Institutional Review Board
Report to the Faculty Senate
AY 2017-2018

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 2017-2018 academic year.

2016-17 IRB membership: Tim Beyer (co-chair) and Joel Elliott (co-chair); Lisa Ferrari (ex-officio); Wendell Nakamura, Mike Pohl, Sara Protasi, Mark Reinitz, Alexa Tullis, Andreas Udbye; Jan Wolfe (community representative).

To date, the Institutional Review Board has reviewed 91 proposals this academic year. Of these 2 were full board, 85 were expedited, and 4 were exempt.

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

1) **Identify appropriate modules from CITI for training of faculty**
   The Faculty Senate charged the IRB to **identify appropriate modules from CITI for training of faculty** who submit protocols to the IRB. Currently, all student researchers are required to complete the CITI student module. The IRB committee members reviewed the CITI training modules in relation to the following specific questions: 1) Should *ALL* faculty complete the *SAME* module(s)? If so, which one(s)? 2) Should *SOME* faculty complete *SPECIFIC* modules? (e.g., should faculty who submit a protocol involving children to the module(s) on research with children, regardless of their disciplinary background, prior training or experience working with children, etc.) If so, which track(s) and module(s)? 3) Should faculty complete *NO* modules? After compiling responses from committee members and then deliberating the pros and cons of each training module, the IRB committee decided on the following recommendation:

   Faculty members underwriting research protocols need to have passed a block of five CITI courses consisting of: 1) Belmont Report and CITI Course Introduction, 2) Informed Consent, 3) Cultural Competence in Research, 4) Assessing Risk, 5) Unanticipated Problems and Reporting Requirements in Social and Behavioral Research. Research involving vulnerable populations or specific procedures may require additional course modules (e.g., Internet-based research, International Research, Research With Prisoners, Research With Children, Research in Public Elementary and Secondary Schools, Vulnerable Subjects, Research Involving Pregnant Women, Fetuses, and Neonates). Certification will be valid for three years after which some of the modules have refresher courses or will need to be retaken.

The IRB sent these recommendations to the Faculty Senate to obtain some initial feedback, and the Senate's response was positive and recommended that the IRB obtain additional feedback from department chairs in those disciplines that submit a substantial number of protocols to the IRB.

2) **Develop a policy for uniform assessment of international research conducted by Puget Sound faculty, students, and staff**
At the start of AY 17-18, the IRB did not have a policy for international research. Because of this, approval of international research was handled on a case-by-case basis resulting in inconsistencies during review and approval. In order to standardize how international research reviewed and approved, Beyer, Elliott, and Ferrari reviewed policies from peer institutions and federal guidelines and presented their findings to the full board. Based on these findings, the full board agreed that:

   - The university's "Travel Abroad Policy for High-Risk Areas" must be upheld. As such, the IRB cannot review projects for independent research in travel warning countries;
   - The IRB policies must reflect the "International Compilation of Human Research Standards" compiled by the Office for Human Research Protections at the U.S. Department of Health and Human Services
   - Special attention must be given to ensuring cultural sensitivity and linguistic equivalence

   Based on these considerations, Beyer, Elliott, and Ferrari drafted a policy for international research, which was approved by the full board in Fall, 2017, and can be found in Appendix A. The policy is also live on the IRB website (https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/policy-for-international-research/)

3) **Review the common rule and our policies to see where our policies are more stringent than federal guidelines, and determine whether and when such requirements are justified.**
The IRB could not complete this charge because the federal government has not yet decided which version of the common rule will apply in the future.

   On January 18, 2017, President Obama approved a revised version of the common rule, which is a portion of the Code of Federal Regulations (45 CFR 46) that addresses research with human subjects and applies to many federal agencies. The new common rule was set to come into effect on January 19, 2018, which would allow research institutions a year to update their procedures. In the meantime, President Trump came into office and voiced a strong anti-regulatory stance. On January 19, 2018, the Trump administration announced that it was postponing the effective date of the revised common rule to July 19, 2018, in part to assess whether the common rule should be changed at all. In the meantime, IRBs are prohibited from applying the revised common rule and must use the pre-2018 version.

Some of the 2018 revisions to the common rule would have an impact on our IRB procedures in such areas as informed consent, what qualifies for exemption from ongoing IRB oversight (which is not the same as being excused from submitting an IRB protocol), and which types of research fall under IRB purview. However, at this point we can't know which, if any, of these revisions will become the law. Therefore, the IRB has postponed addressing this charge until the federal government decides which version of the common rule will apply going forward.

