

Faculty Senate Meeting

May 12th, 2014

McCormick Room, Library

Present: Brad Dillman (chair), Leslie Saucedo, Derek Buescher, Andrew Gardner, Cynthia Gibson, Andrea Kueter, Mike Segawa, Kris Bartanen, Paige Maney, Haley Andres, Nila Wiese, Tim Beyer (guest), Renee Houston (guest), Amanda Mifflin, Kriszta Kotsis, Ariela Tubert, Maria Sampen, Matt Warning (guest).

Chair Dillman called the meeting to order at 4:02.

Announcements

As his final meeting as chair, Dillman stated that this year's work on the Senate was good and bid farewell.

Approval of Minutes

M/S/P to accept minutes of May 5th, 2014 as slightly revised.

Institutional Review Board (IRB) end-of-year report presented by co-chairs Beyer and Houston.

Beyer and Houston provided brief summary of report (attached as appendix). Beyer noted that there were 95 protocols reviewed by the committee this year, up from 10-15 most years. This increase was due to abolishment of internal department reviews in order to align with federal guidelines. Several new documents have been drafted to assist with the adherence to federal guidelines. Some examples are MOUs for the Office of Institutional Research (OIR) and use of deceptive procedures in research. The committee intends to review the documents once more in the fall before uploading onto the website.

They noted that there need to be more opportunities for training and recommend consideration of CITI – an online resource developed by a consortium of institutions that stays updated with federal guidelines. They also highlighted a need for better guidelines for student-generated protocols to ensure more efficient approval and to reduce multiple rounds of editing and submissions.

Wiese moved to accept the report. It was seconded and discussion ensued.

Gardner expressed appreciation for the work accomplished this year. He also hoped that the committee might consider a charge to “think outside the box” next year in terms of employing federal guidelines for all university research. He wants the IRB to maintain the right of faculty to approve non-federally funded research.

Houston acknowledged the need, pointed to the guidelines for “deception research” as an example and agreed that creating guidelines to meet faculty needs should continue.

Beyer mentioned 2-way communication between departments and the IRB is important.

Buescher asked how many departments usually submit proposals and would a charge to collaborate with those departments next year make sense?

Houston and Beyer said yes. Beyer said now that the committee has seen the total number of proposals from this year, they'll have a good idea of each department's needs.

Gardner asked how many proposals were federally funded. Answer was none.

Dillman mentioned IPE students who conduct research overseas, notably in less democratic countries, face much suspicion and was wondering if the IRB might have suggestions about overcoming this issue?

Beyer answered that the IRB focuses on safety of participants, not method.

Buescher asked how well the co-chairship worked and would they recommend it for next year?

Beyer said given the amount of changes, having 2 chairs significantly helped to make the workload doable. Houston added that the amount of work was astounding and that it helped to consult with each other in interpreting guidelines. She felt it would likely be a good model for next year.

Dillman asked if the size of the committee was appropriate.

Houston said it was barely enough. Beyer said each member needed to read 10-15 protocols individually, then the remainder in the context of the full board. Additionally, several new documents were produced this year.

Dillman asked if an additional member was needed, and if there was a certain expertise they would prefer to add to the committee?

Houston and Beyer replied Business or Economics.

A vote to accept the IRB report passed unanimously.

International Education Committee (IEC) end-of-year report presented by Matt Warning.

Warning began with an update to the year-end report initially sent to the Senate. Under charge 4, the IEC come up with the following 3 options regarding surveys to measure the effectiveness of Study Abroad:

1. Make revisions to the existing survey, which would likely be minor. We would still want to know what the Senate's goals were for the revision, however.
2. Look into redesigning/rewriting the survey to better assess the benefits of study abroad and/or particular programs.
3. Look into using an outside tool (which may cost some money) to 'scientifically' measure the impact/effectiveness of study abroad on a broader scale.

Warning suggested that, going forward, the IEC would like more feedback from Senate as to the goal of charges.

