

**Institutional Review Board**  
**Minutes**  
**November 7, 2011**

**Present:** Lisa Ferrari, Andrew Gardner, Ann James, Mary Rose Lamb, David Luper, Garrett Milam, Andrew Rife, Yvonne Swinth

Chair Milam called the meeting to order at 2:05 p.m.

Milam raised the question of how best to assure that departmental designates understood the meaning and application of the three levels of review (exempt, expedited, full). Gardner suggested contacting departments individually as problems arose. Milam suggested clearer information on the IRB website. James suggested having a checklist of review factors on the protocol cover sheets.

The Board has received two protocols so far this year, both of which were improperly routed, expedited projects without departmental designate signatures. Ferrari will ask Jimmy McMichael to be sure protocols have the appropriate signatures before they are disseminated to the full Board.

In that spirit, Protocol 1112-002 will be returned to the department designate for approval and signature. Board members agreed that the project qualifies for expedited review.

Milam suggested that the Board develop a strategy for implementing the variety of improvements and changes it plans for the IRB website, handbook, and designate training/support. The Board considered whether such changes should be presented piecemeal on the website or posted all at once as one whole-cloth change. Gardner noted that the U.S. Department of Health and Human Services (HHS) is currently gathering information and opinions in anticipation of some revisions to the Common Rule. These changes could have implications for IRB operation and materials. It might make sense to hold off on revising the IRB website and materials until HHS has concluded its work. Gardner and James also commented that piecemeal changes made to our IRB materials might lead to conflicting information, inconsistent policies, and confusion for investigators.

Milam suggested that the Board could collect revised materials and post them to the website in a few stages or “chunks,” in the hope of finding a form of change that would be both timely and coherent. He suggested that creating a more user-friendly webpage should be a priority. Board members requested that the following items appear on the new IRB webpage:

1. Instructions that address the needs of both scientists and humanists
2. An updated list of departmental designates

3. Examples of good protocols from various disciplines
4. Flow charts for anticipating the likely level of review for the protocol
5. A checklist of considerations for investigators preparing protocols

Last year, in her capacity as IRB Chair, Lamb collected information on departmental designates. She will provide this to Milam. James will circulate a sample IRB cover form that she used at another institution and found useful. Milam and Gardner emphasized the importance of avoiding burdensome forms for investigators.

Gardner expressed concern that the structure of the cover form would reinforce the very issues that he, as an anthropologist, has with the current functioning of IRBs. Instruments such as checklists can assume and impose epistemologies that are not appropriate to some fields of research. Gardner said he would like to try out James' form in order to offer constructive feedback.

Milam summarized the Board's next steps and asked for volunteers to take the lead on them:

1. Website information, such as posting the departmental designate list (Lamb, Milam)
2. Preparation of flow charts for linking to IRB website (Ferrari, Milam)
3. Overall plan of new forms and documents

The third item will be assigned after the first two are underway. Board members agreed to review the current website with an eye toward desirable changes, particularly from their disciplinary perspectives.

The Board turned to discussion of the American Anthropological Association's (AAA) concerns about federal regulations regarding IRBs. Gardner had provided Board members with an AAA document responding to proposed changes to the Common Rule. The AAA document stated that the current IRB purview and functioning (under federal regulations) is not conducive to certain types of social research, including anthropological research. Milam asked whether there would likely be any changes to university policy on human subjects research based on objections like those of the AAA. Ferrari said that the widespread practice among American universities and research institutions is to apply federal IRB regulations to all human subjects research, regardless of whether that research is federally funded. The university is unlikely to initiate a change from that practice. Milam requested that Gardner report to the Board examples of some institution-specific problems that colleagues have encountered in the university's IRB process, or some discipline-specific problems that concern investigators. Gardner will do so.

The meeting was adjourned at 1:55 p.m.

Respectfully submitted,  
Lisa Ferrari