

Institutional Review Board  
Report to the Faculty Senate  
AY 2016-2017

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 2016-2017 academic year.

2016-17 IRB membership: Tim Beyer (chair); Tatiana Kaminsky (secretary); Kris Bartanen (ex-officio); Joel Elliott, Mita Mahato (Fall), Sarah Moore, Geoff Proehl, Sara Protasi (Spring), Brad Richards, Andreas Udbye, Barbara Warren; Jan Wolfe (community representative).

To date, the Institutional Review Board has reviewed 130 proposals this academic year. Of these 12 were full board (2 approved, 7 pending, 1 denied, 2 withdrawn), 103 were expedited (96 approved, 6 pending), and 9 were exempt (7 approved, 2 pending), and 6 modifications (5 approved, 1 pending).

In addition, the board focused on addressing the following formal charges from the Senate:

**1) Make recommendations on how the Institutional Animal Care and Use Committee (IACUC) fits into the IRB structure**

The current bylaws state that non-human animal research falls under the jurisdiction of the IRB. Currently, the IRB is not set up to review, approve, or monitor research involving non-human animals; rather these processes have been handled by the Institutional Animal Care and Use Committee (IACUC). Currently, the IACUC does not report to the IRB. For these reasons, the IRB was tasked to make a recommendation on how the IACUC fits into the current IRB structure.

In Fall 2016, Elliott and Warren met with Alyce DeMarais, chair of the IACUC. Based on this discussion, it became clear that the IACUC utilizes significantly different review, approval, and monitoring processes than the IRB as Federal Guidelines for non-human and human research differ substantially (see outline in Appendix A). Thus, in agreement with Alyce DeMarais, the IRB full board voted to amend the university bylaws to make the IACUC a separate entity from the IRB and also suggested modifications to the bylaws (see Appendix A). Beyer communicated this recommendation and suggested modifications in Fall 2016 with Ramakrishnan, the IRB Senate liaison, to share with the senate.

**2) Develop training for new IRB members including procedures for follow-up/transition of protocols and regular reviews of Memoranda of Understanding (MOUs)**

In Fall 2016, Proehl and Udbye, both new to the IRB, and Beyer created a training packet designed to provide consistent and systematic training on internal IRB review processes, review of MOUs, and support from an IRB mentor. Protasi, who joined the IRB in Spring 2017, used this packet for training, and after providing feedback, the training packet was further refined. The most updated training packet is found in Appendix B.

Highlights of the training packet include:

- An IRB mentor, who is a more veteran IRB member, will meet with a new member and aid in the review of the first few protocols assigned to the new member. This will increase consistency in review.
- A timeline, which outlines when the Collaborative Institutional Training Initiative (CITI) training for IRB members, review of internal IRB review procedures and MOUs, and meetings with the assigned mentor and chair should occur. The timeline allows new IRB members to complete the training within the first four weeks of a given term, before protocols are typically received for review.
- A sample protocol, which demonstrates several consistent issues IRB reviewers encounter and how to respond to these. We hope that sample protocols such as this will increase consistency in review.

**3) Formulate practices for outside researchers to conduct research with members of our campus community**

At the start of AY 16-17, the IRB did not have a policy for how outside researchers could apply for Puget Sound IRB approval and requests by outside researchers were handled on a case-by-case basis. In order to further standardize application procedures, Kaminsky and Mahato reviewed the policies governing outside research from our peer institutions in Fall 2016 and presented their findings to the full board. Based on these findings, the full board agreed that outside research must go through the typical Puget Sound approval process and that outside researchers must motivate, in writing, why Puget Sound is necessary to complete their research. In addition, outside researchers must identify a member of the campus community to be listed on the coversheet of their protocol.

Due to outstanding legal questions (e.g., whether outside protocols and consent forms could be approved by the Puget Sound IRB), Kaminsky and Beyer worked with Bartanen, who consulted with the university legal team, in Spring 2017. Based on this feedback, Kaminsky drafted a policy for outside researchers, which was approved by the full board in Spring 2017, and can be found in Appendix C. The policy is also now live on the IRB website and has already been used twice since mid-March 2017.

In addition to the formal Senate charges, the board worked on the following self-charges:

**1) Follow-up on CITI student training module now required for all student research protocols**

Starting AY 16-17, all student researchers were required to complete the *Student Module* of CITI training. This requirement was implemented to further educate student researchers on the purpose of the IRB and to increase the consistency and quality of proposals submitted for IRB review. In order to assess whether these goals were met, qualitative feedback was sought from (a) chairs/faculty who teach methods courses, and (b) IRB members and Jimmy McMichael. This is outlined below:

- a. Feedback from chairs/faculty who teach methods courses:** In Spring 2017, Elliott communicated with the chairs/faculty of the main departments/schools which submit protocols for review. These included Psychology, Sociology and Anthropology, Business and Leadership, Physical Therapy, and Occupational Therapy. Overall, department chairs report that the CITI training was relatively easy for students to complete, especially after updated instructions were posted on the IRB website. Faculty found that the training was useful for students but did not appear to have a significant impact on protocol writing.
- b. Feedback from IRB members and Jimmy McMichael:** In Spring 2017, Beyer solicited feedback from IRB members and Jimmy McMichael. In general, IRB members commented that while the proposals in general appeared to be better quality this year, it is not clear whether it was due directly to the CITI training or other changes aimed to standardize submission and review of protocols. However, most IRB members noted that CITI training likely served to increase students' level of awareness of ethics in research more broadly (i.e., beyond information that may be covered in a discipline-specific methods class) and that the IRB is not idiosyncratic to Puget Sound, but rather is part of a national/international effort to ensure the well-being of research participants. As such, CITI provides an important educational experience for students. Jimmy McMichael received no student questions about CITI training in Spring 2017 (he had received a few in Fall 2016) and reported no issues in tracking CITI training for students.
- c. Updated Instructions:** Based on instructor and student feedback in Fall 2016, the initial instructions on how to create a CITI account were unclear. In response to this, Richards created instructions with screen shots and detailed written instructions which can be found in Appendix D and are now published available on the IRB website. There have been no issues reported after these new instructions were created.

**2) Work on standardizing IRB procedures**

In an on-going effort to standardize IRB procedures and make them more transparent, the full board has completed the following tasks this academic year:

- a. Standardized and updated e-mail correspondence:** E-mail correspondence to be used with student researchers during the review process has been standardized to include (a) request for reply within one week for in-progress protocols, (b) notification that approval is good for one year from the approval date, (c) reference to the Informational Follow-up Form (see Point 3 below), and (d) instructions to bring both a hard-copy of the consent form and approval documentation to the Associate Dean's Office when stamping consent forms. Please see updated e-mail correspondence in Appendix E.
- b. Updated review procedures:** In order to streamline internal review procedures, the committee will now only use the "Protocol Decision Document" to document final approval/disapproval, not intermediary steps (e.g., asking for changes to the protocol before approval). This small change will simplify our internal review procedures tremendously due to streamlining how feedback is given to researchers. The updated Protocol Decision Document is attached in Appendix F.
- c. Standardized tracking and storage of verbal consent:** Prior to AY 16-17, there was no systematic way in which verbal consent was tracked or stored. (Verbal consent is typically used in ethnographic research methods and oral histories.) Thus, in the case of an adverse event, the IRB could not verify that verbal consent was obtained from participants. To address this, Moore, Richards, Udbye, and Beyer, in consultation with Monica DeHart (chair of Sociology and Anthropology) and Andrew Gardner developed a documentation process for verbal consent. Here, researchers simply complete a document which lists the participant's pseudonym, whether verbal consent was obtained (Yes/No), and the initials by the researchers. At the end of data collection, this document is e-mailed to the IRB for record keeping. This procedure will be used across all SOAN courses, which produce the largest number of protocols that utilize verbal consent. Please see Appendix G for the verbal consent document crafted by DeHart and Gardner.
- d. Updated protocol template and checklist:** The current protocol template and checklist available on the IRB website do not show a one-to-one correspondence. In addition, the protocol template itself is not very user-friendly in its instructions. For these reasons, it may be that the protocols received are not always uniform in how information is presented. In order to increase transparency in what information the IRB needs to review protocols, in Spring 2017, Warren, in collaboration with Proehl and Beyer, updated the protocol template and checklist. In particular, because many protocols do not have the appropriate level of detail for methods and materials, which can impact the review process, the updated protocol template now contains more detailed questions for this section. Moreover, researchers are now asked to provide an explicit statement of purpose and provide qualifications for

carrying out the research. These updated documents are found in Appendix H and will aid in creating more uniform protocols.

**3) Work on standardizing the storage of consent documentation and Informational Follow-up Forms as required by Federal Guidelines**

Although the current IRB processes are generally aligned with Federal Guidelines, two major issues remain: how consent documentation is stored and the lack of providing study closure information via Informational Follow-up Forms.

- a. Currently, consent forms are stored as hard copies in the department from which that associated protocol originated. Although Federal Guidelines specify how long consent forms are to be stored, there is currently no University-wide IRB policy governing what happens with stored consent forms, including when and how they are to be destroyed. Thus, individual departments differ in how consent forms are stored and destroyed. Currently, there exists no University-wide IRB policy on how verbal consent information is tracked and stored (Point 2 c above is the first step to establish this).
- b. Upon completion of data collection, the researcher must alert the IRB that the data collection phase has ended so that the IRB can close that particular study. Although this information is requested by the IRB, the necessary “Informational Follow-up Form” is not submitted to the IRB by the researchers listed on the protocol.

In order to address both issues, Beyer, Moore, Richards, and Udbye worked to create a new policy in Spring 2017. Instead of simply providing the administrative assistant of a department with consent forms, researchers will be asked to provide consent forms and a completed Informational Follow-up Form. Much like student evaluations for faculty, the administrative assistant would be asked to scan the consent forms and Informational Follow-up Form and e-mail this scanned document to the IRB. The IRB can then store the consent documentation and Informational Follow-up Form with the approved protocol. In this way, Puget Sound IRB practices will be in line with Federal Guidelines. The verbal consent document described in point 2c above would be scanned and e-mailed to the IRB along with an Informational Follow-up Form. The new policy, as well as changes to the Consent Form and Informational Follow-up Form, are found in Appendix I. The IRB would like to implement these changes in Fall 2017, and is in communication with Dean Bartanen to assess feasibility.