Saucedo moved to accept the report. It was seconded and discussion ensued.

Gardener asked whether the incentive behind Senate charge #2 (*Review the current list of study abroad programs and eliminate expensive programs that do not provide something distinctive*) was simply to save money?

Warning said no, that some programs simply didn't offer much more than direct enroll.

Tubert asked if it offered an opportunity for student to go places that didn't have an international program.

Warning said that we are already out of scale with other schools. That we have ~120 programs compared to 20-something at Lewis and Clark. Several of the programs that we have offered didn't appear academically strong.

Gardener asked how new programs start.

Warning said students bring back ideas when abroad or professors bring them up.

Gardener asked as the list shortens, is there a commitment for a "one-off" program?

Warning said they (students?) can always petition and that no one has complained about removed programs. He stated that the programs professors like will stay.

Buescher asked for ideas for charges for next year.

Warning responded that the IEC needed to know where to go from here. He walked through several of the charges.

Regarding Charge #1, if a program doesn't provide data on sexual violence, do we continue with them? He felt that decision should come from higher up than the IEC. How should the IEC assess safety? Having the charge has everyone thinking about it but the committee was unclear as to the desired outcome.

Pertaining to Charge #4, does the Senate want to know how Study Abroad impacts our students? Existing surveys change year to year preventing longitudinal studies. Right now the data is self-reported; people indicate how the experience affected them. Would it be better to approach 'impact assessment' in terms of the university's mission to prepare global citizens? For example, we could compare students who went abroad to those that didn't. In short, the IEC needs to know what the Senate wants from the survey in order to design it.

Lastly, approaches to Charge #5 have not proven sustainable over time. There needs to be an attempt to institutionalize the integration of study abroad experiences into curricular and co-curricular activities. He felt the first incarnation was not structured well. What unites the students is the particular country or subject studied, not the general "abroad experience."

Mike Segawa indicated they had expected juniors and seniors would organize organically but this didn't happen. Michel Rocchi is interested in helping foster community building next year. While the students come back feeling transformed, they feel as if others don't care. The hope is to tap into their appreciation for diversity at large. In response to what it is that we want to measure, we should identify student learning outcomes from going abroad but how to do that beyond self-reporting? He reiterated the question of what goals and outcomes we are looking for?

Gardener asked where the conversation about financial concerns stood for short-term programs (charge #3).

Warning indicated that study abroad money may be able to roll over if not all used. If so, those funds could support exploratory work to investigate new programs. It needs to be sorted out if students will pay summer tuition. He indicated that there is not much institutional history of how to make programs happen but that International Programs is putting together a handbook.

Tubert clarified whether charge #2 needed to be continued next year. Warning said yes, that the IEC is looking at ~20% of programs each year and started with the most expensive ones.

Dillman wondered if information that students provide (write ups, exit surveys) can be used to evaluate a program. Warning noted that the surveys are not heavy on academics but that departments usually have a sense of the academic rigor of programs their majors are in.

Segawa said that the student self-assessments are satisfaction surveys and that it has been a long, persistent issue to know how good the programs are academically.

Segawa inquired about how well sexual assault data has been gathered. Warning said the few programs have the data but it is good that we are asking for it.

Bartanen affirmed that financial questions for short, summer abroad programs are moving forward. She noted that there is a start-up fund for exploratory work and that the handbook means we don't have to start from scratch.

Stockdale mentioned his understanding that students can apply only need-based aid and not merit-based aid to study abroad programs. He asked whether that meant some of our best students don't get to go abroad and is that the best payoff for the university?

Bartanen clarified that merit aid is often used to meet need and that only the merit aid "above need" does not get applied to study abroad programs. She noted that additional merit aid is now on the table to reconsider for availability for study abroad.

Maney explained that when she attended the slideshow for study abroad, she walked away thinking that none of her merit aid could be used.