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

1) **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. **Updated e-mail correspondence:** E-mail correspondence to be used with student researchers during the review process has been updated to ensure that the correct dates are used when determining how long a study is approved for. Please see Appendix B.

   b. **Updated protocol template and checklist:** In order to further increase transparency in what information the IRB needs to review protocols, the committee has further refined our protocol templates and checklists during AY 17-18. This updated protocol and checklist is currently being used alongside the previous version, which will no longer be accepted by the IRB in AY 18-19. This updated protocol and checklist has made review simpler for IRB members as specific information needed for review is now more explicitly requested. These updated documents are found in Appendix C.

2) **Summer review policy**
   The IRB cannot maintain its review capacity over the summer months due to limited resources over the summer months. For this reason, the full board decided on the following actions:

   - Individuals from the full board will volunteer to serve as reviewers of IRB protocols during the summer months
   - The IRB will only review exempt and expedited protocols
   - The IRB will not review full board protocols

   This policy has been communicated with the departments that produce the largest number of IRB protocols and is available on the IRB website. This policy can be found in Appendix D.

The IRB has identified the following issues which should be addressed in 2018-2019:

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 online research**
Currently, there is no official policy for online research. As the IRB is seeing more protocols that use online research tools (both in terms of data collection and storage), it is suggested that the IRB reviews best practices in how to use online research tools to (a) protect the identity of participants, (b) protect the integrity of data collection, and (c) review who "owns" data stored by online data collection tools. The IRB must develop a uniform policy to be used with online research.

3) **Review updated Common Rule and incorporate changes**
As the federal government makes decisions about The Common Rule, the IRB should review any potential changes to the Common Rule to ensure that our procedures are in line with new Federal Guidelines.

4) **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. In addition, although the board is quite diverse in terms of academic disciplines, many questions surrounding oral histories and ethnographic research methods often arise. For this reason, having a colleague from Sociology and Anthropology serve on the committee could be helpful in navigating different research methods during IRB review processes.

Respectfully Submitted,
Tim Beyer, PhD and Joel Elliott, PhD
IRB Co-Chairs AY 2017-18

Appendices:
A: International Research Policy
B: Updated standardized e-mail responses
C: Updated protocol template and checklist
D: Summer review policy

Appendix A: International Research Policy

Policy for International Research

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

Additional considerations:

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

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

For Students Planning to Conduct Research Outside the United States

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

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

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

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

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

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

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

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

- Seek guidance from representatives of the community when developing and implementing protocols within their communities

- Consider adding members with expertise in the community under study as part of the research team.

- Use *equivalent protections* when considering cultural norms. The OHRP guidance for equivalent protections is found here). For example:

    - Minors who are treated as adults in their own locale will be treated as minors for the purpose of protection in research.

    - "Parental consent" for minors may be viewed more broadly and grandparents, elders, or tribal leaders, who serve as the head of the household in a specific cultural context, may be approached to provide parental consent.

    - Written consent may be waived in favor of verbal consent due to cultural reasons. For example, in some cultural contexts, signing a consent form may be inappropriate due to religious reasons or issues of literacy. Researchers who seek a waiver of written consent must justify this request in their protocol by describing local customs that

may impede using written consent. Criteria for waiver of written consent are found here.

Linguistic Differences

If research is not conducted in English, researchers must provide back-translated versions of all materials a participant will see, including recruitment materials, consent procedures (written consent forms, verbal consent scripts, assent forms), testing materials, and debriefing forms. Back-translation involves taking a document in one language, translating it to the other language, and having someone else translate it back to the original language. The original document and the back-translated document can then be compared, and any discrepancies between the two documents must be resolved. Once the two documents are deemed semantically equivalent, successful back translation has occurred. Semantically equivalent means that the content is the same, although individual words may differ. For example, if a researcher wants to conduct research in Spain:

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

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

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

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

The researcher must submit to the IRB:

- The original version, the version in the other language, and the final back-translated version of all materials.
- A description in the protocol which explains:
    - How the back-translation was obtained
    - Who created the initial translation into the non-English language and who created the back-translation. For both individuals include:
        - Contact information, and
        - Qualifications (i.e., a description of why the person is linguistically and culturally competent to provide a translation)

Appendix B: Updated Standardized E-mail Responses

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 submission 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 submission 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. Please highlight all the requested changes and/or clarifications to the protocol, and submit this revised, highlighted version to me 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. Please highlight all the requested changes and/or clarifications to the protocol, and submit this revised, highlighted version to me 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)

Appendix C: Updated Protocol Template and Checklist

(A) PROTOCOL DESCRIPTION:

1. **Introduction:** Introduce the topic of your research with background information and citations.
2. **Purpose:** Clearly state what your study seeks to address and why this is important.
3. **Exposition:** Explain how your project adds to or expands the body of knowledge that relates to your topic.

