

**Institutional Review Board
Report to Faculty Senate
AY 2018-2019**

The Institutional Review Board (IRB) exists for the purpose of protecting the rights, health, and well-being of human beings solicited and volunteering for participation as research subjects. In the context of reviewing proposed research studies involving human subjects, the IRB attends to issues such as potential risks to participants, protection of participants' identities and disclosed sensitive information, safety, ethical recruitment practices, and the accessibility and adequacy of informed consent. This is a report to the University of Puget Sound Faculty Senate regarding activities of the IRB during the 2018-2019 academic year.

2018-19 IRB membership: Alexa Tullis (co-chair); Ann Wilson (co-chair); Kristine Bartanen (Lisa Ferarri) (ex-officio); Jane Sweeney (community member); Wendell Nakamura; Derek Buscher; Brad Reich; Mike Pohl; Mark Reinitz; Hajung Lee; Andreas Udbye (Fall only)

Protocol Review

The main quotidian duty of the IRB is to review protocols for research involving human subjects. The Institutional Review Board has reviewed 100 protocols this academic year. Of these, 13 were full board, 84 were expedited, and 3 were exempt. Of the 100 submitted, 82 were approved (many after revisions), 16 are pending, and 2 were withdrawn.

Senate Charge

In addition, the IRB addressed the following charge from the Faculty Senate:

- *Investigate best practices for the use of online tools in research, especially tools used for online data storage and data collection, in consultation with the Library, Media, and Information Systems Committee and their draft of "Best Practices for Managing Sensitive Documents."*

There are two issues with respect to managing sensitive documents that are relevant to the IRB:

1. The potentially sensitive material that could be contained in the protocols we review.
2. Our role in ensuring the proper treatment of sensitive data collected during research involving human subjects.

1. Protocols sent to the IRB to review.

Although there typically has been little to no sensitive information in the protocols themselves, they are managed carefully. Protocols are first sent by researchers through email to Jimmy McMichael (irb@pugetsound.edu) who then emails them to committee members. They are given a protocol number which is used in the subject line of emails. Protocols are stored on a shared drive on a university server and is only accessible by current IRB members.

There is a one side-issue related to sensitive information in student research protocols that the IRB continues to deal with – that of prohibiting the use of personal contact information (e.g., personal phone numbers). The IRB believes that our role in protecting human subjects extends to protecting student researchers, and that the use of personal contact information on consent forms and recruiting information may put student researchers at risk. The IRB feels that Puget Sound email addresses and faculty research advisor office phone numbers or department phone numbers provide adequate mechanisms for participants to contact the university if needed.

2. Ensuring the proper treatment of sensitive data collected during research involving human subjects.

Preserving confidentiality of human research participants is one of the main concerns of the IRB. When we review protocols, we specifically look for evidence that researchers have mechanisms in place to ensure the anonymity of research subjects and the security of sensitive data that may be collected. To that end, the board IRB Handbook explicitly states how and where data should be stored. We are currently in the process of taking steps to revise the Handbook to further highlight this information.

Institutional RB members are required to complete on-line Collaborative Institutional Training Initiative (CITI) training modules to learn the mechanisms by which confidentiality of research subjects is maintained and what to look for in protocols they are reviewing. This training is followed up by conversations with veteran IRB members as well as documentation within the IRB Handbook.

This past year, the IRB obtained the “Best Practices for Managing Sensitive Documents” draft from LMIS and used it as the basis for further discussion about sensitive data management. Recognizing, as does LMIS, that there is a range of sensitivity levels when it comes to data, the IRB is discussing ways to best provide guidance to researchers in their dealings with sensitive data.

Additional Efforts of the IRB during 2018/2019

In addition to reviewing protocols and attending to the charge from the Senate, the IRB has been involved in several additional endeavors related to our mission.

Community member

- The IRB is required to have one member who is not affiliated with the University. Our existing community member left at the beginning of the academic year and we recruited a highly qualified replacement – Jane Sweeney, PhD, PT – at the beginning of the year. Jane brings the perspective of an experienced researcher to the board and we are fortunate to have someone of her caliber serving in this capacity.

Faculty and CITI training modules

- Student researchers are required to complete on-line CITI training modules undertaking research with human subjects. The IRB is now moving ahead with requiring faculty members who underwrite research protocols or serve as research advisors to complete (and pass) a block of five CITI courses consisting of: 1) Belmont Report and CITI Course Introduction, 2) Informed Consent, 3) Cultural Competence in Research, 4) Assessing Risk, 5) Unanticipated Problems and Reporting Requirements in Social and Behavioral Research. This training is required for any researcher who receives federal funding and the board believes that it is best practice for all faculty advisors at Puget Sound as well. The IRB has solicited feedback from the chairs of the departments that submit the majority of protocols to the IRB, i.e., Psychology, Exercise Science, Occupational Therapy, and Physical Therapy. Chairs of these departments have been generally supportive of the proposal. The Department of Sociology and Anthropology (SOAN) still needs to be contacted.

The IRB Handbook

- The IRB has begun efforts to update the IRB Handbook to make it easier for both researchers and IRB members to find information. We are also updating it so that the language is consistent with that of the revised Federal Policy for the Protection of Human Subjects, known as the Common Rule, that took effect at the beginning of the year (<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>). Work on the Handbook revisions is likely to continue through next year.

Standardized responses to researchers

- The IRB has also worked on revising our standardized responses to researchers when requesting protocol revisions.

Memorandum of Understanding

- We are working with the SOAN and Psychology departments to update and/or reaffirm their MOUs.

Faculty concerns

- One ongoing challenge of the IRB is responding to concerns from faculty across campus about the role of the IRB in overseeing research with human subjects. Members of the IRB have spent time discussing and responding to these concerns. We hope that requiring faculty to complete the CITI modules will mitigate at least some of these concerns.

Self-charges for the next academic year and beyond

- Continued work on the IRB Handbook to make it more user-friendly for both IRB members and researchers
- Consider ways to streamline the application process so that it can be completed on-line
- Update informed consent form
- Review the policy requiring that student protocols involving international research be automatically reviewed by the full board.

- Continue working with departments to update and/or reaffirm MOUs as needed
- Solidify procedures for “end of project” reporting.
- Address challenges of inconsistency in faculty advisor oversight of protocol writing and revising.
- Work on a mechanism to coordinate with the University Enrichment Committee to ensure that no research funds are released to summer research student working with human subjects until their protocols are approved by the IRB.