Saucedo asked if the IEC year-end report will be updated to include the updated information for charge #4. Warning replied that it would.

Sampen asked if a different chair for each semester worked well for the IEC. Warning said yes but that the committee had trouble getting members to show up in the spring.

A vote to accept the IEC report passed unanimously.

Buescher wondered what the Senate should do about the failure of receiving a curriculum committee report.

Dillman responded that we will have to take it up 1st thing in the fall. He added that the written report needs to be in the record, but not necessarily formally presented.

Wiese stated that the Senate may need to provide more guidance about when work should be done and perhaps move due dates for reports earlier.

Segawa indicated he would want a presentation.

Sampen said she felt it was the role of the current chair of the curriculum committee to give the report in the fall.

Stockdale wondered if we should discuss it before the start of the fall semester?

Gardener noted we'd need a chance to first see the report.

Tubert said we need the report before we could form new charges in the fall.

Buescher suggested that we ask Lisa to get us the report before the fall retreat.

Stockdale asked for a reminder of who was leaving the senate: Dillman, Kessel, Kotsis, Mifflin and Andres indicated they were.

Tubert thanked the leaving members for their work.

The meeting adjourned at 4:59pm.

Submitted by Leslie Saucedo

IEC Final Report

2013-2014

Presented to the Senate May 12, 2014

The IEC was charged with the following tasks for the 2013-2014 academic year (in bold). What was accomplished by the committee is indicated following each charge.

CHARGES

1. With respect to the issue of sexual violence particularly, determine a process for assessing, as part of the approval processes for Puget Sound study abroad programs:

- (1) the student support resources and response protocols for student safety;**
- (2) the number of reported instances of sexual violence at the international program;**

The OIP has required that providers have established emergency procedures but not procedures specific to sexual violence. In response to this charge, the Office of International Programs (OIP) has begun requesting the relevant information from program providers. They have found that few (eight) providers currently collect such information but hope that OIP's requests and those of other institutions will persuade them to do so. If requested to do so, the OIP could establish a requirement that providers have procedures, support resources and responses protocols for sexual violence and that they provide data on the reported incidences of sexual violence.

The assessment process established by the IEC is therefore that the OIP collect the relevant information and include it in the approval and review processes. We seek guidance from the Senate on how programs that do not collect or report such information should be evaluated.

- (3) the efficacy of Puget Sound's safety information for students before they study abroad; and**
- (4) the efficacy of Puget Sound reporting and response processes should a sexual violence incident occur.**

Associate Dean of Students and Director of Counseling, Health & Wellness Services, Donn Marshall, who has done extensive work on sexual assault prevention on campus, has begun working with the OIP to assess the efficacy of the study abroad pre-departure information on sexual assault prevention.

2. Review the current list of study abroad programs and eliminate expensive programs that do not provide something distinctive (e.g., language, discipline, or geography.)

The IEC began addressing this problem in 2012-2013, focusing on areas where programs are expensive, duplicative and have no language component. We began with Australia, eliminating programs or changed our offering to less-expensive direct enrollment options that provided significant support to incoming international students in order to meet any student support needs

for our students. In 2013-2014, the IEC formed a subcommittee to identify redundant programs in the UK as well as direct enrollment options. Direct enrollment options allow students to have fully integrated experiences with host country students. The subcommittee did not complete their evaluation of UK programs so this work will continue in 2013-2014.

3. Once a financial model is resolved for short-term study abroad programs, develop a clear template for proposing, organizing, and leading short-term study abroad programs.

The financial model was never fully resolved; nevertheless, the IEC formed a subcommittee that includes faculty who have led short-term summer study abroad programs and this subcommittee is creating a “how-to” guide for interested faculty which it will make available in the fall of 2014.

4. Work with the Office of Institutional Research to evaluate the questions addressing study abroad that are currently on sophomore and senior surveys, as well as the returning questionnaire for study abroad students.