The IRB has identified the following issues that should be addressed in 2017-2018:

**1) Formulate a policy for how staff/faculty are used for surveys and interviews**

It is unclear how many protocols the IRB reviews and approves use staff and faculty as research subjects. Here, the IRB should work with Sherry Mondou (Vice President for Finance and Administration) and Ellen Peters (Director of Institutional Research and Retention) to ensure that student researchers are:

- a. Using the appropriate channels to recruit,
- b. Not overloading faculty and staff with research requests, and
- c. Not replicating existing research conducted through Office of Institutional Research and Retention

In addition, the sunset clause for the MOU with Institutional Research and Retention is expiring. It is therefore suggested that this new policy for staff/faculty who are used in research should be incorporated when the existing MOU is reviewed next AY.

**2) Develop policy for international research**

Currently, there is no official policy for international research. It is suggested that the IRB develop a policy for the uniform assessment of international research. In particular, the IRB must standardize requirements and resources for back-translation (the main method used to ensure linguistic equivalence when research is not conducted in English), identify how international laws apply to data collection and storage, and how consent forms/oral consent documentation are safely maintained while abroad.

**3) Explore the utility of registering the IRB and applying for a Federalwide Assurance (FWA) number**

In order to further align with Federal Guidelines, it is suggested that the Puget Sound IRB is registered federally. Moreover, the IRB should explore whether applying for a FWA number would be a useful long-term option. A FWA number would allow easy approval from other institutions that have a FWA number, making it easier to approve outside research at Puget Sound (and having Puget Sound research be approved at other institutions). However, applying for a FWA number can be costly; the benefits of a FWA should be weighed against the application cost.

**4) Review updated Common Rule and incorporate changes**

The Common Rule, which outlines IRB functions, operations, record keeping, and so on, was updated in January 2017 at the Federal level. The IRB must review the main changes to the Common Rule to ensure that our procedures are in line with changing Federal Guidelines. For example, oral histories are now considered to be fully exempt from IRB oversight; however, our policies request that oral histories submit a full protocol for IRB review. While our IRB policies can be more stringent than Federal Guidelines, the IRB should review such cases to ensure that it is not unnecessarily so (as may be the case with oral histories, for example).

**5) CITI training for faculty**

In order to further standardize IRB procedures, it is suggested that the IRB explore whether CITI training for faculty researchers should be required. CITI training for faculty is valid for three years and would require faculty to continually update their understanding of how changing Federal Guidelines impact research procedures. It is suggested that the IRB identify possible modules for faculty researchers to complete.

**6) Meet the Federal Guidelines requiring a representative board**

Current Federal Guidelines specify that the board must consist of scientists and non-scientists as well as a community member who is not part of the university. Our current board meets these criteria. In addition, Federal Guidelines state that the board must also be diverse in terms of race and ethnicity. Our current board does not meet this criterion. With the understanding that we are a small faculty with many service assignments, the IRB requests that extra attention, when possible, is taken to meet the Federal Guidelines to create a representative, diverse board.

Respectfully Submitted,  
Tim Beyer, PhD  
IRB Chair AY 2016-17

Appendices:

A: Recommendation for IACUC and IRB distinction

B: Training packet for new members

C: Policy for outside researchers

D: Updated instructions for student researchers

F: Standardized e-mail responses and review flowchart

G: Verbal consent document

H: Updated protocol template and checklist

I: Recommendation for storing consent documentation and Informational Follow-up Forms

## Appendix A: Recommendation for IACUC and IRB Distinction

### IACUC workgroup: Make recommendations on how the IACUC fits into the IRB structure.

- 1) Members: Joel Elliott and Barbara Warren
  - 2) 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/>
- a. 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.
  - b. 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.
  - c. 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.
- 3) 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:
    1. 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.
- 4) 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.

## **Appendix B: Training Packet for New Members**

### **Welcome to the Institutional Review Board (IRB)!**

The IRB is charged with approving, monitoring, and reviewing research involving humans. As a member of the IRB, your role is to support the IRB in carrying out these charges. A main consideration in reviewing research involving humans is conducting a risk-benefit analysis in order to determine whether research can be approved. You will be asked to do this individually (for research protocols with only minimal risk) and contribute to decisions made by the full board (for research protocols with greater than minimal risk). Thus, you will serve as the reviewer of protocols that are submitted by the Principal Investigator (PI) responsible for carrying out the research project.

This document outlines the *training components* to allow you to successfully review and approve research using the standardized process of the Puget Sound IRB.

**New IRB Members:** Please utilize the resources and timeline provided on the next page to complete the training necessary to begin reviewing protocols.

**IRB Mentor:** Every member new to the IRB will be paired with a more veteran member who will serve as the new member's mentor. The mentor's role is to:

- 1) Meet individually to go over internal training materials and familiarize you with the IRB share drive (see specifics on the *Timeline* on the next page);
- 2) Be a direct resource during the first (and second, if needed) individual review of a research protocol and debrief after the first (and second) review; and
- 3) Remain a consistent resource as needed over the course of subsequent reviews.

Thus, the mentor should provide a consistent contact person for the new member and aid in standardizing the review process. In addition to the official mentor, new members are encouraged to contact the current IRB chair or other members of the committee as questions or issues arise.

### Training for New Committee Members: Timeline

Order	Task	Resources	Timeline
1	<b>Welcome and Introduction to IRB</b> document and familiarize with <b>University website</b>	IRB/Resources for IRB Members/Training and <a href="http://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/irb-member-information">http://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/irb-member-information</a>	As early as possible, but prior to first full board IRB meeting of the term
2	Complete <b>institutional CITI training</b> (you should anticipate 5-15 hours to complete the training)	Instructions found on IRB/Resources for IRB Members/Training/CITI training instructions.pdf	Must complete before second full board meeting of the term
3	Review the following <b>internal training materials</b> a) Protocol Flowchart.pdf b) Level of Risk.pdf c) Level of Review Guide.pdf d) Sample training protocols	All materials found under IRB/Resources for IRB Members/Training	Complete prior to meeting with IRB mentor
4	<b>Meet with assigned IRB mentor</b> to go over internal training materials, preview share drive, and discuss protocol flowchart and review process	TBD	By 2 <sup>nd</sup> week of the term
5	Review the following <b>documents</b> : a) Protocol Decision Document b) Standardized e-mail responses c) Memorandum of Understanding	Documents found under: a) IRB/Resources for IRB Members/Forms/Protocol Decision Document.docx b) IRB/Resources for IRB Members/Training/Standardized E-mail Responses.docx c) IRB/Resources for IRB Members/Memorandum of Understanding (MOUs)	Prior to reviewing protocols
6	<b>Meet with chair</b> to review documents used for review and process	TBD	By 3 <sup>rd</sup> week of the term
7	<b>Ongoing review</b> of materials: a) Familiarize with IRB Handbook b) Ethical considerations	Materials found under: a) IRB/Resources for New Members/Training/Handbook.pdf b) IRB/Resources for IRB Members/Training/Keyton – Research Ethics.pdf	Ongoing

### **Instructions to complete CITI training:**

Institutional training is completed through the Collaborative Institutional Training Initiative (CITI). To complete the training, navigate to:

<https://www.citiprogram.org/>

Next, create a new account affiliated with the University of Puget Sound (be sure to type this into the affiliation and/or select it from the possible responses you get). You'll be asked some background questions in order to associate your account with the correct modules. Please be sure to select the following responses for these questions:

- a) *Human Subjects Research*, select "*IRB Member*"
- b) For *Responsible Conduct of Research*, select "*Social and Behavioral Science Researchers (includes Education and Business)*"

\*\*\*\*\*You can select a different branch (e.g., Humanities) once you have completed the "Social and Behavioral Science Researchers" one. To do so, under "My Learner Tools for University of Puget Sound" select "Add a Course" and select a different branch

- c) For *Conflict of Interest*, select "*Yes*"
- d) For *IACUC*, select "*No*"

Once you've created an account associated with IRB Members, you must complete all required modules in the following three courses: "Conflicts of Interest"; "IRB Members"; and "Social and behavioral science researchers." You can complete the "optional" modules based on your time and interest. All modules have a test at the end; you must achieve a passing score across all required modules before the system will recognize that you have "passed" the training for IRB members.

## Protocol Flowchart (updated 2/2017)

- 1) The principal investigator (PI) submits their protocol to Jimmy McMichael as:
  - a. A hardcopy in Jones 212 (CMB 1020); and
  - b. An electronic copy ([irb@pugetsound.edu](mailto:irb@pugetsound.edu))
- 2) Upon receipt, Jimmy logs the details of the protocol into our database. Using the level of review identified by the PI, Jimmy will either assign a *single reviewer* (for protocols marked exempt/expedited) or send the protocol to the *full board* (for protocols marked full board).
- 3) For exempt/expedited protocols:
  - a. Jimmy will notify you via e-mail when a protocol has been assigned to you. The protocol will be attached in the e-mail. You can also access this protocol via the shared IRB drive (`//merlin2/irb/`). Once logged in, the folder *Protocols* contains sub-folders with the protocol number that has been assigned to you. You will find the protocol in that folder.
  - b. Confirm that the PI has identified the correct level of review (see “Levels of Review Checklist”)
    - i. If correctly identified as exempt/expedited, please review protocol.
    - ii. If incorrectly identified as exempt/expedited, please e-mail Jimmy to alert him that this protocol requires full board review and must be sent to the full committee.
- 4) Review of exempt/expedited protocols:
  - a. *If revisions are required* before the protocol can be approved, the required changes must be communicated with the PI via e-mail. The PI must resubmit the revised document(s) to the reviewer via e-mail. All requested revisions must be satisfied before the reviewer can approve the protocol.
    - i. Considerations during the review process:
      1. The reviewer should communicate with the PI within 3 business days of receipt of a protocol or resubmission.
      2. Use the standardized e-mail responses found on the share drive (under *Resources for IRB Members/ Training/ Standardized E-mail Responses*) for all *student protocols*. You can amend these responses for non-student protocols.
      3. If the PI is a student, include the student’s advisor on all correspondence. The advisor’s name is on the coversheet.
  - b. *Once the protocol can be approved*, communicate this decision with the PI by using the Protocol Decision Document, found on the share drive under *Resources for IRB Members/Forms*.
    - i. Upload the following into the appropriate protocol folder on the share drive:
      1. Protocol Decision Document
      2. All revised documents

- ii. Bring the list of protocols you reviewed since the last full board IRB meeting. We will collect protocol numbers and status (approved, revisions required, rejected).
- c. All written communication between the reviewer and the PI *must* be retained. Thus, please cc [irb@pugetsound.edu](mailto:irb@pugetsound.edu) on all e-mail correspondence

\*\*\*\*Once review of an expedited/exempt protocol is complete, each folder on the IRB share drive *must* contain the following:

- a. Original protocol (uploaded by Jimmy)
- b. Revised protocol (if any revisions were requested by the reviewer)
- c. Protocol Decision Document

If a protocol requires full board review, Jimmy will make the protocol available to the full committee. We will discuss the protocol at the next full board meeting. The IRB chair will communicate decisions, including if revisions are required, with the PI.

