

IRB meeting minutes November 9, 2016

Attendees: Tim Beyer, Mita Mahato, Sarah Moore, Brad Richards, Andreas Udbye, Barbara Warren, Tatiana Kaminsky, Joel Elliott, Geoff Proehl, Jan Wolfe (community member)

Call to order: 12:02 pm by Beyer

A question arose about verbal consent and the expectations about inclusion of contact information.

There was also a question about whether or not the investigator needs to sign a document stating that verbal consent was obtained. The committee members recognized the need to maintain flexibility of the verbal consent process for ethnographic research but also wanted to ensure that procedures are being followed as described in the IRB protocol. We will revisit next semester.

Minutes from 10/12/16 approved

Exempt/Expedited protocols approved since October 12, 2016 meeting

1617-004	Expedited	1617-025	Expedited
1617-006	Exempt	1617-026	Expedited
1617-007	Expedited	1617-027	Expedited
1617-008	Expedited	1617-028	Expedited
1617-010	Expedited	1617-029	Expedited
1617-011	Expedited	1617-030	Expedited
1617-012	Expedited	1617-031	Expedited
1617-013	Expedited	1617-032	Expedited
1617-014	Expedited	1617-033	Expedited
1617-015	Expedited	1617-034	Exempt
1617-016	Expedited	1617-035	Expedited
1617-018	Expedited	1617-037	Expedited
1617-019	Expedited	1617-038	Expedited
1617-020	Expedited	1617-040	Expedited
1617-021	Expedited	1617-042	Expedited
1617-022	Expedited	1617-043	Expedited
1617-023	Expedited		

Updates and announcements

- IACUC/IRB distinction
 - The IRB's recommendations that the faculty bylaws be changed to make the IACUC a separate entity from the IRB were sent to Siddharth Ramakrishnan, our Senate Liaison. He will bring the recommendation to the Senate. No further action for the committee at this time on this matter.

- 1617-005 Full Board update
 - Beyer spoke with the faculty advisor on the research. The protocol was reviewed at Seattle Children's as well. Additional requirements from Seattle Children's have led to substantial changes for the direction of this study. As a result, the researchers will be withdrawing 1617-005 and submitting a new protocol for a modified study which will be assigned a new number.
- Keep eye out for Sample Protocols
 - Please forward Beyer the names of researchers who submit protocols that can be used as examples for training of new members. These can be good protocols and protocols with some of the common errors that are seen during the review process.
- A question arose about background information in protocols and the amount that should be expected. The concern was that it is difficult to assess cost/benefit ratio if there is little to no background to create the context for the need for the study. Discussion followed about what the expectations should be and what types of information that would be helpful. Further discussion about how to communicate the expectations to researchers. Will revisit at a later meeting and update the instructions to researchers as is appropriate. Beyer will then follow up with the departments that send the most student protocols to alert them to the clarification about expectations.

Report from Research Guidelines Workgroup to formulate practices for off-campus researchers to conduct research with members of the campus community.

- Mahato and Kaminsky shared their findings about what comparison schools are doing (see report below). There are three main options:
 - Allow no researchers from outside the University of Puget Sound to conduct research with members of the campus community.
 - Consider each proposal on a case-by-case basis (essentially what is being done at this time).
 - Create a more formal process for outside researchers to follow with clear expectations and guidelines.
- The committee discussed the options proposed by the working group. The pros and cons for each option were discussed. Committee members agreed that welcoming outside researchers was important but that strict and formal guidelines would be helpful. One guideline to be implemented was requiring outside researchers to partner with a member of the campus community. The committee discussed what that role would entail. The committee also wanted the guidelines to require that outside researchers articulate why the Puget Sound campus community would be needed and how it may benefit from the research. Further discussion about what constitutes "on campus" led to a clearer definition about which types of research would need IRB oversight. Discussion about CITI training and whether or not outside researchers need to undergo the training.

- Recommendations are as follows:
 - Outside researchers need to have IRB approval from their home institution and provide documentation to the University of Puget Sound IRB.
 - When the protocol is submitted for IRB review, outside researchers need to articulate why the Puget Sound campus community is needed and how members of the Puget Sound community may benefit from the research.
 - Outside researchers need to partner with an on-campus community member. The on-campus member must be involved in the research. That person should be listed on the consent form and cover sheet.
 - Outside research that needs IRB oversight does one or both of the following:
 - uses members of the student body as research subjects
 - uses on campus resources (physical or virtual) for recruitment or data collection (e.g. accessing email distribution lists or posting flyers on campus).
 - Outside researchers need to complete CITI training and provide documentation to the IRB when the protocol is submitted. The specific training units will be decided at a later date.

- Next steps: Beyer will share the committee's recommendations with Dean Bartanen and find out next steps, including consultation with the university's attorney. The outstanding question about whether or not outside researchers need to use University of Puget Sound letterhead for consent forms will be asked of the campus attorney.

Adjourned 12:50 pm.

Respectfully submitted,
Tatiana Kaminsky

Outside Researchers at the University of Puget Sound

Prepared by Tatiana Kaminsky and Mita Mahato

Three main options:

1) Allow no outside researchers to conduct studies on our campus.

- Comparison schools following this protocol:
 - Bard College
 - Connecticut College

2) Review case-by-case (essentially what we're doing now).

- Comparison schools following this protocol:
 - Allegheny College (they expect some sort of partnership with someone on campus)
 - Dickinson College
 - Lewis and Clark College (require IRB approval from the home institution and consultation with their attorney [who sits on the IRB])

3) Do accept outside research.

- Comparison schools following this protocol:
 - Kenyon College – very clear and explicit guidelines for outside researchers:
<http://www.kenyon.edu/directories/offices-services/office-of-the-provost/conducting-research-at-kenyon/institutional-research-board-irb/guest-researchers/>
 - Reed College – “Projects conducted on the Reed campus by non-Reed investigators must also undergo review by the Reed IRB. Projects conducted by Reed investigators at off-campus sites having their own process of institutional review will undergo minimal additional review at Reed.”
 - University of Portland – clear guidelines for outside researchers:
<http://www.up.edu/irb/default.aspx?cid=5705&pid=1929>
 - Willamette University – MUST collaborate with a member of the Willamette community.
<http://willamette.edu/offices/irb/>
- There are a number of variations here. Options include:
 - Proof of IRB approval from the outside researcher's institution.
 - On-campus sponsor. May or may not be listed as a co-investigator
 - Training requirements (e.g. CITI training)
- If we choose option 3, there are some outstanding questions:
 - Do we need the consent forms on our letterhead?
 - Do we need a separate form/checklist for outside researchers?