The IEC learned from Ellen Peters of OIR that there actually is no “Sophomore Survey” but rather short surveys given to first-year and sophomore students the content of which varies every year, ruling out comparisons over time that assess the impact on individual classes of study abroad. The content of the Senior Survey also changes every year so comparisons of senior classes are difficult.

The committee examined some common tools used to measure study abroad effectiveness, including one that was designed by a consortium of liberal arts colleges with Teagle funding. The committee sees three options for proceeding on this issue:

1. Make revisions to the existing survey, which would likely be minor. We would still want to know what the Senate’s goals were for the revision, however.
2. Look into redesigning/rewriting the survey to better assess the benefits of study abroad and/or particular programs.
3. Look into using an outside tool (which may cost some money) to ‘scientifically’ measure the impact/effectiveness of study abroad on a broader scale.

5. Continue to work with faculty to encourage the integration of study abroad experiences into on-campus classes and research symposia, and work with the SLC and the Dean of Students to encourage integration of study abroad experiences into co-curricular activities.

The IEC met with Dean Segawa specifically to discuss the improvement of the student experience in the Michel Rocchi International District (MRID) in Commencement Hall. Because the MRID is located on two different floors of CH in three different flats, and because students come from varied academic concentrations and study abroad experiences, and because some leave half-way through the year to study abroad, and others return at that time from study abroad, cohesion among the MRID cohort has been an issue. The committee gave him input about how to better ascertain cohesion among MRID students, which would allow for a greater possibility of successful programming led by Res Life staff or by faculty. One problem that was

identified was the recruitment of students to live in the MRID and their placement in the different flats. After the meeting, Diane and Roy met with Shane Daetwiler in Res Life to discuss the process for applying to the MRID and crafted an informative email that was sent out to all FLLD students as well as AS students. The result was a healthier applicant pool for the MRID for next year. Furthermore, Michel Rocchi will assume directorship of the MRID for next year. Having a dedicated faculty member to the MRID will help provide cohesion so that this district of Commencement Hall will be a better academic experience for students.

6. Study and report on the feasibility and desirability of increasing the number of direct study abroad exchange programs.

This is discussed in relation to charge 2 above.

Exchange programs would meet both our financial needs and our international student needs. On exchange programs the funds stay on campus instead of being used to pay an outside program provider. This allows Puget Sound to allow more students to study abroad at a lower cost to the university. Additionally, with only eight current international students we need to increase this number. Exchange programs would allow us to have additional international students on campus.

We are currently working on possible exchange programs in England and potentially with Turkey.

7. Examine study abroad application documentation for clarity regarding application rules for students placed on probation.

Here is the language approved by an IEC subcommittee and approved by the whole committee. This language will be clearly indicated online, at OIP and in official documents.

For students on Conduct Probation:

- Students on Conduct Probation Level II (CP II) are not allowed to represent Puget Sound, and no waivers are permitted. Students may not apply for study abroad, nor may they participate in a study abroad program while on CP II.
- Students on Conduct Probation Level I (CP I) are not allowed to represent Puget Sound, unless they obtain a waiver for a specific purpose. A student wanting to apply to study abroad may petition for a waiver by following the process outlined here: http://www.pugetsound.edu/files/resources/922_ConductWaiverProcess11-12.pdf.
- If a waiver is granted, the IEC may consider the student's application, or may consider allowing the student to study abroad.

Respectfully submitted,

Diane Kelley, chair, F13

Matt Warning, chair, S14

Institutional Review Board
Report to the Faculty Senate
AY 2013-2014

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 gives very careful attention to issues such as potential risks to participants, protection of participants' identities and disclosed information of a sensitive nature, 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 2013-2014 academic year.

2013-14 IRB membership: Tim Beyer (co-chair), Renee Houston (co-chair); Lisa Ferrari (ex-officio); William Breitenbach, Eda Gurel-Atay, Jung Kim, Garrett Milam, Emelie Peine, Siddharth Ramakrishnan, Kirsten Wilbur; Troy Christensen (community representative).