On the following pages, you will find the necessary documentation to assess level of review as well as some department specific information and consideration. These documents can also be found on the share drive, as indicated on the Timeline on pg. 2 of this document.

## Levels of Review Checklist

### Does my project need IRB review?

Your project needs to be reviewed by the IRB if it meets **both** of the criteria below

- A. The project meets the federal definition of research: systematic investigation intended to produce generalizable knowledge. [45 CFR 46.102(d)]
- B. Human participants are involved. Human participants are living individuals about whom you are conducting research and gathering
  1. data through intervention or interaction with the individual, or
  2. identifiable private information. [45 CFR 46.102(f)]

If your project meets **either** criterion A **or** B, but not both, your project does not need IRB review. If your project meets **both** criteria, you need IRB approval before beginning your research. Generalizable knowledge refers to the planned dissemination of results in a public forum or academic publication. Classroom projects, for which such dissemination is beyond the scope of the course, are not research according to this definition.

### What are the types of IRB review?

The federal government has established different levels of review, depending on the method and content of your research.

1. Full Board: must be reviewed by the full committee, requires IRB oversight and follow-up.
2. Exempt: requires no further IRB oversight or follow-up
3. Expedited: may be reviewed by one member on behalf of the full IRB, but requires IRB oversight and follow-up

When you prepare your protocol, you will see that the Puget Sound cover sheet asks you to give your best estimate of the appropriate level of review for your project. However, the final decision about types of review rests with the IRB. In order to determine the level of risk to participants, please refer to the **Level of Risk** document available on the IRB website. You can use the following checklist to estimate the level of review for your project.

### **1) Full IRB Review.**

If your project meets **ANY** of the following criteria, then it will require review by the full IRB committee:

- \_\_\_\_\_ receives support from non-university sources that require full IRB approval
- \_\_\_\_\_ involves greater than minimal risk (e.g., physical, psychological or emotional, legal, social or economic, etc.) to participants than they would likely encounter every day
- \_\_\_\_\_ involves personality tests, inventories or questionnaires of a personal and sensitive nature where participants' identities will not be anonymous to the researcher and/or where the information you collect can be connected back to individual study participants
- \_\_\_\_\_ involves sensitive aspects of a participant's behavior that could reasonably place a participant at risk of criminal or civil liability or be damaging to a participant's financial standing or employability
- \_\_\_\_\_ involves sensitive aspects of a participant's behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol
- \_\_\_\_\_ involves active deception or procedures that are not known to the participant (e.g., the participant will not be fully informed)
- \_\_\_\_\_ involves health care procedures that are not conducted for the primary benefit of the participants
- \_\_\_\_\_ includes diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice
- \_\_\_\_\_ involves special populations (e.g., prisoners, pregnant women, or individuals who are mentally or psychologically ill, or incompetent)
- \_\_\_\_\_ involves subjects under 18 years of age and involves more than minimal risk
- \_\_\_\_\_ involves collection of blood samples or other body fluids in any amount

If any of these apply to your research, your project will need approval from the full Board before you begin your research. Your next step is to prepare a research protocol and submit it to the IRB for review. If none of these apply, then go to (2) below.



**2) Exempt Review.** If your research did not meet **any** of the criteria for full review, it will qualify for either exempt or expedited review. Examples of exempt research may include:

- \_\_\_\_\_ surveys or interviews in which responses will be recorded in such a manner that a participant **CANNOT** be identified directly or through identifiers linked to a participant **AND** any disclosure of participants' responses outside the research will **NOT** place the participants at risk of civil or criminal liability, or be damaging to the participants' financial standing, employability, or social standing.
- \_\_\_\_\_ investigations of commonly accepted educational practices in established or commonly accepted settings.
- \_\_\_\_\_ observations of public behavior.
- \_\_\_\_\_ collection or study of publicly available existing data, documents, records or specimens.
- \_\_\_\_\_ collection or study of existing data, documents, records or specimens in which information will be recorded in such a manner that a participant cannot be identified directly or through identifiers linked to a participant.
- \_\_\_\_\_ research or demonstration project conducted by or subject to approval of the U. S. Department of Health and Human Services for the purpose of studying procedures, benefits, changes, and payments of entitlement programs.
- \_\_\_\_\_ analysis of information from educational tests that will be recorded in such a manner that participants cannot be identified.

If you checked **any** of the descriptors in (2) above and **no** descriptors from category (1), your research project probably meets the criteria for **Exempt Review**. Your next step is to prepare a research protocol and submit it to the IRB for review. Your protocol likely can be reviewed by one IRB member on behalf of the full Board and, if it is approved for **Exempt** status, will require *no further oversight or follow-up from the IRB*. If you checked no descriptors in (1) or (2), go to (3) below.

### **3) Expedited Review**

The third category allows for expedited review. Does your research project:

- involve only minimal risk (e.g., physical, psychological or emotional, legal, social or economic, etc.) to participants, or only as they would likely encounter every day?
- involve participants under 18 years of age with at most minimal risk to subjects
- involve recording data from participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice?
- involve analysis of voice recordings made for research purposes?
- involve moderate exercise by healthy volunteers?
- involve the collection or study of existing data, documents, records or specimens?
- involve research on individual or group behavior, or characteristics of individuals, without manipulation of a participant's behavior and in a manner that does not cause stress to participants that is greater than they would encounter in everyday life?

If you checked any of the descriptors above, and none in (1) or (2), your project probably meets the criteria for **Expedited Review**. Your next step is to prepare a research protocol and submit it to the IRB for review. Your protocol likely can be reviewed by one IRB member on behalf of the full Board. If it is approved with **Expedited** status, your project will be subject to continued oversight and follow-up with the IRB and you will be required to submit requests for modification to methods, sampling, etc. should the need arise.

## **Department/Discipline Specific Recruitment Methods, Methodologies, and Ethical Considerations**

**Psychology:** Many of the protocols from the Department of Psychology use the Subject Pool to recruit participants. Here, students enrolled in lower division Psychology classes must fulfill a research participation requirement. This requirement can be fulfilled by participating in research studies (where 30 minutes of participation equals 1 participation credit) or by completing a written assignment (which is equivalent in terms of time as participating in studies). Thus, protocols from Psychology may make reference to research credits or units; these refer to compensation from the Subject Pool.

*Ethical considerations:* Because participants volunteer their time, participants must receive their research credits *even if they withdraw from the study*. This should be explicitly stated in the Project Description and/or the consent form in all protocols that use the Psychology Department Subject Pool.

**Ethnographic Research Methods:** Many of the protocols from the Department of Sociology and Anthropology (SOAN) use ethnographic methods which include recording interviews with their participants. Because of this, these protocols typically use a verbal, not written, consent form. (More details are found in the Memorandum of Understanding with SOAN on the IRB share drive.)

*Ethical considerations:* Some topics covered in protocols are sensitive in nature, and although the researcher may not directly ask about illegal activities and behaviors (e.g., drug use, criminal activities, given a topic, a participant may inadvertently report on their own (or other's) illegal activities and behaviors. If the research topic is such that a participant may report on illegal activities and behaviors, the project description must clearly state that the researcher will stop recording, redirect the participant, and only start recording again once the participant has ceased talking about illegal activities and behaviors.

UPS IRB PROTOCOL #

**University of Puget Sound INSTITUTIONAL REVIEW BOARD**  
**Application for Approval of Research Involving Human Subjects**  
(Cover Sheet)

(Protocols meeting Full Board Review must be submitted two weeks prior to the date of the IRB meeting on which the review is to occur.)

Please Check One:  New Project  Renewal  Modification (Attach Renewal/Modification Form)

Date of Submission: October 11, 2016

Protocol Title: Tattoos and the Workforce

Principal Investigator: Typed name: Jane Doe  
Signature: \_\_\_\_\_  
Department or School: Department of Sociology and Anthropology  
Email: [jdoe@pugetsound.edu](mailto:jdoe@pugetsound.edu)  
Telephone number: (123) 456-7890

Co-Investigator: Typed Name: Joe Doe  
Signature: \_\_\_\_\_  
Email: [jdoe2@pugetsound.edu](mailto:jdoe2@pugetsound.edu)

Co-Investigator: Typed Name: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Email: \_\_\_\_\_

Co-Investigator: Typed Name: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Email: \_\_\_\_\_

**Faculty Advisor's Statement** (student projects only): I, George Doe am the advisor for the above named students. My signature below indicates that I have read the attached protocol and have checked the contents with the IRB Guidelines. I thereby recommend this protocol as:  
Exempt Review  Expedited Review  Full Board Review   
Signature: \_\_\_\_\_ Email: [gdoe@pugetsound.edu](mailto:gdoe@pugetsound.edu)

Source of Support (if any):

Level of Risk to Human Participants:  Minimal  Greater than minimal

Number of Participants: 15

\*Normal participants are (a) over the age of 18 (b) able to make independent decisions with full mental capacity. Children are minors under the age of 18.

Are vulnerable populations involved?\*  yes  no Are children involved?\*  yes  no

Has this proposal been or will it be submitted to other Human Subjects Review Boards, departmental committees, or community agencies for review and approval?  
 Yes (attach approval letters)  No

Tim Beyer 4/10/2017 8:32 AM

**Comment [1]:** Title must be consistent throughout the entire document.

Tim Beyer 4/10/2017 8:33 AM

**Comment [2]:** Department should be listed unless the researcher belongs to the School of Education, Physical Therapy, or Occupational Therapy.

Tim Beyer 4/10/2017 8:33 AM

**Comment [3]:** All co-investigators must be listed.

Tim Beyer 4/10/2017 8:35 AM

**Comment [4]:** Faculty advisor statement must be completed. Ensure that faculty advisor's name and e-mail are present and a level of review (exempt, expedited, full board) has been checked. After reviewing the protocol, you must confirm that the appropriate level of review has been selected.

Tim Beyer 4/10/2017 8:36 AM

**Comment [5]:** Exempt and expedited levels of review correspond to "minimal" risk. If "greater than minimal" risk is selected, the protocol must be reviewed by the full board.