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

1. Subject Recruitment:

- **a.** What is the total number of subjects?
- **b.** How and where subjects will be recruited (word of mouth, posters on campus emails, etc.)? Provide any recruitment materials (e.g., sample flyers, sample emails, etc.).
- **c.** What are the criteria, if any, 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 at the University of Puget Sound in terms of age, ethnicity, and gender.

- **d.** How will you obtain informed consent?
- **e.** Are there any special conditions or procedures that will be necessary for the project? If no, write N/A.
- **f.** Does your proposed study (a) involve non-English speakers, or (b) take place outside of the United States? If yes, review the International Research Policy (https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/policy-for-international-research/) and address all questions as they relate to your study. If no, write N/A.

2. Risks to Subjects:

- **a.** 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/)
- **b.** Describe the precautions you have taken to minimize risks.

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

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

5. **Data Analysis:** Explain clearly how the data will be analyzed (e.g. qualitative research themes, ANOVA, t-tests, etc.).

(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. If applicable, describe deception and/or assent procedures.

If applicable, the following standard statement may be used:

> 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 at the University of Puget Sound.

(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: e.g., Jamila 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 a *student* is involved, please indicate why they are qualified to conduct the research: e.g., Jane Johnson is a senior in the Department of Psychology and has taken the following classes which provide her the skills to conduct this research: Developmental Psychology, Applied Psychological Measurement, Cross-Cultural Psychology and Social Psychology.

(F) **REFERENCES:** Provide the list of references you cited throughout the protocol (e.g., *Introduction* section, *Methods and Materials* section, etc.).

CONSENT FORMS: Consent forms are required for most research involving human subjects. Please see the instructions for consent forms in the IRB Handbook, Section 6, found on the University of Puget Sound Institutional Review Board 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
_____ 2. Purpose
_____ 3. Exposition
_____ 4. References

(B) Methods 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 (if applicable)
_____ f. International research considerations (if applicable)

2. Risks to Subjects
_____ a. Risks to subjects
_____ b. Precautions to minimize risks

_____ **3. Instrumentation**

_____ **4. Data collection**

_____ **5. 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) REFERENCES

CONSENT FORMS: Consent forms are required for most research involving human subjects. Please see the instructions for consent forms in the IRB Handbook, Section 6, found on the University of Puget Sound Institutional Review Board website: https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/

Because consent forms must be representative of each project, below is a general checklist. Each Principal Investigator (PI) must ensure that the consent form(s) submitted for IRB review are a complete and accurate description of the research project that allows a potential subject to give voluntary informed consent.

Procedural Details:

_____ a. Page 1 is on appropriate institution letterhead.
_____ b. Project title (identical title used on consent form and protocol).
_____ c. Pages numbered (protocol and consent form numbered separately).
_____ d. List all investigators, email addresses, and business telephone numbers (personal numbers, e.g., cell phone numbers may not be used).
_____ e. If consent form is longer than 1 page, line for subject's initials appears in lower right corner of each page of consent form.
_____ f. Signature lines for all that apply to a specific study, e.g., subject, witness, parent, corroborator.

Consent forms are required for all individuals who need to consent. Separate consent forms are required for individuals who experience different levels of the study. For example, adults in a treatment group, the control group, parents/guardians all require separate consent forms. Children require assent scripts/forms dependent on age and purpose of study. Additional consent forms may be needed given a specific study's design.

Content:

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

Appendix D: Summer Review Policy

Protocol Review during Summer

Due to diminished resources during the summer (about mid-May to late August), the IRB will:

- Not review ***full board*** protocols
- Continue to review ***exempt and expedited*** protocols

Responses from the IRB for exempt and expedited protocols may take longer than three business days, the review timeframe the IRB upholds during the academic year. Principal Investigators should be aware of the potential for a longer review time during summer.