

HUMAN SUBJECTS POLICY BOARD

MINUTES

11:00-1:30 p.m., February 11, 2005

301 Gerberding Hall

MEMBERS

Hogan, Craig (Chair)
Brown, Zane A.
Bruce, Harry
Brunzell, John*
Burke, Wylie*
Cauce, Ana Mari*
Crutchfield, Robert
Eaton, David
Handsfield, H. Hunter
Kharasch, Evan
Kuszler, Patricia*
McCutchen, Deborah
McGough, Helen*
Mitchell, Pamela
Moe, Karen
Parks, Malcolm (left at 11:30)
Rein, Rebekah*
Robinson, Nancy
Sherrard, Donald*
Streidl, Gigi
Thummel, Kenneth
Tolnay, Stewart
Wilensky, Alan J.
Zuiches, Carol*

**Denotes member's absence*

Welcome (Craig Hogan)

Review of Minutes of 11/12/2004 Meeting (Craig)

Minutes of the 11/12/04 meeting were available for review. They will be corrected to note that Stewart Tolnay was present. Members are asked to let Craig know if any additional changes are recommended. [NOTE: Minutes are posted at <http://www.washington.edu/research/hspb.html>.]

Name Change to Office for Human Research Review (Craig)

Plans to change the name of the Human Subjects Division have been placed on hold. The goal is to find a name that appropriately identifies the function of the office and to take "Subjects" and "Division" out of the name.

Report on Outsourcing Contract to WIRB (Mac Parks)

Discussion about outsourcing industry-sponsored clinical research to Western IRB (WIRB), which began about three years ago, has resulted in a contract that will be signed within a few days. There will be at least a two-month process of working out details with WIRB. A deployment plan will be developed with the involvement of departments who will be affected most by outsourcing. Efforts will be made to deploy with the greatest consistency and efficiency. There will be "gray areas" to work out (for example, determining whether a trial is industry-sponsored or not). The assumption is that WIRB will be, by default, the IRB for industry-sponsored clinical trials. Investigators will be able to opt out of using WIRB if they can make a case; and, if there is a trial we want to

manage through the UW IRB, we can do so. The UW is in the early stage of discussion with FHCRC and SCCA to have a consortium IRB to review multi-site cancer studies.

Legislative Update: Bills to Amend Uniform Healthcare Information Act (Helen McGough)

This item was tabled since Helen wasn't present at the meeting.

OHRP Site Visit Preparation Report (Karen Moe)

A few weeks ago the Human Subjects Division was notified that there would be a three-day OHRP "Not-for-Cause" site visit on February 23-25. Four persons (two from OHRP and two external consultants) are expected to conduct the site visit. Karen provided copies of the site-visit agenda. OHRP has conducted nine other similar site visits in past years—the UW is the first institution to be visited this past year. OHRP will have meetings with university officials, IRB staff, IRB chairs, IRB members, and researchers. OHRP has selected thirty-two applications that received full-committee review for examination. They also will examine forty minimal risk applications, all certifications of exemption for the past two months, and minutes of committee meetings.

Accreditation Report: Metrics, Policies (Karen Moe)

Metrics. Karen provided a handout, "Work and Performance Metrics, Calendar Years 2003 and 2004." The purpose of the metrics is to evaluate a variety of measures to assess the Human Subjects Division work load and performance, to provide feedback to staff, to identify needs, and to deal with inconsistencies. In summary, the number of active studies has consistently increased over the past two years (with the exception of certifications of exemption). The biggest increase has been in minimal risk applications and modifications. The review turnaround time for minimal risk applications in the last quarter dropped from 45 to 26 business days. The turnaround time for industry-sponsored trials (according to hand-recorded metrics provided by Gigi Steidl) has been 91 days. Members raised the following questions, which Karen answered:

- Are data available for turnaround time for modifications?
It's difficult to extract data from the HSD Access database to measure turnaround time for modifications; also, it's difficult to determine whether the delay is on the researcher's side or HSD's side. Modifications are often complex and require full-committee review.
- Can exemption categories be examined to be more in line with what peer institutions accept as exempt (for example, secondary data and studies with audio/video recording)?
Karen and Helen have been meeting with the minimal risk review teams to create clear guidelines for determining categories of exemptions and minimal risk. The regulations are general and somewhat imprecise.
- Is the increase in number of applications due to keeping studies open for longer times?
The overall number of active applications has increased in part due to more new applications, and in part because applications are kept open for longer periods.
- Have resources available to HSD kept up with increased workloads?
The complexity of regulations has increased workload for investigators, committees, and staff. HSD has found ways to "fix" some things but there are some things that can't be done faster. Some of the problems lie with the units themselves.

Policies. Karen is working on writing policies and procedures, revising those that exist and creating new ones. Written policies and procedures will need to be ready before June for the accreditation application. Subgroups of policy board members will be asked to provide feedback on draft policies and procedures and the whole board will have a chance to review and approve the final document. Approximately two weeks after the accrediting agency (AAHRPP) receives the application for accreditation they will schedule a visit. They will then write up their findings and give the UW a month to respond. Karen will circulate a memo with specific areas of policies and procedures and time periods within the next two weeks and ask for input from board members. Karen said she is almost ready to circulate policies for dealing with noncompliance. Recently there have been ten cases of noncompliance in which research has been conducted by graduate students in Arts and Sciences and fellows in medicine without review and approval. Historically, noncompliance has been handled as follows: 1) information is obtained from the researcher; 2) the noncompliance is reviewed by a full committee; 3) the committee determines

the level of review that would have been required if the researcher had submitted an application for review; 4) the committee sends a letter to the researcher with copies to the dean, department chair, and/or advisor; 5) for more egregious noncompliance the issue is referred to the Office of Scholarly Integrity. Members commented that every graduate program should have explicit guidelines for research requirements and should spell out the consequences for not obtaining approval. The Policy Board members agree that the role of the Human Subjects Division in noncompliance issues should be to investigate and to report. The University should defer to other units for sanctions. The Board recommends that the University should develop a plan for how to deal with sanctions.

OHRP Guidance on research involving coded private information or biological specimens (see

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>. (Helen McGough)

This item was tabled because Helen McGough wasn't present. Karen explained that OHRP issued new guidance in August 2004. We haven't determined how this guidance influences our review process.

The meeting adjourned at 12:50 p.m.

Recorder: Nancy E. Grout