Tim Beyer 4/10/2017 8:38 AM

**Comment [6]:** Double-check that all boxes are checked and are appropriate for project and level of review; e.g., if "yes" is selected for "vulnerable populations" it is likely that full board review is necessary.

## Careful Considerations: Tattoos and the Workforce

- (A) **Project Description:** *Describe the purpose of the research, the methods to be used including data collection procedures and any features of the research design that may involve special conditions or procedures for the subjects. Identify any risks to which subjects may be exposed.*

In my research I will be trying to determine how aspirations about future employment shape and reflect tattoo considerations for undergraduate students at the University of Puget Sound. Much of the literature on the subject of tattoos in the workplace suggests that people with tattoos are considered to be untrustworthy, unmotivated, unprofessional and less approached than their un-tattooed counterparts. This stigma against tattooed people can make it harder for them to secure a job. Upon completing this research, I hope to gain an understanding of the extent to which students who have tattoos on this campus have considered this potential challenge as they plan for their lives after college, and the ways their professional aspirations have shaped and been reflected by their tattoos. I also hope to address whether or not college students see tattoos as a deviant act, or if they perceive tattoos as now a part of mainstream culture and foresee the biases against tattoos becoming obsolete.

In my audiotaped (consent to record will be obtained before interviewing begins) semi structured interviews I will try to get a sense of how students think about tattoos. Interviews will be conducted in person and one-on-one, location to be determined on a case-by-case basis.

- (B) **Subject Recruitment:**

1. *Identify the number of subjects to be recruited for the research. Identify how and where subjects are recruited and the criteria used to select and exclude subjects.*
2. *Describe the characteristics of the subjects with regard to age, sex, race, special affiliations which cause them to be included in the study population, institution status (i.e., patients or prisoners), and their general state of mental and physical health. Explain why it is necessary to use any particular population subgroups or special populations.*

I will recruit 15 subjects, starting with a list of acquaintances known to have tattoos and then using the chain referral method to ask respondents for the names of other people who fit the criteria and might be willing to participate in my research. Respondents must be undergraduate students at the University of Puget Sound, they must have at least one tattoo (visible or not) and they must be older than 18 years old. For the purpose of this study I will not limit my respondent pool to exclude any gender, sexual, or racial identities and will allow respondents within any mental or physical health as long as participation does not put them at risk of emotional or physical harm. The subject population will resemble the subject pool at the University of Puget Sound in terms of age, ethnicity, and gender.

Tim Beyer 4/10/2017 9:24 AM

**Comment [7]:** Title does not match the title on the coversheet. One, consistent title must be used throughout.

Tim Beyer 4/10/2017 9:01 AM

**Comment [8]:** Should have citations to support writing.

Tim Beyer 4/10/2017 9:05 AM

**Comment [9]:** Ensure that there is a clear "purpose of the study" statement in the project description. If not, then request a clear statement from the researchers before approval.

Tim Beyer 4/10/2017 9:02 AM

**Comment [10]:** As per the MOU with SOAN, ethnographic research methods which employ semi-structured interviews must include an interview guide. This is not included and must be requested before approval.

Tim Beyer 4/10/2017 9:04 AM

**Comment [11]:** Reviewer should indicate how long the interviews will take, on average. In addition, any potential risk is not identified in this section.

Tim Beyer 4/10/2017 9:07 AM

**Comment [12]:** How will the researchers assess this? If the researchers believe that certain mental/physical health differences will impact participation negatively, then they must outline what these are and how participants may be screened out. This must be clarified before approval.

(C) **Confidentiality of Data:** *Explain how data will be secured to safeguard identifiable records of individuals.*

The names of participants will not appear on any materials containing their responses. All identifying materials such as consent forms will be kept in a locked file in the Sociology and Anthropology Department at the University of Puget Sound. That said, I will be researching tattoos which are unique in tier design and placement so there is some danger of the identify of the person being discernable through a description of their tattoo(s). To minimize this concern I will leave out any descriptive information that is not pertinent to the findings. I will also include a statement in the consent form saying that any respondent will be granted the option to have descriptions of tattoos left out of the final paper when they are identifiable. Digital and audio files will be kept on a password protected personal computer. All files will be destroyed within six months of the end of the study unless otherwise stipulated by the subjects.

(D) **Risks to Subjects:** *Describe in detail any immediate or long range risks to subjects that may arise from the procedures used in the study. (Risks may be physical, psychological, social, legal, or economic.) Describe the precautions you have taken to minimize these risks.*

There are minimal risks associated with this study and I will be careful to minimize potential risk wherever possible. I will avoid sensitive subject matter in my interview by asking only about the respondent's tattoos in relations to their potential future jobs, and I will protect their identities as thoroughly as possible as mentioned in the above section.

(E) **Benefits:** *Describe the anticipated benefits to subjects, science, and/or society, that may occur as a result of this study.*

Subjects do not receive benefits for participating, but I hope that this study will contribute to the academic discourse of tattoos in the workplace and provide the participants an opportunity to consider how best to proceed as they enter into the workforce.

Tim Beyer 4/10/2017 9:11 AM

**Comment [13]:** This is a good safeguard by the researchers. Ensure that this statement appears on the consent form and is readily understandable by the reader.

Tim Beyer 4/10/2017 9:14 AM

**Comment [14]:** It is typical that audio files are destroyed immediately after transcription is complete. In addition, transcription should remove any identifying information. This should be specified by the researcher.

Tim Beyer 4/10/2017 9:17 AM

**Comment [15]:** This is unclear; does this mean that files can be destroyed sooner? Later? The researchers must specify what is meant here before approval.

Tim Beyer 4/10/2017 9:19 AM

**Comment [16]:** The researcher can be asked to specify this in more detail if the reviewer feels that there are some risks inherent in the project that the researchers have not yet identified.

Tim Beyer 4/10/2017 9:20 AM

**Comment [17]:** This cannot be assessed as an interview guide has not been submitted with the project. This must be requested before approval can be granted.

## Consent to Act as a Subject in a Research Study

TITLE: Careful Considerations: Tattooed Students Joining the Workforce

INVESTIGATORS: Jane Doe (123) 456-7890 Joe Doe (123) 456-7899

SUPERVISOR: George Doe DEPARTMENT: Sociology and Anthropology PHONE: 253 879-1234

DESCRIPTION: This project seeks to examine the ways future employment aspirations shape and reflect tattoo considerations among students at the University of Puget Sound. Students will be recruited based on referrals from their peers, using the snowball method. The purpose of this study is to gauge student's perspective on workplace discrimination against people with tattoos, and how they plan on mitigating any potential impact their tattoos might cause as they enter the workforce. The goal is to garner an understanding of the general perceptions of anti-tattoo stigma in the chose field of UPS students, and to observe any trends relating to fiends that are though to be more or less discriminatory. The study will include approximately ten (15) students, each of whom will participant in one-hour long initial audiotaped interviews, with the possibility of short follow-up interviews.

RISKS AND BENEFITS: I understand that there are no anticipated risks associated with my participation in this research.

COSTS AND PAYMENTS: I understand that I will incur no costs as a result of my participation in this project; all project costs will be born by the principal investigator. Likewise, I will receive no monetary compensation for my participation.

\*\*\*\*\*  
CONFIDENTIALITY: To ensure confidentiality of the participant, the primary researcher will use pseudonyms to refer to all interviewees in the final report. I understand that any information about me obtained from this research, including answers to questionnaires, laboratory data, or audio or videotapes will be kept strictly confidential. Information that will carry personal identifying information will be kept in locked files in the SOAN department at the University of Puget Sound OR will be kept on a password-protected personal computer that will remain in my possession. I understand that I have the right to request that identifiable descriptions of my tattoos will be omitted from the final report to protect my identity. I do understand that my research records, just like hospital records, may be subpoenaed by court order. It has been explained to me that my identity will not be revealed in any description or publication of this research. Therefore, I consent to such publication for scientific purposes.

RIGHT TO REFUSE OR END PARTICIPATION: I understand that I am free to refuse to participate in this study or to end my participation at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled.

Tim Beyer 4/13/2017 10:51 AM

**Comment [18]:** Consent form needs to be on Puget Sound letterhead.

Tim Beyer 4/10/2017 9:27 AM

**Comment [19]:** Title is not consistent with the coversheet. One consistent title must be used throughout.

Tim Beyer 4/10/2017 9:40 AM

**Comment [20]:** There may be no spelling or grammar issues on the materials that the participant sees, including consent forms. The reading level of a consent form should be 8<sup>th</sup> grade.

Tim Beyer 4/10/2017 9:41 AM

**Comment [21]:** Any inconsistencies on the consent form and between the protocol and the consent form must be rectified.

Tim Beyer 4/10/2017 9:44 AM

**Comment [22]:** All sections above the "asterisks" on the consent form must be in the third person, not first person. Moreover, the potential risks are not described (refer the researcher back to the "Risks" section in the protocol). In addition, benefits are not described (again, refer the researchers back to the "Benefits" section in the protocol). The consent form should be an accurate reflection of what is covered in the protocol.

Tim Beyer 4/13/2017 10:51 AM

**Comment [23]:** This section should also be written in the third person.

Tim Beyer 4/10/2017 10:10 AM

**Comment [24]:** This should be spelled out.

Tim Beyer 4/10/2017 10:11 AM

**Comment [25]:** This is unclear; audio files should be erased after transcription and transcription should remove identifying information. Ask researchers to clarify intended meaning.

Tim Beyer 4/10/2017 10:12 AM

**Comment [26]:** When a consent form is longer than two pages, there must be a space to initial on every page that does not have the signature line. This must be added before approval can be granted.

VOLUNTARY CONSENT: I certify that I have read the preceding or it has been read to me and that I understand its contents. Any questions I have pertaining to the research have and will be answered by Jane Doe. Any questions or concerns I have regarding my rights as a research subject will be answered by the Office of the Associate Dean (253-879-3207). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this study.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's signature

INVESTIGATOR'S CERTIFICATION: I certify that I have explained to the above individual the nature, potential benefits, and possible risks associated with participating in this research study, have answered any questions that have been raised, and have witnessed the above signature.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator's signature

Tim Beyer 4/10/2017 10:17 AM

**Comment [27]:** Ensure that this contact information is included in the consent form.



## Appendix C: Policy for Outside Researchers

Thank you for your interest in conducting research at the University of Puget Sound. Outside research, conducted by anyone who is not a student of or employed by the university, is permitted, after the following process is completed.

