IRB meeting minutes October 12, 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: 12:00 pm by Beyer

Minutes from 09/21/16 approved with minor wording change

Introduction

Introduction of Jan Wolfe as our new community member. History of work in public health. Welcome, Jan!

Review of Exempt/Expedited protocols

1617-003 Expedited Approved

Updates and announcements

- 1) 1617-002 Full Board update
 - a. *Issues*: (1) No clear connection in materials to OT program here (despite being named in protocol), (2) materials not prepared using UPS documents, and (3) concerns noted after first submission was denied still not adequately addressed.
 - b. Solution: spoke with George Tomlin (OT) who (1) supports this project, (2) will serve as co-investigator, and 3) will help with revising submitted protocol to fit UPS documents/standards.
 - c. Close out 1617-002: Beyer spoke and e-mailed with PI to clarify issues; because the IRB cannot review the protocol in its current format, 1617-002 is denied. The PI will work closely with George Tomlin and resubmit an improved protocol that uses Puget Sound documents. We should expect a new protocol soon.

2) Share drive

- a. Share drive was not infected even though corrupted files had been uploaded. A new share drive was not formatted and the original one should be used. The corrupted files have been removed.
- b. Please send feedback on reorganization to Beyer
- 3) IRB webpage updates
 - a. CITI instructions clarified; CITI training requirement added to *Checklist for Investigators*
 - b. Informational Follow-up Form (Study Closure Form) added
 - c. If you see anything else that could be clarified, added, etc., pass information on to Beyer.
- 4) Standardized E-mail Responses for Students
 - a. Updated on share drive to include:

- i. A request for a one week turn around with revisions OR to let the reviewer know within one week when they can expect revisions
- ii. Reminder to complete *Informational Follow-up Form* once study is completed
- iii. Please review and let Beyer know of any other changes/suggestions
- iv. Please begin using these standardized responses for Student Protocols
- 5) Keep eye out for good *Sample Protocols* that come with typical issues that could be used as a training example for new members of the IRB. If you see one, send names of student researchers to Beyer and he will contact them for permission to use the protocol for training.

Review of Full Board Protocol 1617-005

The committee discussed this protocol in depth. Beyer will send the student researcher the IRB's concerns. The recommendation is that the protocol will need to be revised and resubmitted to the IRB for further review.

Discussion of IRB/IACUC distinction

Elliott and Warren met with IACUC and reported back to the IRB with findings (See report below). Recommendation is that a motion be made for the faculty bylaws to be changed to make the IACUC a separate entity from the IRB. Motion made to accept the recommendation. Seconded and approved unanimously. Beyer will send the recommendation to the Faculty liaison.

Adjourned at 12:56.

Respectfully submitted, Tatiana Kaminsky IACUC workgroup: Make recommendations on how the IACUC fits into the IRB structure.

a. Members: Joel Elliott and Barbara Warren

b. Contact Alyce DeMarais to collect information on the general function of the IACUC.

- We met with Alyce on 9/28/2016 and she provided an overview of the IACUC.
- The IACUC is governed by policies and laws of the Office of Laboratory Animal Welfare (OLAW). Kristine Bartanen is the named Institutional Official for animal care at the University of Puget Sound, and provides assurance that the institution complies with Public Health Service Policy on Human Care and Use of Laboratory Animals. The IACUC is mandated to report directly to the Institutional Official.
- The IACUC has a website that outlines its mission and procedures:
 http://www.pugetsound.edu/gateways/faculty-staff/institutional-animal-care-use/
- i. How many protocols are typically reviewed per academic year?
 - There were 9 faculty or student research protocols reviewed in 2014, 3 in 2015, and 9 so far in 2016. In addition, there were 2 student independent class project protocols reviewed in 2014, 14 in 2015, and one so far in 2016.

ii. How is the review process structured? Who sits on the committee?

- The IACUC follows the review process in accordance with the Guide for the Care and
 Use of Laboratory Animals and the Animal Welfare Act and Animal Welfare
 Regulations.
 The IACUC website has Faculty and Student Research Animal Use
 Protocol Forms and Student Class Project Animal Use Protocol Forms.
- The IACUC committee prepares biannual reports that are sent directly to the Institutional Official who submits the reports to Office of Laboratory Animal Welfare (OLAW) as mandated by federal policy.
- There are nine members on the committee, and they include faculty, staff, a community member, and a veterinarian. See website for names of present members.

iii. What else falls under their purview (e.g., walk through of non-human animal facilities, lab safety issues, etc.)

- As stated on the IACUC website: To fulfill its mission, the IACUC will meet the following goals:
 - Review Puget Sound's program for humane care and use of animals at least once every six months;
 - Inspect all animal facilities at Puget Sound at least once every six months;
 - Report on the above evaluations to the Academic Vice President;
 - Review any concerns regarding the care and use of animals at Puget Sound;
 - Make written recommendation to the Academic Vice President regarding any aspect of Puget Sound's animal program, facilities, or personnel training; and
 - Review protocols for activities related to the care and use of animals at Puget Sound.

- c. Make recommendation re charge; Alyce DeMarais suggested that the IACUC should be separate and that the bylaws ought to be changed.
 - We concur with Alyce that the IACUC should be a separate entity from the IRB, and suggest the following changes to the Faculty Bylaws covering the Institutional Review Board (page 11).

I. Institutional Review Board.

- a. The Board shall consist of the Dean of the University (ex-officio) and no fewer than four appointed members of the faculty. Members may be added or chosen so that the composition of the committee is in compliance with current federal regulations.
- b. The duties of the Institutional Review Board shall be:
 - To apply the University's policies on the protection of human and animal subjects to the board's review of faculty, student, and staff proposals for research involving human and animal subjects and to proposals from persons outside the University planning research involving University employees or students.
 - 2. To carry primary responsibility for ensuring that the University's policies and procedures and its *Protection of Human Subjects and Protection of Animal Subjects* documents are consistent with the will of the University and that they comply with regulatory requirements governing the protection of human and animal subjects in research.
 - 3. To establish definitions, procedures, and dates for the review of research involving human or animal subjects.
 - 4. Such other duties as may be assigned to it.

d. Recommendation possible by 10/12?

• We recommend that a motion be made for the faculty bylaws to be changed as stated above at a future faculty senate meeting.