

**Minutes of the Institutional Review Board**  
**December 5, 2011**

**Present:** Lisa Ferrari, Andrew Gardner, Anne James, Mary Rose Lamb, Julia Looper, David Lupher, Garrett Milam, Andrew Rife, Yvonne Swinth

Lisa Ferrari reported on a talk with Kris Bartanen. KB approved the addition of a non-voting student member to the committee. She also suggested that the IRB's consideration of changes to its protocol procedures wait until the U.S. Department of Health and Human Services makes its awaited ruling on common procedures to improve rules protecting human research subjects. She would be willing, however, to receive a proposal from the IRB for two forms, one of them accommodating the concerns of social scientists, who tend to find the current procedures inappropriate for their own work with human subjects.

Garrett Milam urged committee members to consult with colleagues at other institutions to discover how IRBs there are adjusting to the wait for the new HHS guidelines. He also proposed that we should proceed with bringing further clarity to the website, the handbook, and the procedures, as well as developing a contingency plan in case the HHS mandates sweeping changes.

Andrew Gardner noted that the HHS's proposed changes are quite substantial, especially regarding consent forms, and that they will be apt to require us to do our work twice should we decide to anticipate them now. Accordingly, we should hold off even on revisions of procedures that will definitely fall under the purview of the IRB. Milam then suggested that we revisit this issue in the spring, giving especial thought to things that won't be subject to HHS changes.

The IRB then proceeded to a consideration of **Protocol 1112-003**.

Garrett Milam and Julia Looper expressed some doubts about the precise nature of the procedure, not only in the consent form (where greater clarity would be welcome), but also in the project description, where further information about the experimental protocols seems needed. Julia Looper also asked how the return to base-line will be determined. Further discussion of this protocol, especially comments by Anne James and Garrett Milam, revealed the need for the IRB to discuss as a general matter the recurrent problem that the boiler-plate consent forms tend to include a good deal of information that won't be in the actual project at all. It seems advisable to consider ways of adapting the standard form to more efficiently fit particular projects.

The protocol was approved, pending minor revisions.

The committee then turned to consideration of **Protocol #1112-0004**.

Several questions were raised:

- Milam: What measures will be taken should the animal act unpredictably?

- Milam: Given that the subject who is consenting (or assenting) is just one member of a group session, is the dog present just for the study and the single individual, or will it be there for the group as a whole?
- Looper: Will the researcher be introducing the dog, or will the dog have been already in place?
- Milam: What if the subject consents to the study, but the dog does something untoward to some other member of the group (not one who's issued consent or assent)?
- Milam: Where is the approval of the host facility (*viz.* Franke Tobey Jones)? The researcher should ask the facility to invite the handler to bring in the animal.
- Looper: Granted that someone with dementia who does not have a designated Power of Attorney is technically able to grant consent/assent, just how informed is that consent/assent likely to be in this situation?
- Ferrari: Where is there provision for a consent form to be signed by the subject? All we have is a form to be signed by a family member and a letter to the subject (not in itself a consent form). Does the person who gets that letter also receive a consent form?

In addition, Lisa Ferrari noted inconsistencies in the wording of the consent form. Anne James suggested that an assent form modeled on the kind used for child subjects could be appropriate here. Yvonne Swinth pointed out that there should be a list of behaviors that would be deemed to constitute a *de facto* withdrawal of consent.

It was agreed that the chair should circulate among the committee further information gleaned about the dog and its handling and about the consent/assent forms.

The protocol was approved, pending revisions.

