

IRB meeting minutes April 26, 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: 12:03 pm by Beyer

Minutes from 03/22/17 approved.

Exempt/Expedited protocols approved since March 22, 2017 meeting

1617-069-1	Expedited	1617-109	Expedited
1617-074	Expedited	1617-110	Expedited
1617-075	Expedited	1617-111	Expedited
1617-076	Expedited	1617-112	Expedited
1617-094	Exempt	1617-113	Expedited
1617-095	Expedited	1617-114	Exempt
1617-097	Expedited	1617-115	Expedited
1617-101	Expedited	1617-122	Expedited
1617-103	Expedited	1617-124	Expedited
1617-104	Exempt	1617-126	Exempt
1617-105	Expedited	1617-127	Expedited
1617-106	Expedited	1617-128	Expedited
1617-107	Expedited	1617-129	Expedited
1617-108	Expedited		

Announcements

- Beyer submitted the IRB end of year report to the Senate and it was accepted. He reported that Kris Bartanen complimented the committee on a job well done this year.

Review modified Protocol and Checklist (please see attached documents)

The committee members discussed the modifications that were made to the IRB Protocol and Checklist by Warren and Proehl. They went through and broke out some of the longer sections and added in additional detail (e.g. asking researchers to provide some background/rationale for studies with references). Warren pointed out that there is one more section on the IRB website (including the handbook) that needs to be brought in line with the updates. Beyer will go through the handbook after the semester ends to make sure all changes are reflected. Updated consent form examples also need to be uploaded. Moore suggested a change in some of the headings. Elliott asked if both the checklist and the longer protocol description were needed. There were concerns that it would be difficult to make sure both were updated in the future with changes. Eliminating one form would decrease the chances that something was overlooked and better ensure consistency. It was pointed out that the checklist had some details about consent forms that weren't included on the longer protocol. It was proposed that the longer protocol document be kept with

reference to the consent form information. A separate document with information about written and verbal consent will be created by Beyer. The proposal was approved unanimously.

Review of resubmission of full board protocols

1617-090: The protocol was discussed by the full board. It was approved with one minor change.

1617-091: The protocol was discussed by the full board. It was approved with minor changes.

1617-116: The protocol was discussed by the full board. It needs some minor revision. Beyer will work with the researchers and will approve the protocol when the changes have been made.

1617-118: The protocol was discussed by the full board. It needs some minor revision. Beyer will work with the researchers and will approve the protocol when the changes have been made.

1617-119: The protocol was discussed by the full board. It needs more substantial revision. The researchers will be given feedback and asked to resubmit the protocol to the full board.

1617-120: The protocol was discussed by the full board. It needs some minor revision. Beyer will work with the researchers and will approve the protocol when the changes have been made.

1617-121: The protocol was discussed by the full board. It needs more substantial revision. The researchers will be given feedback and asked to resubmit the protocol to the full board.

Adjourned 1:47 pm.

Respectfully submitted,
Tatiana Kaminsky

Addendum:

The IRB met on 05/26/2017 to complete business for the 2016-2017 academic year. Tim Beyer (chair), Geoff Proehl, Brad Richards, Sarah Moore, and Jan Wolfe (community member) were in attendance. In that meeting, the minutes from 04/26/17 were approved without modification. Committee members then reviewed full board protocols. 1617-091-1 and 1617-119 were approved. 1617-121 was approved after minor changes were received by Beyer (IRB chair).

The following expedited and exempt protocols were approved after 04/26/17:

1617-034-1	Expedited	1617-125	Expedited
1617-066	Expedited	1617-130	Expedited
1617-117	Exempt		
1617-123	Expedited		

Revised IRB Checklist

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 8th 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

Revised IRB Protocol

(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/>