

Minutes
Institutional Review Board
December 13, 2010

Present: Mary Rose Lamb (Chair), Julia Looper, Alexa Tullis, Andrew Gardner, Lisa Ferrari

The meeting was called to order at 11:03 a.m.

Business:

1. Minutes:

Minutes from the October 20th meeting were approved

2. Review of Protocols

IRB Protocol # 1011-007:

Members discussed the following issues:

- How will the non-human participant(s) be located, screened, and handled during the study?
- What are the liability issues related to using the non-human participant(s)?
- Where will the research be conducted?
- The process of subject selection and recruitment needs modification; at present, the process violates standards set out in HIPAA.
- Is cognitive impairment an exclusion criterion for subjects?
- The investigator needs to indicate when the data will be destroyed.
- The name of a subject should not be included on the demographic sheet.

Action: The protocol was approved with modifications that will go directly to the chair of the IRB.

IRB Protocol # 1011-008:

Members discussed the following issues:

- Subjects need to be told what the potential risks of participation are.
- Clarify what is meant by “dressing”.
- The parent consent form needs to be modified so that it also gives consent for the parent to act as a participant in the study. Alternatively, there needs to be a separate consent form for the parent to act as a participant in the study.
- The title on the parental consent form needs to be changed to reflect the fact that the parent is giving “Consent for my child to act as participant.”
- The title on the therapist consent form needs to be changed to reflect the fact that the therapist is giving “consent to act as a participant”
- The consent form of the child should be signed in person as opposed to being signed and then mailed.
- The consent forms need to clarify the number and nature of the various participants.
- There needs to be an explicit statement that the documents related to the study will be destroyed.
- There needs to be clarification and justification about why the study will take 5 months..

Action: The protocol was approved with modifications that will go directly to the chair of the IRB.

IRB Protocol # 1011-009:

Members discussed the following issues:

- The clinician involved in recruiting subjects should be named as part of the study team.
- Clarification is needed about how the clinician will be trained.
- The development of the survey used in the study needs to be approved by the IRB as a separate proposal.

Action: The committee was unable to render a decisions of whether or not to approve the proposal because the survey essential for the project was not developed or included. A pilot study to develop the survey needs to be approved by the IRB. This protocol could undergo an expedited review process. Following this, the current protocol, with the complete survey, should be resubmitted to the IRB as a modified protocol. The chair may approve this modification or may elect to send it out to full committee.

3.. Summary of this semester's activities & looking forward to next semester:

- The committee is in the process of reviewing and revising the scientific misconduct policy.
- Currently working on what to do about training undergraduate students in research ethics given the new NSF requirements. There are many questions the committee needs to find answers to before making a recommendation to the university and communicating with departments.
- When the scientific misconduct policy has been finalized, the committee will begin revising the handbook and website to reflect the changes and to make both more user-friendly. Barbara Weist in communications will be consulted about web design.
- When the above tasks are complete, the committee will continue with its work on clarifying and refining the standards for research conducted internationally.
- Before beginning any work next semester, the committee will choose a meeting time.
- The committee also needs to find a community member to replace the current one.

The meeting was adjourned at 12:10pm

Respectfully submitted,
Alexa Tullis