IRB meeting minutes
January 25, 2017

Attendees: Tim Beyer, Sara Protasi, Sarah Moore, Andreas Udbye, Barbara Warren, Tatiana Kaminsky, Geoff Proehl, Joel Elliott, Brad Richards, Jan Wolfe (community member)

Call to order: 12:00 pm by Beyer

Welcome to new IRB member Sara Protasi

Report on *Training for New Committee Members* (please see attached document)

This will be piloted by Protasi, who is a new member on the IRB this semester. One thing that is needed is a person to serve as a mentor. Moore volunteered to serve in this role for Protasi. There was some discussion about the procedures and new member training documents.

Minutes from 12/7/16 approved.

Exempt/Expedited protocols approved since December 7, 2016 meeting

1617-047	Expedited
1617-056	Expedited

Announcements

- Full board protocol 1617-052 (PI Sam Scott – *Understanding the Impact of Attachment on Cortisol Reactivity and Synchrony in Pediatric Occupational Therapy Patient/Caregiver Dyads*) **approved** after revisions (sent directly to Beyer)
- Full board protocol 1617-053 (PI Julie Anderson – *Effect of Sleep Education and Intervention on Preschoolers Attention and Behavior*) **no response as of this date.** Beyer to follow up with the researcher.
- Dan Burgard (Chemistry) and potential THC project. The project will be looking at questions about metabolism of marijuana. He would like to study a group of marijuana users and test their urine and feces for information about metabolism. There are some legal questions since marijuana is a federally controlled substance and cannot be legally used on campus. Beyer will follow up with Dean Bartanen about some of the legal questions.
- Some discussion about protocols, specifically the expectations of the amount of detail that is needed, materials that are needed, etc. Also discussion about the role of the IRB reviewer with students vs. the role of the instructor/faculty advisor in working with the students. The thought was that if the forms are updated/clarified, there may be improvement in the quality of proposals the IRB reviewers are receiving.
- One of the policy questions that is being explored addresses the storage of consent forms. At this time, there isn't room for the consent forms to be stored. A question

about whether or not electronic copies of documents are sufficient is outstanding. Udbye has been trying to find more details.

Review of resubmission of full board protocol 1617-002-1 (which was reviewed as 1617-051 last meeting)

The protocol was discussed by the full board. It needs some minor revision. Beyer will work with the researcher and will approve the protocol when the changes have been made.

Work group tasks and selection of assignments

Beyer reviewed the workgroup tasks and membership to ensure that work toward Senate charges is complete by the end of the semester.

New IRB members workgroup. The materials that were created by the workgroup is being piloted this semester by Protasi and will be revised as needed. Planned outcome: to complete training materials by the end of the semester. Members: Geoff Proehl, Andreas Udbye, Tim Beyer, Sara Protasi

Off-campus researchers workgroup. Currently waiting for some answers to questions from the campus attorney. When those answers are received, policy can be written and presented to the full board for approval. Planned outcome: refine and finalize policy for off-campus researchers. Member: Tatiana Kaminsky

Policies workgroup. Continuing to work on answering several questions about policies, including: verbal consent and tracking verbal consent, protocol template and stronger/clearer language on content, CITI training and follow-up, Study follow-up form and tracking, written consent form storage. Planned outcome: updated forms and policies by the end of the semester. Beyer would like to subdivide this workgroup to allow more focused work on these issues. Members: Sarah Moore, Brad Richards, Andreas Udbye, Tim Beyer, Joel Elliott, Barbara Warren

Adjourned 12:49 pm.

Respectfully submitted,
Tatiana Kaminsky

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 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	***Welcome and Introduction to IRB*** document and familiarize with **University website**	IRB/Resources for IRB Members/Training and http://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/irb-member-information	As early as possible, but prior to first full board IRB meeting of the term
2	Complete ***institutional CITI training*** (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 ***internal training materials*** a) Protocol Flowchart.pdf b) Level of Risk.pdf c) Level of Review Guide.pdf d) Sample training protocols (CREATE)	All materials found under IRB/Resources for IRB Members/Training	Complete prior to meeting with IRB mentor
4	**Meet with assigned IRB mentor** to go over internal training materials, preview share drive, and discuss protocol flowchart and review process	TBD	By 2nd week of the term
5	Review the following **documents**: 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	**Meet with chair** to review documents used for review and process	TBD	By 3rd week of the term
7	**Ongoing review** 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 12/2016)

1) All protocols are to be submitted by the principal investigator to Jimmy McMichael as:
    a. A hardcopy in Jones 212 (CMB 1020)
    b. An electronic copy (irb@pugetsound.edu)

2) Upon receipt, Jimmy will log details of the protocol into a database for record keeping. Jimmy will also assign a *single reviewer* for that protocol, if the protocol does not merit full board review.
    a. Jimmy will notify you via e-mail when a protocol has been assigned to you. In that e-mail, you should find the protocol that has been assigned to you.
    b. You can also access this protocol via the shared IRB drive (//merlin2/irb/). Once logged into the shared IRB drive, you will find a folder called *Protocols* which contains sub-folders with the protocol number that has been assigned to you. In that folder, you will find the protocol. Please note that *all* communication with the principal investigator listed on the protocol and revisions (if necessary) must be saved into this folder (see more information below).

3) Reviewer confirms level of review (see "Levels of Review Checklist")
    a. PI's will be asked to assign a level of review to their protocol from the following options:
        i. Exempt/expedited (qualifies for single member to review). The assigned reviewer should look over the protocol (see below)
        ii. Full board (must be reviewed by all members). All members on the board must review the protocol for discussion at the full board meeting.

4) If a protocol is exempt/expedited, the assigned reviewer reviews protocol
    a. If the protocol can be approved, the reviewer communicates this decision with the PI
    b. If revisions are required before the protocol can be approved, the reviewer communicates the required changes with the PI via e-mail. The PI will then resubmit a revised protocol for review to the reviewer via e-mail. All revisions required by the reviewer must be satisfied before the reviewer can approve the protocol.
    c. Considerations during the review process:
        i. The reviewer should communicate with the PI within 3 business days of receipt of an initial protocol or a resubmission.
        ii. If the PI is a student, please always include the student's advisor on all correspondence. (The student's advisor can be found on the coversheet.) This is true for both communicating approval and in asking for revisions.
    d. All written communication between the reviewer and the PI *must* be retained. Thus, please cc irb@pugetsound.edu *on all e-mail correspondence*
    e. Once a protocol has been approved, please upload the revised protocol to the folder for that protocol on the share drive. Also use the Protocol Decision Document (found on the share drive under *Resources for IRB Members/Forms*) to indicate final

approval. E-mail this document to the PI and upload the document to the folder for that protocol on the share drive.

f. There are standardized e-mail responses for each possible decision uploaded in a document on the share drive (under *Resources for IRB Members/ Training/ Standardized E-mail Responses*). You must use these for student protocols and amend them for non-student protocols.
g. Please 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).

5) Once review of an expedited/exempt protocol is complete, each folder on the IRB share drive *must* contain the following:
    a. Original protocol (Jimmy should have uploaded this)
    b. Revised protocol (if any revisions were requested by the reviewer)
    c. Protocol Decision Document
    d. *All* e-mail correspondence between reviewer and anyone associated with the review (as covered in 4D above, Jimmy will upload the correspondence on the reviewer's behalf. Be sure to cc Jimmy on all correspondence!). This will include, at minimum, the PI of the protocol, but may also include any other e-mails the research supervisor, other IRB members, and so on.

6) 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 possible 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) <u>Full IRB Review</u>.

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) <u>Exempt Review</u>. 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.