

Minutes
Institutional Review Board
March 15, 2013

Present: Grace Faucett (Grad Student Rep), Lisa Ferrari, Andrew Gardner, Mita Mahato, Garrett Milam (chair), Kirsten Wilbur

Meeting was ordered at 1:00 P.M.

Minutes from prior two meetings were approved

Discussion turned to review of IRB protocol 1213-009

Gardner remarked that the proposal was clear and straightforward. However, chronology of enrollment was confusing (particular of consent forms). Offered a recommendation for clarification of sequence of enrollments/consent and to save enrollment until end of semester.

Ferrari clarified that design issues *are* the concern of the IRB. Even if innocuous, if the study is poorly designed, then issues should be raised.

Milam expressed concern about how the investigator will protect the researcher and student relationship. Agreed that clarification would be good on sequence of enrollment.

Ferrari explained that consent forms become issues because confidentiality and recommended asking the investigator to destroy all identifying information before she leaves the university.

Gardner asked for clarification about previous conversations on what kind of research/education classwork requires IRB approval. Milam responded that if the goal is to present generalizable knowledge, then yes, but if just testing for own purposes, then no IRB is required.

Milam continued by recommending that the investigator find someone else to administer the surveys. Distance would be good.

Faucett added that inconsistency in the consent form should be corrected.

Overview:

- Clarify sequencing and provide justification of it
- Request that consent forms be destroyed if the investigator leaves the university
- Suggest that a second party administer the surveys

The committee voted to approve protocol 1213-009 with minor revisions

The committee then moved into a discussion of other IRB-related matters:

Gardner asked Ferrari whether there had been any debates regarding consent forms at the conferences she has attended. Ferrari answered that there have been some conversations about gaining consent and whether it can be waived, but emphasis has been on clarity and conveying necessary info to subjects. She clarified that part of what we're looking for is whether the consent form actually conveys in an understandable way what is being asked of the subject, what's going to happen to them, etc.

Milam brought up the point that we request two-week lead time to meet about full-board protocols, but that we generally never look at a protocol two weeks in advance. He asked whether it be feasible to change to one-week lead time to allow researchers more time to compile their materials? After some conversation, the consensus was that we should keep the deadline as is.

Ferrari next brought up an issue that she learned about through Dean Sarah Moore about a protocol we had approved. Some concern was raised by a faculty member about the recruitment fliers related to this protocol and how they (or the study) could impact a student who might have an eating disorder. Further concern was raised about whether the study conducted adequate screening for eating disorders. Although the study asked for medical clearance for participating students, it did not discuss how investigators would handle ongoing issues that may arise. Ferrari asked whether we had vetted adequately.

Milam explained the revisions that had been made to the protocol after the IRB had given provisional approval, specifically sharing that the investigator did bring someone on as a co-investigator to be involved on that level of screening.

Ferrari then posed the more general question of what are our procedures for stopping research. What happens if we approve a protocol and some issue comes up? Where is the locus of decision-making whether research is proceeding appropriately? Gardner asked whether it is the responsibility of the IRB to monitor, to which Ferrari explained that it is not, but the IRB is the place where those concerns would come. Milam added that Dean Kris Bartanen would have the authority to intervene if it got to that point. Ferrari asked whether we need to have an articulated way of dealing with these things. Gardner agreed that it might be good to have something formal written, at least within the IRB.

Meeting adjourns 1:36

Respectfully submitted by Mita Mahato