Institutional Review Board Minutes
Oct 11, 2017

Participants:
Tim Beyer (Co-chair), Joel Elliott (Co-Chair), Lisa Ferrari, Wendell Nakamura, Mike Pohl, Sara Protasi, Mark Reinitz, Alexa Tullis, Andreas Udbye, Jan Wolfe (community representative)

Call to Order:
The meeting was held in Wyatt Hall, Rm. 326. Beyer called the meeting to order at 1:00pm.

Approval of Minutes:
Beyer moved to approve the minutes from the meeting held on Sept. 20, 2017. Pohl seconded the motion. All members voted in favor to accept the minutes.

Review of Exempt/Expedited Protocols:

1718-005	Expedited	Approved	1718-001	Expedited	Approved
1617-071-2	Expedited	Approved			

Updates and announcements:
Mentor/Mentee meetings: Beyer encouraged newly appointed IRB members to seek advice from their mentor when reviewing their first expedited protocols.

Beyer stated that the IRB has received criticism from the campus community for being inconsistent in terms of review. He recommended that all committee members make use of the resources provided to them on the shared drive (e.g. Level of Review Guide, Level of Risk Guide).

Beyer asked whether any committee members had begun reviewing expedited protocols. Several members had received their first expedited protocols to review. Reinitz raised a discussion regarding how stringent the review must be. He provided an example related to recruitment, where the investigator team had stated they would recruit participants from their own social networks. Reinitz asked whether he should request recruitment materials (e.g. text to be used in emails/online social networks) to ensure the process was free from coercion. Beyer recommended that reviewers should request any extra materials from PIs until they are comfortable that they can make an educated decision.

Reinitz also raised a question as to how critical reviewers should be in terms of the quality of the research in the proposal. Pohl stated that it can often be difficult to evaluate protocols involving research outside of the reviewer's area of expertise. Elliott mentioned there are certain

circumstances where it is possible to evaluate the research quality e.g. lack of citations to develop the rationale/methods of the protocol. Ferrari stated it if any reviewer has concerns over the quality of the study then they should raise the issue so as not to waste potential study participants' time.

Review and Discussion on Institutional Research MOU:

Udbye expressed some confusion regarding the language used to describe that the OIR may not share data that can be used for purposes of financial profit. Amended terminology was discussed and agree upon by all committee members.

Minor changes were proposed to the MOU by Beyer and the committee unanimously voted to approve the document. Beyer is to send the document to Ellen Peters.

International Research Discussion:

Training for PI's engaging in international research:
Pohl recommended that it would be valuable for faculty/students wishing to engage in international research to complete the optional module "International Research" offered by the CITI. This recommendation was accepted by the rest of the committee.

Review and discussion of written sections for International Research Policy:
Ferrari drafted the language for international policy. Beyer had added additional information to the document which was reviewed during the meeting by the rest of the committee.

Pohl mentioned it would be worth asking PI's/students to declare whether they are collaborating with someone when conducting international research. The issue is pertinent in terms of whether they need to seek approval from a local IRB in the country where they are conducting the research.

Further discussion ensued and clarifications on criteria for waving written consent will be drafted by Ferrari to be added to the International Research Policy. In addition, Reinitz and Tullis suggested that some definitions (e.g, semantically equivalent) be added to the policy. Further comments were aimed at further specifying (a) the process of back-translation and (b) that the qualifications for both translators be added.

The updated International Research policy is appended to the minutes.

The meeting was adjourned at 1:50pm. The next meeting will be **Wednesday, November 15, 2017, 1:00-1:50pm, Wyatt Hall, Rm 326**.

Respectfully submitted,
Mike Pohl and Tim Beyer

Policy for International Research

Puget Sound's IRB reviews your research protocol to see that it meets the ethical standards of the university and the U.S. government. Many other countries have regulations and requirements for conducting human subjects research within their borders. The IRB expects that researchers associated with the University of Puget Sound will acquaint themselves with the regulations and standards of any country, region, or locality in which they plan to do research. Thus, researchers must ensure that their project is conducted within the context of local political, legal social, economic, and cultural standards and norms. Researchers are responsible for guaranteeing to the IRB that their research meets such standards and norms.

Additional considerations:

- All student researchers who wish to conduct international research must complete the International Research - SBE (ID: 509) module of the CITI Program and provide their successful completion report with their protocol to the IRB.