This process applies to you if:

- Members of the student body are used as research subjects, and/or
- On-campus resources (physical or virtual) are used for recruitment or data collection

Examples include recruitment of research subjects through on-campus email distribution lists, through flyers posted on campus, or through the on-campus physical and/or occupational therapy clinics.

The following requirements must be satisfied before research is conducted by outside researchers:

- You must have IRB approval from your home institution and provide documentation to the University of Puget Sound Institutional Review Board (PS-IRB).
- You must follow the same procedures for submission of protocols as on-campus researchers (completion of cover sheets, articulating the risks and benefits of the study, recruitment methods, consent forms, etc.) For further information about the requirements for submission, visit <https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>
- When your protocol is submitted for PS-IRB review, you need to articulate why the Puget Sound campus community is needed and how members of the Puget Sound community may benefit from the research.
- You need to partner with an on-campus faculty or staff member. The on-campus member must be actively involved in the research. That person should be listed on the consent form and cover sheet.
- You need to complete the CITI training modules associated with “Social and Behavioral Science Researchers.”
  - If you *do not* already have a CITI account, navigate to [www.citiprogram.org](http://www.citiprogram.org) and create a new account:
    - Select “University of Puget Sound” as the home institution.
    - After entering the requested demographic information, select:
      - “Researchers” (Question 1).
      - “Social and Behavioral Science Researchers (includes Education and Business” (Question 2).
      - “No” (Question 3).

- “No” (Question 4).
  - Complete the nine associated modules and submit your certificate of completion with your protocol.
- If you already have a CITI account, but have not completed the training modules associated with “Social and Behavioral Science Researchers,” please:
  - Select “Add a course” from “My Learner Tools”.
  - Input the information listed above for Questions 1-4.
  - Complete the nine associated modules and submit your certificate of completion with your protocol.
- If you already have a CITI account and have completed the training modules associated with “Social and Behavioral Science Researchers” simply submit your certificate of completion with your protocol.

You may direct questions about this process to the current chair of the PS-IRB. The name of the chair may be found here:

[https://cascade.pugetsound.edu/cascade/faculty.committee\\_list?p\\_committee\\_id=5](https://cascade.pugetsound.edu/cascade/faculty.committee_list?p_committee_id=5)

## Appendix D: Updated Instructions for Student Researchers

# CITI Account Creation Instructions for Students

Before you can start CITI training, you must first create an account at the CITI site. Start by going to [citiprogram.org](http://citiprogram.org) and click on the “Register” button in the “Create an account” box. It should take you to a page like the one shown on the right. Enter “University of Puget Sound” and click the box to agree to their terms of service (after reading them, of course). Then click the “Continue to Step 2” button

The screenshot shows the CITI Learner Registration page. At the top, there is a navigation bar with the CITI PROGRAM logo and the text "Collaborative Institutional Training Initiative". There are links for "Home", "About Us", "Subscribing", "Online Courses", "CMEs/CEUs", "News", and "Contact Us". A search bar for the "Search Knowledge Base" is also present. The main content area is titled "CITI - Learner Registration" and shows a progress indicator for "Steps: 1 2 3 4 5 6 7". A message states "You must make a selection below." The "Select Your Organization Affiliation" section includes a search box with "University of Puget Sound" entered. Below the search box, there is a checkbox labeled "I AGREE to the Terms of Service for accessing CITI Program materials." which is checked. At the bottom of this section, the "Continue to Step 2" button is highlighted. The "Independent Learner Registration" section provides instructions for users not affiliated with a CITI Program subscriber organization and includes a "Continue as Independent Learner (Fees Apply)" button.

Step 2 asks for your name and email address. Use your @pugetsound address here, and Continue to Step 3.

USA - English Text Size: A A Log In | Register | Help

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CITI - Learner Registration - University of Puget Sound

Steps: 1 2 3 4 5 6 7

**Personal Information**

\* indicates a required field.

* First Name Jane	* Last Name Doe
* Email Address jndoe@pugetsound.edu	* Verify email address jndoe@pugetsound.edu

We urge you to provide a second email address, if you have one, in case messages are blocked or you lose the ability to access the first one. If you forget your username or password, you can recover that information using either email address.

Secondary email address  
Verify secondary email address

Continue to Step 3

**SITE NAVIGATION**  
Home CMEs/CEUs Accessibility

**CONTACT INFORMATION**  
CITI Program, a Division of BRANY  
1091 Mosses Avenue, Suite 200

Pick a user name that's not already taken and create a password for your account. Then set up a security question for yourself before you Continue to Step 4.

USA - English Text Size: A A Log In | Register | Help

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CITI - Learner Registration - University of Puget Sound

Steps: 1 2 3 4 5 6 7

### Create your Username and Password

\* indicates a required field.

Your username should consist of 4 to 50 characters. Your username is not case sensitive; "A12B34CD" is the same as "a12b34cd". Once created, your username will be part of the completion report.

\* User Name  
jndoe

Your password should consist of 8 to 50 characters. Your password is case sensitive; "A12B34CD" is not the same as "a12b34cd".

\* Password  
\*\*\*\*\*

\* Verify Password  
\*\*\*\*\*

Please choose a security question and provide an answer that you will remember. NOTE: if you forget your login information, you will have to provide this answer to the security question in order to access your account.

\* Security Question  
What color was your first car?

\* Security Answer  
Yellow

Continue to Step 4

Your country of residence will be the United States, even if that's not your home country.

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CITI - Learner Registration - University of Puget Sound

Steps: 1 2 3 **4** 5 6 7

\* Indicates a required field.

**\* Country of Residence**

Search for country: Enter full or partial name (e.g., "United States") OR your country's two or three character abbreviation (e.g., "US", "USA"), then pick from the list of choices provided.

United States

Continue to Step 5

**SITE NAVIGATION**

Home	CMEs/CEUs	Accessibility
About	News	Copyright
Subscribing	Contact Us	Privacy Notice
Online Courses		Terms of Service

**CONTACT INFORMATION**

CITI Program, a Division of BRANY  
1981 Marcus Avenue, Suite 210  
Lake Success, NY 11042  
888-529-5929 (U.S. toll free)  
+1-305-907-3100 (Outside U.S.)  
support@citiiprogram.org

Unless you *want* to pay money to take your training courses, make sure you select “No” when asked if you want Continuing Education Unit credit. Decide whether CITI can contact you for research purposes, and Continue to Step 6.

**\* Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses?**

CITI is pleased to offer CE credits and units for purchase to learners qualifying for CE eligibility while concurrently meeting their institutions training requirements.

CE credits/units for physicians, psychologists, nurses, social workers and other professions allowed to use AMA PRA Category 1 credits for re-certification are available for many CITI courses – with that availability indicated on course and module listings. **Please register your interest for CE credits below** by checking the “YES” or “NO” dots, and, when applicable, types of credits you wish to earn at bottom of page. Please read texts entered for each option carefully.

**Yes**

At the start of your course, you will be prompted to click on a “CE Information” page link located at the top of your grade book and to VIEW and ACKNOWLEDGE accreditation and credit designation statements, learning objectives, faculty disclosures, types, number and costs of credits available for your course.

Yes

**No**

The CE functionality will not be activated for your course. Credits and units will therefore not be available to you for purchase after you start your course. You can change your preference to “YES” before such time however by clicking on the “CE Credit Status” tab located at the top of your grad book page.

No

**If you picked “YES”, please check below the one type of credit you would like to earn**

MDs, DOs, PAs - AMA PRA Category 1 Credits TM

Psychologists – APA Credits

Nurses – ANCC CNE

Other Participants – Certificates of Participation

Social Workers – Florida Board of Clinical Social Work, Marriage & Family Therapy and Mental Health Counseling

**\* Can CITI Program contact you at a later date regarding participation in research surveys?**

Yes

No

Not sure. Ask me later

[Continue to Step 6](#)

Enter your email address and the department in which you're doing your research. Select "Student Researcher – Undergraduate" from the drop-down menu, then Continue to Step 7.

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Steps: 1 2 3 4 5 6 7

Please provide the following information requested by University of Puget Sound

\* indicates a required field.

\* Institutional email address  
jdoe@pugetsound.edu

\* Department  
Psychology

\* Role in research  
Student Researcher - Undergraduate

Continue to Step 7

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CITI Program, a Division of BRANY  
1981 Marcus Avenue, Suite 210  
Lake Success, NY 11042  
888-529-5929 (U.S. toll free)  
+1-305-907-3100 (Outside U.S.)  
support@citi-program.org



Despite the fact that you just identified yourself as a student researcher, you need to select “Student” here rather than “Researcher” for your role, otherwise CITI will make you do extra training courses! You can opt out of the Responsible Conduct of Research, Conflicts of Interest, and IACUC sections as well. IACUC stands for Institutional Animal Care and Use Committee and this training is required for some research projects using non-human animals; please check with your instructor. Click “Complete Registration” when you’re finished.

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CITI - Learner Registration - University of Puget Sound

Steps: 1 2 3 4 5 6 7

### Select Curriculum

\* indicates a required field.

You will be provided a series of enrollment questions. Your responses will determine the curriculum for the courses you are going to take. Please read the questions carefully. Please read the responses carefully to make the best choice. Click [here](#) to review the University of Puget Sound instructions page.

#### Question 1

##### Human Subjects Research

Please choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group.

Choose one answer

- Researchers
- Students
- IRB Members
- IRB Chair

#### Question 2

##### Responsible Conduct of Research

Please make your selection below to receive the courses in the Responsible Conduct of Research.

Choose one answer

- Biology and biomedical researchers
- Humanities researchers
- Physical science researchers
- Social and behavioral science researchers (includes Education and Business)
- Not at this time.

#### \* Question 3

##### Conflicts of Interest

Would you like to take the Conflicts of Interest course?

Choose one answer

- Yes
- No

#### Question 4

##### IACUC

Would you like to take the IACUC course?

Choose one answer

- Yes
- No

Ok, you *thought* you were done, but now you have to *finalize* your registration by clicking on the link.