The Institutional Review Board did not receive any formal Senate charges this academic year, hence we focused on the self-charges from the 2011-12 and 2012-13 academic years which remained outstanding in addition to the self-charges described below. By and large, apart from reviewing research protocols, much of our attention was directed towards crafting and implementing a new review system that is in line with Federal Guidelines.

Many of the self-charges from the past two years (AYS 2011-2012, 2012-2013) as well as this AY (2013-2014) remain the same as they essentially deal with updating the review process. In the sections below we describe how we addressed and resolved these multiple charges from multiple years.

Remaining Self-charges from AYS 2011-2012 and 2012-13:

1. Continue to monitor protocols and maintain and manage records for research involving human subjects.
2. Develop recommendations for the replacement of the departmental designate system for preliminary review of all protocols and complete review of exempt and expedited protocols. (These recommendations and the need for the changes are discussed in detail below.)
3. Continue progress on revisions to the IRB website, including a revision of the handbook documents.

The following actions were taken by the IRB in response to these charges:

1. The IRB engaged in the review and monitoring of research protocols involving human subjects throughout the 2013-14 academic year. A major change for the 2013-2014

academic was that the IRB reviewed all protocols, not just full board protocols. This procedure is described in (2) below.

Ninety-five protocols were reviewed by members of the full board. Of these 6 were full board (3 approved, 1 rejected, 2 pending), 83 were expedited (72 approved, 9 pending), and 7 were exempt (6 approved, 1 pending).

2. Throughout the year the IRB worked on crafting and implementing a replacement for the departmental designate system in order to bring our procedures into compliance with Federal Guidelines. The complete recommendations are described in detail in Appendix A.

3. The IRB discussed changes to the website which represents the campus community's primary resource for information regarding human subjects research. Documents crucial to outlining the new review process were revised this year and will be uploaded onto the IRB website after the last Full Board Committee meeting on May 16th. Further changes to increase the website's usability will be recommended for 2014-2015.

Self-charges for the IRB for the 2013-14 AY:

4. Implement and inform the campus community regarding changes to the IRB review process resulting from the elimination of the departmental designate system. We successfully communicated these changes broadly to the campus community via facultycoms. Please see message in Appendix B.

5. Finalize the implementation of a memorandum of understanding (MOU) with the Office of Institutional Research regarding IRB oversight of OIR work. In addition, we reviewed the existing memorandum of understanding with the Department of Psychology regarding active deception in research. Both MOUs will be reviewed every three years and are attached in Appendix C.

6. Update documents to (a) expedite the review process for IRB members, and (b) clarify the new process for investigators. The following documents were created and/or updated: protocol decision document, coversheet, level of risk assessment, level of review guide, IRB protocol checklist, and consent form guidelines. These documents are attached in Appendix D.

7. Monitor changes at the federal level regarding regulations and requirements related to human subjects research. No new guidelines that impact the current process have been identified.

Self-charges for the IRB for the 2014-15 AY:

1. Continue to monitor protocols and maintain and manage records for research involving human subjects.

2. Monitor changes at the federal level regarding regulations and requirements related to human subjects research.

3. Continue to make progress on revisions to the IRB website, including a final revision of the handbook documents.

4. Identify and implement training resources for IRB members that meet budgetary constraints. CITI should be further explored as an optimal choice that allows for convenient on-line training and certification in IRB review. In addition, CITI continuously updates training modules to incorporate changing Federal guidelines. This would allow members to be fully trained and keep us advised of current guidelines (see self-charge 2 for the 2014-15 AY above).

5. Create opportunities to connect with departments that typically produce student protocols to further support best practices that ensure the timely review of protocols.