- Researchers may need to seek approval from an IRB, ethics committee, or equivalent governing body in the country the research will take place. If a foreign institution is engaged in the research project, then approval from that institution will need to be secured. To be engaged means that the foreign institution recruits and secures consent from participants, conducts the research procedures, or receives/shares private, identifiable information.

For Students Planning to Conduct Research Outside the United States

The university relies on assessments by the U.S. Department of State and the Centers for Disease Control and Prevention to determine the safety of student travel outside of the U.S. Please consult the Travel Abroad Policy for High-Risk Areas, which you can find in its entirety here [get URL].

Before you submit a protocol to the IRB, please make sure the University of Puget Sound can support your project. Some important provisions for student researchers include:

- Students may not use university resources (which includes funding, faculty advising, and IRB review) for <u>independent research</u> in any country under State Department travel warning or CDC travel health warning. This policy cannot be waived.

- Students who will be <u>accompanied by a Puget Sound faculty member</u> while conducting research abroad may ask that faculty member to petition for a waiver of the restriction on travel to travel warning countries.

- These restrictions apply only to countries under travel warning and travel health warning. For areas on lower levels of alert (e.g., travel alert, travel notice), independent student travel is not restricted.

Information on State Department travel advisories is available online, as are CDC travel health advisories.

International Compilation of Human Research Protections

To help international researchers familiarize themselves with regulations in other countries, the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (HHS) has compiled an extensive list of national laws, regulations, and guidelines from more than 100 countries. Please note that there may be provincial, tribal, or local regulations that are not included in the OHRP compilation. Much of the information concerns biomedical research, but each country's listing begins with a "general" section that concerns all types of human subjects research. You can find the International Compilation of Human Research Standards on the OHRP website by following the link on this page.

Cultural Differences

International research may raise special issues related to cultural differences and researchers must ensure that local customs are taken into account in developing research, creating recruitment material(s), drafting consent/assent documents, and constructing data collection instruments. Research proposals submitted to the IRB must explain how cultural norms were taken into account in the development of the research project. In particular, researchers should:

- Seek guidance from representatives of the community when developing and implementing protocols within their communities
- Consider adding members with expertise in the community under study as part of the research team.
- Use *equivalent protections* when considering cultural norms. The OHRP guidance for equivalent protections is found here). For example:
    - Minors who are treated as adults in their own locale will be treated as minors for the purpose of protection in research.
    - "Parental consent" for minors may be viewed more broadly and grandparents, elders, or tribal leaders, who serve as the head of the household in a specific cultural context, may be approached to provide parental consent.
    - Written consent may be waived in favor of verbal consent due to cultural reasons. For example, in some cultural contexts, signing a consent form may be inappropriate due to religious reasons or issues of literacy. Researchers who seek a waiver of written consent must justify this request in their protocol by describing local customs that may impede using written consent. Criteria for waiver of written consent are found here.

Linguistic Differences

If research is not conducted in English, researchers must provide back-translated versions of all materials a participant will see, including recruitment materials, consent procedures (written consent

forms, verbal consent scripts, assent forms), testing materials, and debriefing forms. Back-translation involves taking a document in one language, translating it to the other language, and having someone else translate it back to the original language. The original document and the back-translated document can then be compared, and any discrepancies between the two documents must be resolved. Once the two documents are deemed semantically equivalent, successful back translation has occurred. Semantically equivalent means that the content is the same, although individual words may differ. For example, if a researcher wants to conduct research in Spain:

- The researcher first constructs all materials in English and then someone who is competent in both English and Spanish, translates the materials into Spanish.

- Second, a different person, who may not be the researcher, translates all Spanish materials back into English.

- Third, the two versions of the English materials (the original version and the back-translated version) are compared and any semantic differences are resolved.

- The process of translating and back translating continues until the two versions are semantically equivalent.

The researcher must submit to the IRB:

- The original version, the version in the other language, and the final back-translated version of all materials.

- A description in the protocol which explains:

    - How the back-translation was obtained

    - Who created the initial translation into the non-English language and who created the back-translation. For both individuals include:

        - Contact information, and

        - Qualifications (i.e., a description of why the person is linguistically and culturally competent to provide a translation)