the UW. Additionally, some PIs may not be aware of the various levels of oversights that hESC and gene therapy studies will require. She provided the rationale that by keeping these types of studies in-house UW can assist the PIs to meet several needs which include:

- Navigating the oversight review process;
- Standardizing an application process to increase overlapping needs at oversight offices, and
- Meeting compliance requirements.

Some Board members suggested that it would be useful to have one IRB Committee review hESC protocols and one IRB Committee review gene therapy protocols so that each Committee become specialized in their knowledge of applicable regulations and restrictions. Karen confirmed that this policy is already in place, as Committee B is charged with reviewing all hESC protocols. Karen emphasized that by moving the reviews of these types of studies to the UW IRB, more assistance can be provided to the PIs to coordinate and navigate the oversight process. The Board agreed to approve the proposal.

Proposal 2: Elimination of University requirements for department chairs to review exempt research applications:

Karen described that the current review process for exempt research applications is a linear review and approval process starting with the department Chair. The Chair then forwards the exempt application to the HSD Office, who provides a rigorous administrative review to confirm the exempt status. However, there is a wide variation of knowledge and commitment from department Chairs in performing these types of reviews. Some academic units have created a Committee to review exempt submissions and therefore they are knowledgeable in what these types of reviews encompass. However, there are other units who do not have the time, expertise, or resources to dedicate thorough reviews to exempt submissions. The HSD office also does not have the resources to dedicate training to various departments on how to better evaluate exempt applications. Karen reported that the HSD Office is already doing thorough reviews of exempt applications. Because the HSD is already functioning in this capacity, she is proposing that the only requirement that should be imposed upon the Department Chair is a brief overall review of the submission and the Chair's signature and date.

One Board member asked why the department Chair's approval is needed if they are not asked to perform a thorough review of the exempt proposal. The Board discussed that it is important for the department Chair to be informed of what activity is occurring in the academic unit, even if the review requirements are not as stringent. Karen stated that there are over 1000 exempt applications annually at UW and that eliminating the Chair review may actually facilitate the overall review timeline and process. The Board agreed to this approach, with the request that the process be reassessed at a later time, and approved the policy proposal as submitted.

**Research in cyberspace (Robert Mason):**

Board member Robert Mason described that a current contentious issue on the near horizon relates to whether researcher use of Facebook® and similar blogs is considered human subjects research that requires IRB oversight. Robert explained that with technology constantly evolving, questions of research propriety keep changing. An approach that differs from the usual rule-based approach might be useful for behavioral science research in areas such as blogs and Facebook-type communication, and this approach is often referred to as "pragmatic research ethics" or "process oriented" ethical decision making. He described that some faculty on campus are already discussing the ethics of these types of communication and the potential privacy

implications. Whatever group that is formed would discuss potential challenges and the ethics that might arise. Guidelines may be developed out of discussion that might serve the researcher community most engaged in using these types of communications. Several Board members provided names of individuals who would likely be interested in serving on this group. One Board member requested that at some point, whatever discussion and guidance is developed be taken to the national level. Overall, the Board agreed that discussions need to first occur at the local level since it is not clear to researchers what human subjects research regulations, if any, should be applied to this type of communication.

**NIH CTSA funding and impact on clinical research (John Brunzell):**

There was a discussion about whether the budget structures being used to fund NIH's Clinical Translational Science Awards will have a negative impact on the activity and resources of General Clinical Research Centers (GCRCs). The Board discussed and agreed that although NIH budgetary cuts will have an impact on GCRCs in general, the CTSA's will be a substantial organizing force since they will provide central consult and services to the research community and will also help navigate the large and complicated regulatory apparatus currently at the UW, of which HSD is only a small part.

**Update on new HIPAA proposal (Karen Moe)**

Karen informed the Board that there is a new proposed amendment to HIPAA regulations (the Health Information Privacy and Security Act or HIPSA) which may require anyone working with protected health information to be subject to HIPAA regulations, not just covered entities. The status of the proposal in the U.S. Senate is unknown but she will update the Board on the status of this proposal at a future meeting.

**Single Case Reports – when HIPAA applies (Karen Moe)**

Karen led a discussion about the applicability of HIPAA to PHI used for single case reports. She explained that although the IRB does not consider a single case report to be human subjects research, a single case report may be subject to HIPAA laws if the information is shared at a conference outside of the University. However, there is some confusion on the part of researchers about how to handle this requirement when it is not possible to obtain a HIPAA Authorization from the patient/subject. Karen offered to provide a follow-up report at the next HSPB meeting.

**Global Health (Clarence Spigner)**

Clarence described that a high profile issue currently receiving attention in the media involves whether appropriate IRB processes and ethical standards are being applied in the area of international research. He asked whether this Board should start considering whether the University is taking appropriate action to address this issue. Karen described current efforts in place to address this issue, which include:

- The HSD office will be adding a draft supplement addressing international research specific questions in a future IRB application version;
- The Dean of the Graduate School has implemented a new policy requiring all graduate students and their advisors to sign a form prior to beginning their thesis or dissertation work, stating that they are aware of Human Subjects requirements.
- Better coordination with international IRBs that are frequently involved in UW research, such as one in Peru.

Jeff invited the Board to bring specific requests regarding this issue to the next Board meeting, which will be held in May.

**Coordination of efforts specific to the Financial Management Office (Deborah McCutcheon)**

Deborah summarized that researchers are challenged by the current requirements placed upon them by the Office of Financial Management related to the collection of confidential information from research subjects (i.e., subject's Social Security Number) and how this appears to contradict the IRB requirement that specific confidential information cannot be collected. Karen explained that the Office of Financial Management is subject to IRS reporting requirements whenever there is a payment to a research subject that is \$600 or greater in one calendar year. However, the methods of making payments differ considerably in terms of the number of people who have access to the subject's information. The HSD office is educating researchers about which method is least risky

**Update on the requirement that HSPB Board members report any significant financial interest (SFI) disclosures (Jeff Cheek)**

Jeff updated Board members on the status of a proposed Washington State statute to require that UW IRB members (and HSPB members) be required to submit SFI disclosures. Jeff clarified that this proposal did not make it out of committee in this year's State legislative session.

Jeff reminded Board members that the next HSPB meeting will occur on 5/16/08.