Respectfully Submitted,
Renee Houston, PhD and Tim Beyer, PhD
IRB Co-Chairs AY 2013-14

Appendices:

A: IRB procedures

B: Message on IRB process to campus community via facultycoms

C: Memoranda of Understanding, Department of Psychology and Office of Institutional Research

D: New or updated documents: Protocol Decision Document, coversheet, level of risk assessment, level of review guide, IRB protocol checklist, and consent form guidelines

Appendix A: IRB procedures

Protocol Flowchart

- 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 (jmcmichael@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.
 - a. Jimmy will notify you via e-mail when a protocol has been assigned to you. You can then access this protocol via the shared IRB drive (`//merlin2/irb/`).
 - b. Once logged into the shared IRB drive, you will find a folder 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 attached “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.
 - iii. Unsure. If the “unsure” box is checked, the reviewer assigns appropriate level of review. If exempt/expedited, the reviewer should complete the review. If the protocol needs full board review, please send the protocol back to Jimmy and indicate that it requires full board review. Jimmy will then distribute that protocol to all members.
- 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 and Jimmy
 - b. If revisions are required before the protocol can be approved, the reviewer communicates the required changes with the PI. The PI will then resubmit a revised protocol for review. All revisions required by the reviewer must be satisfied before the reviewer can approve a study.
 - 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 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. We will ask that the advisor signs off on their student's resubmission to ensure that all required changes/feedback have/has been appropriately addressed.

- 5) 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 co-chairs will communicate decisions, including if revisions are required, with the PI.

Appendix B: Message on IRB process to campus community via facultycoms

Summary of Protocol Submission, Review, and Approval

- 1) Submit protocols to Jimmy McMichael as:
 - a. A hardcopy in Jones 212 (CMB 1020). Please make sure all required signatures appear on the coversheet.
 - b. An electronic copy (jmcmichael@pugetsound.edu)

- 2) Communication about the approval of the protocol will depend on level of review (exempt, expedited, full board).
 - a. Protocols that meet the criteria for *exempt* or *expedited* review will be assigned to a single reviewer. That reviewer will be in direct contact with the principal investigator listed on the protocol. You can expect a response from the reviewer within three working days of receipt of your protocol.
 - i. If the protocol can be approved, the reviewer will communicate this decision to the principal investigator directly.
 - ii. If revisions are required before the protocol can be approved, the reviewer will communicate all required changes with the principal investigator. The principal investigator will then resubmit a revised protocol for review. All required revisions must be satisfied by the principal investigator before the reviewer will approve a study.
 - b. Protocols that meet the criteria for *full board* review will be distributed to all IRB members. Review of the protocol will occur at the earliest full board meeting date (please see meeting dates as well as corresponding due dates published online each semester). The chair of the IRB committee will communicate any decisions directly with the principal investigator.

- 3) Once you receive notification that the protocol is approved, you will need to have your consent forms officially stamped by Jimmy McMichael in Jones 212. Even if approved, you may not start collecting data until your consent forms have been stamped.

*****Please note that the faculty advisor of student research will be included in all correspondence between the reviewer and the principal investigator. Before a reviewer will look at a resubmission, the faculty advisor must sign off on their student's resubmission to ensure that all required changes/feedback has been appropriately addressed. The easiest way to accomplish this is for the faculty advisor to send the revision directly to the reviewer and include the student researcher(s) on that correspondence.

Please direct any questions to the IRB co-chairs Renee Houston (rhouston@pugetsound.edu) and Tim Beyer (tbeyer@pugetsound.edu).

Proposal for Expedited Review of Psychology Student Research Concerning Studies Using Deceptive Procedures

I. Purpose of this document.

The purpose of this document is to clarify what types of studies may be approved through the expedited review process in the Department of Psychology at the University of Puget Sound. This document is intended for use by the Psychology Department IRB designate serving as the reviewer for expedited proposals, as well as by faculty members and students in the Psychology Department. This document was developed by faculty members in the Psychology Department through careful consideration of the issues involved and was approved by the Puget Sound Institutional Review Board on February 17, 2006. Changes to this document shall only occur with approval from the IRB and Department of Psychology.