The screenshot shows the CITI Program website interface. At the top, there is a header with the USA flag, 'USA - English', a text size selector 'Text Size: A A', and links for 'Log In | Register | Help'. Below this is a blue banner with the 'CITI PROGRAM' logo and the text 'Collaborative Institutional Training Initiative'. A search bar labeled 'Search Knowledge Base' is also present. A navigation menu includes 'Home', 'About Us', 'Subscribing', 'Online Courses', 'CMEs/CEUs', 'News', and 'Contact Us'. The main content area features a blue box titled 'CITI - Learner Registration' containing the text: 'Welcome to the CITI Program. Your registration with University of Puget Sound is complete.' Below this text is a blue link labeled 'Finalize registration', which is circled in red. At the bottom, a dark blue footer contains three columns: 'SITE NAVIGATION' with links to Home, About, Subscribing, and Online Courses; 'CMEs/CEUs' with links to News and Contact Us; and 'CONTACT INFORMATION' with details about the CITI Program, including its address (1981 Marcus Avenue, Suite 210, Lake Success, NY 11042), phone numbers (888-529-5929 U.S. toll free, +1-305-907-3100 Outside U.S.), and email (support@citiiprogram.org).

After completing the registration, you're shown the page on the right, which lists all of the courses you are expected to take. If you selected properly in the earlier stages of registration, it should just have "Students" in the "Course" column. Click on "Students" to go to the full list of modules you're expected to complete as a student.

The screenshot shows the CITI PROGRAM website interface. At the top, there is a header with the CITI PROGRAM logo and the text "Collaborative Institutional Training Initiative". To the right of the header is a search bar labeled "Search Knowledge Base". Below the header is a navigation menu with links for "Main Menu", "My Profiles", "My CEUs", "My Reports", and "Support".

Below the navigation menu, there is a "Main Menu" section with a green checkmark icon and the text "Your registration has been completed successfully." Below this is a blue bar with the text "University of Puget Sound Courses".

The main content area features a table with the following structure:

Course	Status	Completion Report	Survey
Students	Not Started	Not Earned	

The "Students" link in the "Course" column is circled in red. Below the table is a section titled "My Learner Tools for University of Puget Sound" with a list of links: "Add a Course", "Remove a Course", "View Previously Completed Coursework", "Update Institution Profile", "View Instructions page", and "Remove Affiliation".

At the bottom of the page, there are two blue buttons: "Click here to affiliate with another institution" and "Affiliate as an Independent Learner".

At the very bottom of the page, there is a footer with links for "Accessibility", "Copyright", "Privacy Notice", "Terms of Service", and "Contact Us".

Here you see the pair of required “Modules”, “Students in Research” and “University of Puget Sound”. This page is sneaky though. You’re not allowed to click on those links and start the modules until you first click on the link circled on the right.

English    Text size: A A    Jane Doe ID: 5966986 | Log Out | Help

**CITI PROGRAM** Collaborative Institutional Training Initiative    Search Knowledge Base

Main Menu | My Profiles | My CEUs | My Reports | Support

Main Menu > Course Students

### Students - Basic Stage

To pass this course you must:

- Complete all 2 required modules
- Achieve an average score of at least 80% on all quizzes associated with this course's module requirements
- Supplemental modules, if provided, are optional and do not count towards passing the course or the overall score

Your Current Score: **0%**

You have unfinished required or elective modules remaining

[Complete The Integrity Assurance Statement before beginning the course](#)

#### Required Modules

	Date Completed	Score
Students in Research (ID: 1321)	Incomplete	0/0 (0%)
University of Puget Sound (ID: 16686)	Incomplete	0/0 (0%)

#### Supplemental Modules

	Date Completed	Score
NOTE: Supplemental modules are provided for general interest only. You DO NOT receive credit for completing these modules		
Internet-Based Research - SBE (ID: 510)	Incomplete	0/0 (0%)
International Research - SBE (ID: 509)	Incomplete	0/0 (0%)
Avoiding Group Harms - International Research Perspectives (ID: 14081)	Incomplete	0/0 (0%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	Incomplete	0/0 (0%)
Research with Children - CBE (ID: 507)	Incomplete	0/0 (0%)

Clicking the previous link brings you to this page. Read the summary of the Terms of Service and, if you agree to honor them, check the “I AGREE” box and Submit.

English Text size: A A Jane Doe ID: 5966986 | Log Out | Help

**CITI PROGRAM** Collaborative Institutional Training Initiative Search Knowledge Base

Main Menu | My Profiles | My CEUs | My Reports | Support

Main Menu > Assurance Statement

### Assurance Statement

Jane Doe:

CITI Program **Terms of Service** include the following provisions. Please read them carefully.

**No Account Sharing:** I will not share my username and password with anyone. I will contact the CITI Program Help Desk if I believe my account has been compromised.

**Do My Own Work:** I will complete all required quizzes and any other assessments by myself, using only my own work.

**No Quiz Sharing:** I will not share CITI Program quiz questions or answers on any website, via email, photocopying, or any other means.

**No Cheating:** I will not engage in any activities that would dishonestly improve my results, or improve or hurt the results of other learners.

**My Actions Are Logged:** I understand that CITI Program keeps account activity logs, including computer IP addresses, time spent in each content area, number of quiz attempts and scores. Allegations of inappropriate use will be investigated, and the results reported to my institution.

Check the box to accept, then click the Submit button:

I AGREE to the above and the other **Terms of Service** for accessing CITI Program materials.

Submit

Accessibility Copyright Privacy Notice Terms of Service Contact Us

You'll be taken back to this page again, but now the "Students in Research" module is a link that you can click on to begin your training. Congratulations!

To pass this course you must:

- Complete all 2 required modules
- Achieve an average score of at least 80% on all quizzes associated with this course's module requirements
- Supplemental modules, if provided, are optional and do not count towards passing the course or the overall score

Your Current Score

0%

You have unfinished required or elective modules remaining

#### Required Modules

	Date Completed	Score
Students in Research (ID: 1321)	Incomplete	0/0 (0%)
University of Puget Sound (ID: 16686)	Incomplete	0/0 (0%)

#### Supplemental Modules

	Date Completed	Score
NOTE: Supplemental modules are provided for general interest only. You DO NOT receive credit for completing these modules		
Internet-Based Research - SBE (ID: 510)	Incomplete	0/0 (0%)
International Research - SBE (ID: 509)	Incomplete	0/0 (0%)
Avoiding Group Harms - International Research Perspectives (ID: 14081)	Incomplete	0/0 (0%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	Incomplete	0/0 (0%)
Research with Children - SBE (ID: 507)	Incomplete	0/0 (0%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	Incomplete	0/0 (0%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	Incomplete	0/0 (0%)
Research with Prisoners - SBE (ID: 506)	Incomplete	0/0 (0%)

## Appendix F: Standardized E-mail Responses and Review Flowchart

### Standardized E-mail Responses for Student Protocols

Below, please find standardized language for e-mail responses for student protocols. There are four responses, corresponding the different outcomes of review. Please note that the responses differ by *Expedited* protocols (which require continued IRB oversight) and *Exempt* protocols (which do not require continued IRB oversight). Please be sure to use the appropriate response for the level of review.

For **Expedited** Protocols:

1) For **approval**:

- a. *If the first protocol that was submitted can be approved*, use this standardized language:

Dear (*Investigator's Name*),

Thank you for submitting your protocol entitled “(*Enter Protocol Title*)”. It meets the criteria for *expedited* review and has been assigned the protocol number *xxxx-xxx*. Please keep this protocol number for your reference.

As indicated on the *Protocol Decision Document* your protocol is now approved. Please keep the attached document for your records.

Please note that your study is approved for **one year from the date marked on the *Protocol Decision Document***. If you finish data collection before this date, please complete the required *Informational Follow-up Form* (found under *Additional Forms* on <http://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>). If your data collection will continue past the year date, be sure to submit the required *Renewal/Modification Form* (found under *Additional Forms* on <http://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>)

\*\*\*\*\*For studies that require consent forms, please add:

Please note that you must get your consent forms stamped before you may start collecting any data. To get your consent form stamped, please bring a hard copy of your (1) approval document/e-mail, and (2) consent form to Jimmy McMichael (Jones 212).

Good luck with your research!

(*Your name*)

- b. *If a resubmitted protocol can be approved, use this standardized language:*

Dear (*Investigator's Name*),

Thank you for resubmitting your protocol (“Enter protocol number *xxxx-xxx*”) and incorporating the requested changes and/or clarifications. As indicated on the *Protocol Decision Document* your protocol is now approved. Please keep the attached document for your records.

Please note that your study is approved for **one year from the date marked on the *Protocol Decision Document***. If you finish data collection before this date, please complete the required *Informational Follow-up Form* (found under *Additional Forms* on <http://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>). If your data collection will continue past the year date, be sure to submit the required *Renewal/Modification Form* (found under *Additional Forms* on <http://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>)

\*\*\*\*\*For studies that require consent forms, please add:

Please note that you must get your consent forms stamped before you may start collecting any data. To get your consent form stamped, please bring a hard copy of your (1) approval document/e-mail, and (2) consent form to Jimmy McMichael (Jones 212).

Good luck with your research!

(*Your name*)

- 2) To request **minor corrections or clarifications:**

Dear (*Investigator's Name*),

Thank you for submitting your protocol entitled “(*Enter Protocol Title*)”. It meets the criteria for *expedited* review and has been assigned the protocol number *xxxx-xxx*. Please keep this protocol number for your reference.

Minor changes and/or clarifications are necessary before this protocol can be approved. The required changes and/or clarifications are outlined at the end of this e-mail. Once you have made the requested changes and/or clarifications to the protocol, please resubmit your protocol for approval.

Please respond with your revised protocol within *one week* of this e-mail. If you cannot complete the revisions within one week, please let me know by what date you intend to submit your revisions.



Please note that ***no data collection may occur until you have secured IRB approval.***

If you have any questions or concerns, please contact me via e-mail (*enter e-mail address*) or phone (*x-xxxx*).

Best,

*(Your Name)*

3) For **reconsideration after investigator corresponds to identified concerns:**

Dear *(Investigator's Name)*,

Thank you for submitting your protocol entitled "*(Enter Protocol Title)*". It meets the criteria for *expedited* review and has been assigned the protocol number *xxxx-xxx*. Please keep this protocol number for your reference.

Unfortunately, I cannot approve the protocol in its current form. There are serious concerns that must be addressed before approval is possible. These concerns are outlined at the end of this e-mail.

Please seriously reflect on the concerns raised. If the concerns can be addressed, please respond with your revised protocol within *one week* of this e-mail. If you cannot complete the revisions within one week, please let me know by what date you intend to submit your revisions.

Please note that ***no data collection may occur until you have secured IRB approval.***

If you have any questions or concerns about your protocol or this decision, please contact me via e-mail (*enter e-mail address*) or phone (*x-xxxx*).

