

**HUMAN SUBJECTS POLICY BOARD  
MINUTES  
1:30—2:30 p.m., May 31, 2006  
EE (Electrical Engineering) 403**

Members Present

Lidstrom, Mary (Chair)  
Booth-LaForce, Cathryn  
Brunzell, John  
Buck, Steven  
Burke, Wylie  
Chaney, Edmund F.  
Crutchfield, Robert  
Eaton, David  
Mason, Robert M.  
McGough, Helen  
Mitchell, Pamela  
Moe, Karen  
Rimmele, Carl  
Sherrard, Donald J.  
Slattery, John T.  
Streidl, Gigi  
Thummel, Kenneth  
Zuiches, Carol

Members Absent

Barker, Theresa  
Brown, Zane  
Handsfield, H. Hunter  
Kuszler, Patricia  
McCutchen, Deborah  
Morrison, Diane  
Neff, Margaret  
Rein, Rebekah  
Wilensky, Alan

**Introductions and announcements**

**Dr. Mary Lidstrom**

The meeting was called to order by Dr. Lidstrom at 1:35 p.m.

Dr. Lidstrom asked if there were any corrections or additions to the minutes from the 3/15/06 Policy Board meeting. No corrections or additions were raised. The Policy Board voted to accept the minutes from the 3/15/06 meeting. Dr. Lidstrom announced that the Policy Board meeting (on 5/31/06) would be the last meeting of the academic year. Next academic year, the Policy Board will meet every two months.

Dr. Lidstrom described her goals for the process for discussing and/or approving new policy. She explained that she wanted careful consideration of new or revised policies so that the Board's approval would be a continuous improvement process.

**Policy on de-identified human tissues**

**Helen McGough/Karen Moe**

Reason for proposal

Ms. McGough described that current UW HSD policy is that de-identified data is research. The UW HSD Office has allowed some projects involving de-identified or anonymous data to qualify as exempt research. This new policy proposes that: *Research using anonymous or coded specimens or data that exist at the time the researcher begins the project must be registered with the Human Subjects Division, but is not subject to IRB Committee review.*

Background on Exemptions and Exempt Research

Ms. McGough provided the background on exempt research at the UW. The UW current policy on exempt research makes individual departments responsible for the determination of exempt research but provides an additional layer of review by HSD, and so it is therefore more strenuous than what OHRP

guidance recommends. There has been a 10% error rate historically in exemption submissions to the HSD Office (i.e., the submission was labeled as an exemption and should not have been, or conversely an application was submitted that should have been exempt.)

#### Draft policy

In the draft policy, the specimens/data must be registered but not reviewed by the HSD Office. The draft policy defines “coded” and also “anonymous” because the lack of a distinction often causes confusion among researchers, especially if they have coded specimens but do not have access to the linked identities. The draft policy also includes regulatory citations, guidance and state law. Washington Revised Code 79.02 “Health Care Information Act” was changed to specifically include DNA as health care information. This is an example of how Washington State law differs from HIPAA, which specifically excludes DNA.

#### Draft registration form for specimens/data

Ms. McGough also presented the registration form (for research using anonymous or coded specimens that does not need IRB review.) Ms. McGough walked through all the sections of the draft registration form, focusing on two questions which address Washington State law.

The registration form addresses Washington State anatomical gift act, in which consent is required for autopsy donation. Ms McGough explained that UW Attorney General’s office is examining two relevant questions on autopsy specimens: 1) What happens with autopsy samples collected for the specific purpose of research? 2) Would the medical examiner be considered a health care provider?

The second state law requires IRB review if specimens involved DNA, which is addressed in the draft registration form. The Board discussed DNA and how it was identifiable data. Some Board members considered that the technological impact of data collection + the existence of genetic databases would make it much easier to identify subjects 5 to 10 years from now. The Board deliberated if genetic research could be considered exempt from IRB review. Some Board members felt that it was sufficient to allow researchers to have linked data as long as the researchers agreed never to try to identify subjects from which samples/specimens were obtained. The Board did not reach a conclusion.

#### Discussion

The Board debated how NIH requirements for data sharing would impact UW policy. The Board did not reach a conclusion on this issue.

Board members then expressed concern about creating a new process (approving the draft policy in which research involving de-identified specimens would not need IRB review) in that it parallels the current UW policy and the current HSD practice of review of exemptions. The Board debated the ways in which to make the HSD current process of exempt research less onerous to researchers. One suggestion was to allow researchers to make the determination of whether or not their research met exemption criteria. Another suggestion was to allow “registration” of research involving de-identified specimens to remain an internal departmental procedure. Certain members of the Board expressed their reluctance in allowing researchers to determine whether or not their research met the exemption criteria.

The Board also debated if it could approve a policy in which research involving de-identified specimens would not be considered human subjects research. Three questions were raised during this discussion: What would happen with controversial data? What would happen when these data are published, if there was no IRB review? How would this new policy of registering research of coded or anonymous specimens be affected if researchers had pending NIH grant applications?

Dr. Lidstrom reminded the Board that it was 2:30 p.m. and that no conclusion was reached about the draft policy, nor the registration form. She invited those members to leave if they needed to.

The Board concluded that the difficulty in determining policy derived from the internal inconsistency from OHRP about the category of exemption (#4) of existing and de-identified specimens considered as

exempt research. The board discussed whether or not to locally expand the definition to include prospective collection of samples.

Ms. McGough stated that she would like to see the current HSD Office exemption forms revised rather than approve the proposed policy of allowing research involving de-identified specimens to be registered rather than reviewed by the HSD Office.

Dr. Lidstrom suggested the draft Policy and draft registration form be tried as a pilot project to determine feasibility. The Board concluded that in interim the HSD Office would to come up with a way to streamline the exemption process by developing at least three to four exemption forms. The draft registration form considered by the Board at this meeting would be one of those new exemption forms. The Board decided that the goal for the HSD Office would be to create these forms in the UW online catalyst system so that researchers could complete the form(s) electronically and thus would be directed to the right category of exemption.

The new proposed policy was not approved. The rationale for this decision was that human biologics materials bring legal and ethical considerations that may be unknown.

Dr. Lidstrom concluded the meeting by asking the Board if they would consider meeting during the summer. She told the Board that her office would touch base with everyone by email, as well as provide the update on HSD, which was not discussed at the meeting.

The meeting ended at 2:40 p.m.

Minutes recorded by Arna S. Elezovic