

## **Institutional Review Board Report to the Faculty Senate AY 2019-2020**

May 7, 2020

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 2019-2020 academic year.

2019-20 IRB membership: Wendell Nakamura (co-chair, F2019, S2020); Mark Reinitz (co-chair, F2019); Mike Pohl (co-chair, S2020); Renee Houston (ex-officio); Andrew Gardner; Hajung Lee; Brad Richards; Alexa Tullis, Andreas Udbye; Ann Wilson; Jane Sweeney (community representative, F2019); and Marcia Garrett (community representative, S2020).

The minutes from the April 24, 2020 meeting were approved unanimously on May 2, 2020.

As of May 7, 2020, the Institutional Review Board has reviewed 54 proposals this academic year. Of these, 4 were full board, 38 were expedited, and 4 were exempt. Fifteen protocols are still in review and have not yet been approved.

In addition, the board focused on addressing the following charges:

**1) CITI training requirements for faculty advisors of student research and for faculty researchers**

The Faculty Senate charged the IRB to identify appropriate modules from CITI for training of faculty who advise student research or who submit protocols to the IRB. Currently, all student researchers are required to complete the CITI student module. Faculty members underwriting research protocols need to have passed 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. Research involving vulnerable populations or specific procedures may require additional course modules (e.g., Internet-based research, International Research, Research with Prisoners, Research with Children, Research in Public Elementary and Secondary Schools, Vulnerable Subjects, Research Involving Pregnant Women, Fetuses, and Neonates). Certification will be valid for three years after which some of the modules have refresher courses or will need to be retaken.

Before an announcement can be made to all faculty researchers and faculty advisors of student research, the protocol submission coversheet, the IRB website, and the IRB Handbook need to be updated with language that reflects this change in policy. To date, the IRB website has been updated; the protocol submission cover sheet and the IRB

Handbook have not yet been updated. Work on these two aspects of the CITI requirement roll-out will continue in AY2020-21. Nevertheless, an announcement via facultycoms was made on April 20, 2020, with the requirement in force beginning August 31, 2020.

## **2) Federal-Wide Assurance (FWA) for the Protection of Human Subjects**

Consistent with the requirements mandated by the Common Rule (Department of Health and Human Services [DHHS] Title 45 CFR 46 [Public Welfare], Subparts A, B, C, and D) that regulates ethics surrounding federally-funded human subjects research, the IRB sought Federal-wide Assurance from the Office of Human Research Protections (OHRP), a division of DHHS. The OHRP oversees IRB standards, offers educational training, and provides guidance on research ethics.

The University of Puget Sound (#IORG0010265) and its IRB (#IRB00012195) are currently registered with OHRP. The FWA (#FWA00029111) expires on **December 16, 2024**. The status of the FWA may be found at <https://ohrp.cit.nih.gov/search/FwaDtl.aspx>

## **3) Addition of a fourth standing charge by the Faculty Senate**

To ensure that all OHRP regulations are followed, the IRB has been approved for the addition of a fourth standing charge by the Faculty Senate “to monitor requirements of relevant federal programs, such as the Federal Wide Assurance Program, and to ensure that IRB policies and procedures are in compliance and remain current.”

## **4) Memoranda of Understanding (MOUs) for expedited review of student research with the Department of Sociology and Anthropology (SOAN) and with the Department of Psychology (PSYC)**

The MOU for SOAN expired on April 22, 2019. SOAN submitted an updated MOU that included a) procedures for participant observation, b) participant interviews, c) *in process* modifications to the protocol, d) oral consent to participate, and e) procedures to convey potential levels of risk to participants.

The MOU for PSCH was last approved by the IRB on February 17, 2006. PSYC submitted an updated MOU that included a) methods for subject recruitment, and b) procedures for the intentional deception of research subjects. The changes were approved by the IRB on October 2, 2019. The MOU must be reviewed and re-approved before October 1, 2022.

## **5) Protocol Decision Document**

The Protocol Decision Document is a standard form sent to researchers upon approval of their protocol. It serves to document the final approval by the IRB and is archived on the ORB share drive. The Protocol Decision Document was revised to include the University logo, the protocol’s date of submission, and the date of approval. Revisions were approved by the IRB on October 11, 2019.

## **6) Online submission of research protocols for review**

Until the AY2019-20, researcher protocols involving human subjects were submitted by paper copy to the Office of the Associate Dean and by email to [irb@pugetsound.edu](mailto:irb@pugetsound.edu). The IRB decided by unanimous decision to change the way that researchers submit protocol for review. The IRB website was modified in January 2020 to include online submissions, improving the efficiency of archiving protocols and consent forms. Paper and email submissions will no longer be accepted.

## **7) IRB Handbook and inclusive language**

The IRB Handbook had previously used language that was gender binary. In the spirit of fostering an environment that is more inclusive and respectful of the broad diversity of gender identities, the IRB unanimously approved changes to the language in the IRB Handbook. The IRB will continue to review the handbook to change the language that is appropriate for the times.

In the coming academic year (AY2020-21), the IRB will continue the standing charges set forth by the Faculty Senate. These charges include:

1. To apply the University's policies on the protection of human subjects to the Board's review of faculty, student, and staff proposals for research involving human 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 documents are consistent with the will of the University and that they comply with regulatory requirements governing the protection of human subjects in research.
3. To establish definitions, procedures, and dates for the review of research involving human subjects.
4. To monitor requirements of relevant Federal programs, such as the Federal Wide Assurance program, and to ensure that IRB policies and procedures are in compliance and remain current.
5. Such other duties as may be assigned to it.

In addition to the standing charges outlined above, the IRB will address the following self-charges:

1. To update the language of the IRB Handbook to reflect approved changes in procedures for the following:
  - a. Section 4: Protocol Preparation Guide – Add CITI training requirements for faculty advisors of student research and for faculty researchers.
  - b. Section 5: Submission packets for IRB Review – Add online submission of protocols
  - c. Section 6: Elements of Informed Consent and Consent Form Requirements – Improve clarity of the language to assist researchers with deciding which Consent Forms best meets the unique needs of their study design.

- d. Some parts of the Handbook are written with guidelines that are pertinent to IRB members, but not to researchers. Create a separate Handbook for IRB members only. Revise language of current Handbook to only include information relevant to researchers.
2. To update the language of the Cover Page for Student and Faculty Research to reflect approved changes in procedures for CITI training requirements for faculty advisors of student research and for faculty researchers.
3. To update the Informed Consent and Consent Form Requirements to maintain consistency with the changes established in the IRB Handbook, and to improve the readability of the consent forms for research participants.
4. To establish a protocol to notify researchers one month prior to the expiration of IRB approval of their protocols, with a reminder to submit either an Informational Follow-Up Form at the conclusion of their research project, or to submit a Renewal/Modification Form to continue their research project. In compliance with Federal regulations (Title 45 CFR 46), the IRB must retain records of final reports from all researchers upon the completion of their research protocols.

Respectfully Submitted,  
Wendell Nakamura, DrOT and Mike Pohl, PhD  
IRB Co-Chairs AY 2019-20