Best,

*(Your Name)*

4) For **disapproval:**

Dear *(Investigator's Name)*,

Thank you for submitting your protocol entitled “*(Enter Protocol Title)*”. It has been assigned the protocol number *xxxx-xxx*. Please keep this protocol number for your reference.

Unfortunately, this protocol cannot be approved in its current form. **Please understand that this means you may not collect data for your project.** Specific reasons for this decision are outlined in the attached “Protocol Decision Document”. If you have any questions or concerns about your protocol or this decision, please contact me via e-mail (*enter e-mail address*) or phone (*x-xxxx*).

Best,

*(Your Name)*

For **Exempt** Protocols:

1) For **approval**:

- a. *If the first protocol that was submitted can be approved*, use this standardized language:

Dear *(Investigator’s Name)*,

Thank you for submitting your protocol entitled “*(Enter Protocol Title)*”. It meets the criteria for *exempt* review and has been assigned the protocol number *xxxx-xxx*. Please keep this protocol number for your reference.

As indicated on the *Protocol Decision Document* your protocol is now approved. Please keep the attached document for your records.

\*\*\*\*\*For studies that require consent forms, please add:

Please note that you must get your consent forms stamped before you may start collecting any data. To get your consent form stamped, please bring a hard copy of your (1) approval document/e-mail, and (2) consent form to Jimmy McMichael (Jones 212).

Good luck with your research!

*(Your name)*

- b. *If a resubmitted protocol can be approved*, use this standardized language:

Dear *(Investigator’s Name)*,

Thank you for resubmitting your protocol (“Enter protocol number xxxx-xxx”) and incorporating the requested changes and/or clarifications. As indicated on the *Protocol Decision Document* your protocol is now approved. Please keep the attached document for your records.

\*\*\*\*\*For studies that require consent forms, please add:  
Please note that you must get your consent forms stamped before you may start collecting any data. To get your consent form stamped, please bring a hard copy of your (1) approval document/e-mail, and (2) consent form to Jimmy McMichael (Jones 212).

Good luck with your research!

*(Your name)*

2) To request **minor corrections or clarifications**:

Dear *(Investigator’s Name)*,

Thank you for submitting your protocol entitled “*(Enter Protocol Title)*”. It meets the criteria for *exempt* review and has been assigned the protocol number xxxx-xxx. Please keep this protocol number for your reference.

Minor changes and/or clarifications are necessary before this protocol can be approved. The required changes and/or clarifications are outlined at the end of this e-mail. Once you have made the requested changes and/or clarifications to the protocol, please resubmit your protocol for approval.

Please respond with your revised protocol within *one week* of this e-mail. If you cannot complete the revisions within one week, please let me know by what date you intend to submit your revisions.

Please note that ***no data collection may occur until you have secured IRB approval.***

If you have any questions or concerns, please contact me via e-mail (*enter e-mail address*) or phone (*x-xxxx*).

Best,

*(Your Name)*

3) For **reconsideration after investigator corresponds to identified concerns**:

Dear (*Investigator's Name*),

Thank you for submitting your protocol entitled “(*Enter Protocol Title*)”. It meets the criteria for *exempt* review and has been assigned the protocol number *xxxx-xxx*. Please keep this protocol number for your reference.

Unfortunately, I cannot approve the protocol in its current form. There are serious concerns that must be addressed before approval is possible. These concerns are outlined at the end of this e-mail.

Please seriously reflect on the concerns raised. If the concerns can be addressed, please respond with your revised protocol within *one week* of this e-mail. If you cannot complete the revisions within one week, please let me know by what date you intend to submit your revisions.

Please note that ***no data collection may occur until you have secured IRB approval.***

If you have any questions or concerns about your protocol or this decision, please contact me via e-mail (*enter e-mail address*) or phone (*x-xxxx*).

Best,

(*Your Name*)

4) For **disapproval**:

Dear (*Investigator's Name*),

Thank you for submitting your protocol entitled “(*Enter Protocol Title*)”. It has been assigned the protocol number *xxxx-xxx*. Please keep this protocol number for your reference.

Unfortunately, this protocol cannot be approved in its current form. **Please understand that this means you may not collect data for your project.** Specific reasons for this decision are outlined in the attached “Protocol Decision Document”. If you have any questions or concerns about your protocol or this decision, please contact me via e-mail (*enter e-mail address*) or phone (*x-xxxx*).

Best,

(*Your Name*)

## Protocol Flowchart (updated 2/2017)

- 1) The principal investigator (PI) submits their protocol to Jimmy McMichael as:
  - a. A hardcopy in Jones 212 (CMB 1020); and
  - b. An electronic copy ([irb@pugetsound.edu](mailto:irb@pugetsound.edu))
  
- 1) Upon receipt, Jimmy logs the details of the protocol into our database. Using the level of review identified by the PI, Jimmy will either assign a *single reviewer* (for protocols marked exempt/expedited) or send the protocol to the *full board* (for protocols marked full board).
  
- 2) For exempt/expedited protocols:
  - a. Jimmy will notify you via e-mail when a protocol has been assigned to you. The protocol will be attached in the e-mail. You can also access this protocol via the shared IRB drive (`//merlin2/irb/`). Once logged in, the folder *Protocols* contains sub-folders with the protocol number that has been assigned to you. You will find the protocol in that folder.
  - b. Confirm that the PI has identified the correct level of review (see “Levels of Review Checklist”)
    - i. If correctly identified as exempt/expedited, please review protocol.
    - ii. If incorrectly identified as exempt/expedited, please e-mail Jimmy to alert him that this protocol requires full board review and must be sent to the full committee.
  
- 3) Review of exempt/expedited protocols:
  - a. *If revisions are required* before the protocol can be approved, the required changes must be communicated with the PI via e-mail. The PI must resubmit the revised document(s) to the reviewer via e-mail. All requested revisions must be satisfied before the reviewer can approve the protocol.
    - i. Considerations during the review process:
      1. The reviewer should communicate with the PI within 3 business days of receipt of a protocol or resubmission.
      2. Use the standardized e-mail responses found on the share drive (under *Resources for IRB Members/ Training/ Standardized E-mail Responses*) for all *student protocols*. You can amend these responses for non-student protocols.
      3. If the PI is a student, include the student’s advisor on all correspondence. The advisor’s name is on the coversheet.
  - b. *Once the protocol can be approved*, communicate this decision with the PI by using the Protocol Decision Document, found on the share drive under *Resources for IRB Members/Forms*.
    - i. Upload the following into the appropriate protocol folder on the share drive:
      1. Protocol Decision Document
      2. All revised documents

- ii. Bring the list of protocols you reviewed since the last full board IRB meeting. We will collect protocol numbers and status (approved, revisions required, rejected).
- c. All written communication between the reviewer and the PI *must* be retained. Thus, please cc [irb@pugetsound.edu](mailto:irb@pugetsound.edu) on all e-mail correspondence

\*\*\*\*Once review of an expedited/exempt protocol is complete, each folder on the IRB share drive *must* contain the following:

- d. Original protocol (uploaded by Jimmy)
- e. Revised protocol (if any revisions were requested by the reviewer)
- f. Protocol Decision Document

If a protocol requires full board review, Jimmy will make the protocol available to the full committee. We will discuss the protocol at the next full board meeting. The IRB chair will communicate decisions, including if revisions are required, with the PI.

**Appendix G: Verbal Consent Documentation**

**Consent Confirmation\***

**IRB PROTOCOL#** \_\_\_\_\_

**Principal Investigator** \_\_\_\_\_

	SUBJECT PSEUDONYM/CODE	DATE OF INTERVIEW	VERBAL CONSENT Y/N	INVESTIGATOR CONFIRMATION (Please initial)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				

\*This form is to be attached to submitted to \_\_\_\_\_ along with your finalized Informational Follow-up Form for scanning and submission to IRB. It will be archived with your IRB protocol.

## Appendix H: Updated Protocol Template and Checklist

### (A) **PROTOCOL DESCRIPTION:**

1. **Introduction:** briefly introduce the topic of your research with appropriate background information and citations.
2. **Purpose:** clearly state the purpose of the study.
3. **References:** provide a list of the references you have used in providing background information for your study (include this section only if applicable).

### (B) **METHOD AND MATERIALS:** for each of the following subheadings explain how you will conduct your research.

#### 1. **Subject recruitment:**

- a. number of subjects
- b. how and where subjects will be recruited (word of mouth, posters on campus emails, etc.)
- c. criteria by which subjects will be included or excluded (gender, athletes, age, race, etc.).  
(If the study involves students from the University of Puget Sound the following standard statement may be used: The subject population will resemble the \_\_\_\_\_ Department subject pool at the University of Puget Sound in terms of age, ethnicity, and gender.)
- d. explain the method of obtaining informed consent.
- e. explain any special conditions or procedures that will be necessary for the project. (write "N/A" if not applicable)
- f. all studies carry at least minimal risk; explain the nature of risks that might occur to the subjects from participating in this study (physical, psychological, social, legal, or economic; see the IRB website for additional information on how to classify risk:  
<https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>)
- g. describe the precautions you have taken to minimize risks

#### 2. **Instrumentation:** describe any equipment, surveys, software, etc. that will be used in the study, and include validity and reliability of the instrumentation if relevant.

#### 3. **Data collection:** procedures of data collection need to be clearly described. (e.g. how many times the subject must be tested, how long will the testing session last, what is the subject to actually do during the testing session, are there treatments/interventions, for ethnographic research methods specify interview type (structured, semi-structured, unstructured) along with questions and/or interview guide, etc.)



4. **Data Analysis:** explain clearly how the data will be analyzed (e.g. qualitative research themes, ANOVA, t-tests, etc.) and the level of significance, if relevant.
- (C) **CONFIDENTIALITY OF DATA:** Explain how data will be secured to safeguard identifiable records of individuals. This might include how and where the data will be housed, how the data were recorded (audio or visual tapes, paper pencil, etc.), how long the data will be kept, how it will be disposed of, who will have access to the data, etc. Also, in certain studies that require deception and/or assent may need to be addressed.
- (Standard statement: The names of participants will not appear on materials containing their responses. All identifying materials such as the consent forms will be scanned and stored on the secure University computer system. Hard copies of scanned consent forms will be destroyed immediately; scanned consent forms will be deleted after seven years.)
- (D) **BENEFITS:** Describe the anticipated benefits to subjects, science, and/or society, that may occur as a result of this study.
- (E) **QUALIFICATIONS OF INVESTIGATOR(S):**
1. If a faculty member is involved please summarize their qualifications
    - a. e.g. Jim Jensen is an associate professor in the Department of Psychology and has conducted and published many research studies dealing with Social and Cross-Cultural Psychology.
  2. If students are involved, please indicate why you are qualified to conduct the research
    - b. e.g. Joe Johnson is a senior in the Department of Psychology and has taken the following classes which provide him the skills to conduct this research: Developmental Psychology, Applied Psychological Measurement, Cross-Cultural Psychology and Social Psychology.
- (F) **CONSENT FORMS:** Consent forms are required for human research. Please see the instructions for consent forms in the Principles and Procedures Governing the Use of Human Subjects Document found on the University of Puget Sound Website. <https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>

Please use this checklist to ensure that your protocol meets IRB requirements.

