

## IRB Minutes April 22, 2016

Present:

- Beyer, Tim
- Ferrari, Lisa
- Kaminsky, Tatiana (chair)
- Kim, Jung
- Mahato, Mita
- Moore, Sarah
- Richards, Brad
- Warren, Barbara

Tatiana Kaminsky called meeting to order at 10:05 am

Approval of minutes from March 25, 2016 meeting – no corrections – all in favor

The following protocols were reviewed and approved by members since the last meeting:

<u>Protocol Number</u>	<u>Level of Review</u>	<u>Protocol Number</u>	<u>Level of Review</u>
1516-026	Full Board	1516-101	Expedited
1516-043	Withdrawn	1516-102	Expedited
1516-060	Full Board	1516-104	Expedited
1516-062	Full Board	1516-105	Expedited
1516-063	Withdrawn	1516-106	Expedited
1516-065	Full Board	1516-107	Expedited
1516-067	Modification	1516-108	Expedited
1516-079	Expedited	1516-109	Expedited
1516-087	Not research	1516-110	Expedited
1516-089	Expedited	1516-111	Expedited
1516-090	Expedited	1516-112	Expedited
1516-098	Expedited	1516-120	Expedited
1516-099	Expedited		

General discussion points on the SOAN MOU

- Majority of changes on the MOU were typos from the original feedback from SOAN in February
- The statement about risk in the unstructured interviews description from point 2D was removed and placed in point 4 to emphasize that risk should be considered with all types of ethnographic research. The wording was adjusted to involve advising faculty on how interviews will be conducted with risk considerations. The reference to intent was left unchanged.
- Andrew Gardner had no additional feedback to the IRB committee on how the amended/implemented MOU is working for the SOAN department
- Warren brought up a concern when reviewing SOAN IRB protocols that references and investigator qualifications are lacking and/or insufficient, and

seeking possible solutions for this with potential inclusion into the MOU. Beyer stated that the missing references/qualifications may be due to different departments having different forms for protocol completion. Perhaps moving forward making the form templates consistent across applications would eliminate this problem. Kaminsky stated that making any substantial changes to the MOU would require another round of meetings and communications with SOAN, and suggested that committee members continue reminding investigators to include references and qualifications in their applications for now, and to move the motion forward to approve the MOU as currently written to implement changes effective in the current academic year.

- Ferrari suggested that the word “substantial” in point 5 of the MOU be changed to “more than minimal” risk. It was also suggested that a sunset clause be inserted into the MOU to inform SOAN and IRB that the MOU is good for 3 or 5 years after which it is renewable. Beyer stated that Psychology has a 3-year MOU with the IRB. Kaminsky would like to know where and how MOUs from various departments such as SOAN and Psychology will be found and maintained given the constantly changing IRB committee members. Kaminsky raised the question of how information on existing MOUs with departments will be conveyed to new committee members and who will be responsible for maintaining/updating MOU status? Per Beyer, Psychology MOU is available on the IRB server. At present, there is no systematic way of tracking when MOUs expire and need to be renewed/reviewed. Discussed the possibility that Jimmy might be able to assist in maintaining a record on the server dedicated to MOUs
- Motion to approve SOAN MOU was made by Warren, and seconded by Ferrari. Motion passed unanimously

#### Changes on IRB website since last meeting

- Kaminsky would like to have titles added to the cover page to distinguish between faculty and student research
- As CITI training has not been implemented for student research, “hide” the updated cover pages until such time
- Beyer suggested that link to CITI training be included on the website for easy reference

#### Continuing discussion on implementing CITI training for student-directed research

- Kaminsky completed CITI training on student track and estimated time to completion would be ~45 min for average student
- Discussion as to how to communicate to campus at large of upcoming changes to IRB submission for student-directed research with mandatory CITI training requirement
  - While CITI training is not mandated by law, implementing CITI training would inform investigators of best common practices. Therefore, given that CITI is not required by law, how does the IRB enforce and/or justify requiring students to complete the training?
  - Beyer feels that one of the responsibilities of the IRB committee is to educate best practices for all individuals conducting research with human

subjects. One issue that may arise is that when students and departments are not told in advance of upcoming changes to IRB protocols and are caught off guard from unannounced changes the potential for backlash and resistance might become problematic

- Committee feels that requiring students to complete CITI certification will decrease some of the common misunderstandings experienced with past and current protocols, and expedite approval process
- Moore suggests that composing a “personal” email alerting specific departments of upcoming changes to IRB protocols from student research may mitigate potential problems. This would include SOAN and psychology, who teach research courses
- Kaminsky also included OT, PT, and courses taught by Benjamin Lewin to the list.
- It also was suggested that a small blurb on the IRB website of upcoming changes and implementation of CITI training to begin in the 2016-2017 academic year on the IRB website would be helpful for investigators and departments
- Beyer suggested that an announcement also be made via faculty coms about the upcoming changes with a direct link to the IRB website
- The committee agreed that the personal email drafted and edited by the committee be sent to individual departments and faculty who most likely will be impacted by the changes ahead of the faculty coms announcement
- Kaminsky suggested that the implementation of CITI serve as a “trial” to assess its effectiveness in the coming academic year – while the committee agrees that some form of training is needed for all individuals conducting research with human subjects, it does not necessarily have to be CITI and may be some other form of training – this will be the focus of charges for next year’s committee
- The implementation of CITI training involving international research, and vulnerable populations such as children and prisoners will not be required at this time and will be put into consideration during next year’s committee meetings.
- For now, the intent is to require students involved with human research to have a general understanding of policies and regulations, and this requirement includes both primary and co-investigators on all proposals beginning with “1617” prefix, which most likely will be on August 29, 2016.
- Motion to implement CITI training for student research was made by Ferrari and seconded by Warren. The motion passed unanimously.

Long-standing protocols without student action and how to pursue this was discussed and the committee feels that study closure and/or continuity follow-up forms might help with these issues

Discussion of items to be placed into the final end-of-year report to be submitted to the Faculty Senate

- Follow-up with CITI training for students and determine if additional modules for special populations should be included
- Feedback from students on the effectiveness/success of CITI training
- MOUs and sunset clauses in the MOUs – how best to get new IRB committee members up-to-date and trained prior to reviewing protocols
- Implementation of CITI training for faculty?

Ideas for charges for next year were discussed

- How to approve protocols from investigators outside of Puget Sound
- How to approve international research – are there special considerations?
- Is additional information and/or procedures needed on the IRB website?
- Beyer raised concerns with protocols involving research with non-English speaking populations and how back translation of consent forms and questionnaires are completed. Is there a standardized way for making these consistent? This could be a good topic of conversation amongst the committee moving forward

Meeting adjourned at 10:40 am

Respectfully submitted,

Jung Kim