\_\_\_\_\_ **Submit application for full board review before the deadline indicated on the IRB website <https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>**

**Applications for exempt and expedited review may be submitted at any time**

**COVERSHEET**

\_\_\_\_\_ Completed  
\_\_\_\_\_ Typed  
\_\_\_\_\_ Signed (investigators, and if appropriate, faculty advisor)  
\_\_\_\_\_ CITI Training Certificate of Completion attached

**PROTOCOL (5 pages maximum)**

\_\_\_\_\_ Pages numbered throughout

**(A) Protocol Description**

\_\_\_\_\_ 1. Introduction and brief background  
\_\_\_\_\_ 2. Purpose of the Study  
\_\_\_\_\_ 3. References

**(B) Method and Materials**

**1. Subject Recruitment**

\_\_\_\_\_ a. Number of subjects  
\_\_\_\_\_ b. How and where subjects are recruited  
\_\_\_\_\_ c. Criteria for inclusion and exclusion  
\_\_\_\_\_ d. Method of obtaining informed consent  
\_\_\_\_\_ e. Special conditions or procedures  
\_\_\_\_\_ f. Risks to subjects  
\_\_\_\_\_ g. Precautions to minimize risks  
\_\_\_\_\_ 2. Instrumentation description  
\_\_\_\_\_ 3. Data collection procedures  
\_\_\_\_\_ 4. Data analysis

**(C) CONFIDENTIALITY OF DATA:**

\_\_\_\_\_ Procedure used to protect confidentiality  
\_\_\_\_\_ Manner of recording information  
\_\_\_\_\_ Use of audio and visual tapes and their disposition  
\_\_\_\_\_ How long identifying information will be kept  
\_\_\_\_\_ Deception or assent (if applicable)

**(D) BENEFITS**

\_\_\_\_\_ Benefits of the research

**(E) QUALIFICATIONS OF INVESTIGATOR(S)**

\_\_\_\_\_  
Faculty: Qualifications for conducting the research  
\_\_\_\_\_  
Student: Qualifications for conducting the research

**(F) CONSENT FORMS**

Procedural Details:

- \_\_\_\_\_  
a. Page 1 is on appropriate institution letterhead
- \_\_\_\_\_  
b. Title (consent form title and project title are the same)
- \_\_\_\_\_  
c. Pages numbered (protocol and consent form numbered separately).
- \_\_\_\_\_  
d. list all investigators, email addresses, and business telephone numbers
- \_\_\_\_\_  
e. Blank for subjects' initials in lower right corner of each page of consent form.
- \_\_\_\_\_  
f. Signature line for subject, witness, parent, corroborator.

Separate Consent Forms for:

- \_\_\_\_\_  
a. adults in treatment group
- \_\_\_\_\_  
b. control group
- \_\_\_\_\_  
c. children
- \_\_\_\_\_  
d. parent or guardian
- \_\_\_\_\_  
e. other

**CONTENT**

\_\_\_\_\_  
Description of study written in non-technical language no greater than 8<sup>th</sup>  
grade  
reading level  
\_\_\_\_\_  
Risks/benefits  
\_\_\_\_\_  
Alternative treatments, if applicable  
\_\_\_\_\_  
Costs and payments, if applicable  
\_\_\_\_\_  
Confidentiality and use of protected health information  
\_\_\_\_\_  
Dean's phone number  
\_\_\_\_\_  
Right to refuse or end participation  
\_\_\_\_\_  
No compensation for injury, if applicable  
\_\_\_\_\_  
Voluntary consent  
\_\_\_\_\_  
Acknowledgment of parent, if applicable  
\_\_\_\_\_  
Investigator's certification

## Appendix I: Recommendation for Storing Consent Documentation and Informational Follow-up Forms

### Instructions for submitting consent documentation and study closure form (Informational Follow-up Form)

- Upon completion of a study, the PI:
  - Completes the *Informational Follow-up Form* found on the IRB website (<https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>)
  - Gives the completed *Informational Follow-up Form* and *all consent documentation* (all signed consent OR or list of participants who provided verbal consent) to your department's/school's administrative/work study staff and/or course instructor
  
- Upon receipt of completed *Informational Follow-up Form* and *consent documentation*, the administrative assistant, work study staff, or course instructor will:
  - Ensure that the *Informational Follow-up Form* is completed and associated consent documentation is attached
  - Scan the *Informational Follow-up* form and associated consent information
  - Save the scanned document as a .pdf file and name the resulting file using the following convention:
    - Protocol number associated with project listed first, followed by “Closure and Consent”
    - E.g., "1617-017 Closure and Consent.pdf"
    - This will result in one .pdf file for *each* completed study which must be retained for one year and then deleted
  - E-mail the .pdf files to [irb@pugetound.edu](mailto:irb@pugetound.edu) for storage and record keeping
  - Shred all hard copies of consent documentation that has been successfully scanned and e-mailed
  - All .pdf files should be e-mailed by the end of the term during which the *Informational Follow-up Form* and *consent documentation* were received

**Informational Follow-up**  
IRB Approved Research Project

The fundamental charge of the Institutional Review Board (IRB) is to protect human research subjects. Approval by the IRB is for a period of one-year and researchers are to notify the IRB within 90 days of termination of an approved project. An annual report to the IRB is required of all approved protocols. To help simplify this process, please respond to the following questions pertaining to the status of your approved research project. The purpose of this follow-up form is not to have researchers provide self-incriminating documentation in the event of an unanticipated occurrence during the study, it is merely to inform the IRB of the status of the project and report on any modifications made to the originally proposed protocol.

IRB Protocol #: \_\_\_\_\_

Project Title: \_\_\_\_\_

Principal Investigator(s): \_\_\_\_\_

email: \_\_\_\_\_

Phone: \_\_\_\_\_

1. Project status (please check one):

- Complete \_\_\_\_\_ completion date \_\_\_\_\_
- Ongoing \_\_\_\_\_ estimated completion date \_\_\_\_\_
- Discontinued

On a separate page, please state why the study was discontinued.

2. During the course of conducting a research project it sometimes becomes necessary and/or prudent to alter experimental protocols. Did any circumstances require significant modification for this protocol?

- no  yes

If yes, what changes were made and why (use a separate page if necessary)?

3. During the course of conducting the research project did any event occur that may have placed a human subject(s) at risk or caused any human subject to be harmed?

- no  yes

If yes,

a. please describe the situation (use a separate page if necessary).

b. please describe efforts undertaken to minimize harm to the subject or modify the protocol to reduce the probability of similar harm occurring to future subjects (use a separate page if necessary).

# UNIVERSITY *of* PUGET SOUND

Est. 1888

## Consent to Act as a Subject in a Research Study

TITLE: XXXXX

INVESTIGATORS: Principal Investigator Co-investigator 1 Co-investigator 2 Co-investigator 3  
(University Phone)

SUPERVISOR: Faculty Member's Name DEPARTMENT: XXXXX PHONE: 253 879-XXXX

DESCRIPTION: (Describe the general purpose of the study if possible. Describe the nature of procedures and the general content of specific measures. Include a statement about length such as: Participation will take no longer than 30 minutes. The content of the consent form should not exceed an 8<sup>th</sup> grade reading level.)

RISKS AND BENEFITS: (Sample statement: Participation in this study involves minimal risk, such as.... Student participants benefit by gaining experience and familiarity with the process of conducting research in psychology.)

COSTS AND PAYMENTS: (Describe any costs and payments associated with this study.)

\*\*\*\*\*

CONFIDENTIALITY: I understand that any information about me obtained from this research, including answers to questionnaires, laboratory data, or audio or videotapes will be kept strictly confidential. Information that will carry personal identifying information, such as consent forms, will be scanned and stored on the secure University computer system. Hard copies of scanned consent forms will be destroyed immediately; scanned consent forms will be deleted after seven years. I do understand that my research records, just like hospital records, may be subpoenaed by court order. It has been explained to me that my identity will not be revealed in any description or publication of this research. Therefore, I consent to such publication for scientific purposes.

RIGHT TO REFUSE OR END PARTICIPATION: I understand that I am free to refuse to participate in this study or to end my participation at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled.

RIGHT TO REFUSE OR END PARTICIPATION: I understand that I am free to refuse to participate in this study or to end my participation at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled. Additionally, I may refuse to answer any question or set of questions contained in the questionnaires if I choose to do so, without any adverse impact on my participation in this study.

VOLUNTARY CONSENT: I certify that I have read the preceding or it has been read to me and that I understand its contents. Any questions I have pertaining to the research will be answered by the above named investigators. Any questions or concerns I have regarding my rights as a research subject will be answered by the Office of the Associate Dean (253-879-3207). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this study.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's signature

INVESTIGATOR'S CERTIFICATION: I certify that I have explained to the above individual the nature, potential benefits, and possible risks associated with participating in this research study, have answered any questions that have been raised, and have witnessed the above signature.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator's signature

## **Updates to Protocol for Confidentiality Statement:**

The current Confidentiality Statement reads:

**(C) CONFIDENTIALITY OF DATA:** *Explain how data will be secured to safeguard identifiable records of individuals.* This might include how and where the data will be housed, how the data were recorded (audio or visual tapes, paper pencil, etc.), how long the data will be kept, how it will be disposed of, who will have access to the data, etc. Also, in certain studies that require deception and/or assent may need to be addressed.

(Standard statement: The names of participants will not appear on materials containing their responses. All identifying materials such as the consent forms will be kept in a locked file cabinet in the Department of Psychology at the University of Puget Sound.)

The **Standard Statement** needs to be updated to something like:

The names of participants will not appear on materials containing their responses. All identifying materials such as the consent forms will be scanned and stored on the secure University computer system. Hard copies of scanned consent forms will be destroyed immediately; scanned consent forms will be deleted after seven years.