II. What is deception and why is it used in research?

Deception is the intentional misleading of subjects or the withholding of non-trivial information about the nature of an experiment. Misleading or omitted information might include that related to the purpose of the research, the experimental manipulations, the role or identity of researchers, or the information presented in the study.

Deceptive procedures are used because the validity of some research depends on withholding information or manipulating information in a controlled setting. Specifically, using deceptive cover stories or withholding information about the purpose of the research may be necessary because full knowledge by the subject can create demand characteristics that would bias participants' responses. The use of deceptive strategies is also required at times to create experimental situations that can be studied in a controlled environment. Thus, deception is necessary for certain types of behavioral research, and deception is acceptable under federal regulations as long as appropriate protections are provided.

III. Types and degrees of deception.

Deception occurs in varying degrees of severity. Benign to progressively more severe examples include:

Passive Deception

- (a) Incomplete disclosure by withholding information about the experimental hypothesis to ensure that subjects provide unbiased responses.
- (b) Omission of information that might lead participants to make false assumptions about some aspect of the experimental conditions or procedures.

Active Deception

- (c) Deceptive information or instructions that misinform participants about some aspect of the study (e.g., false cover stories, false feedback) in order to ensure

- unbiased responses, maintain experimental control, create experimental conditions.
- (d) Confederate manipulations used to deceive participants about the status of other individuals who they believe to be research subjects.
 - (e) Confederate manipulations used to deceive participants about the status of individuals they believe to be outside of the experiment (e.g., persons allegedly needing help in a study of helping behavior).
 - (f) Concealment and staged manipulations in field settings that create a situation in which participants are not even aware that they are subjects until after the experiment has concluded.
 - (g) Withholding information in order to obtain participation that the participant might otherwise decline.

IV. What ethical concerns have been raised regarding the use of deception?

Arguments have been raised that the use of deception in research jeopardizes the integrity of the informed consent process, violates the fundamental ethical principle of autonomy, and can potentially harm the participants by creating distress or distrust. Nevertheless, Federal guidelines (<http://www.apa.org/science/research/reglaws.html>) and ethical guidelines of the American Psychological Association (<http://www.apa.org/ethics/code2002.pdf>) allow the use of deception under certain conditions. Organizations developing guidelines for the appropriate use of deception, including the University of Puget Sound Psychology Department, allow deception because they believe that the scientific, educational, and/or applied benefits associated with the appropriate use of some deceptive techniques outweigh the potential risks involved.

V. How do Federal guidelines regulate the use of deception?

Federal guidelines PROHIBIT the use of deception when:

- (a) The use of deceptive techniques places subjects at greater than minimal risk.
- (b) The withheld information might change a person's decision to participate in the study.
- (c) Deception is used to obtain enrollments.

Federal guidelines RECOMMEND the following:

- (d) Scientific and ethical justification for deceptive procedures.
- (e) Full debriefing about the deceptive procedures.
- (f) An opportunity for participants to ask questions about the new information.
- (g) An opportunity for participants to withdraw from the study and have their data removed.

VI. When may proposals using deceptive procedures qualify for expedited review by the Psychology IRB designate? (See Appendix A for a summary table.)

Proposals that meet ALL of the following criteria may qualify for expedited review:

- (a) The research does not violate Federal prohibitions and meets Federal recommendations on the use of deception.

- (b) The research meets all other qualifications for expedited review (e.g., it entails minimum risk, does not involve minors, and does not include sensitive information.)
- (c) Alternatives to deception have been considered, and a good-faith effort has been made to find alternatives to deception. For student projects, the instructor or supervisor must concur that deception is necessary to conduct the study in question. IRB proposals must provide clear justification for the use of deception (see VII-a below).
- (d) The least severe form of deception necessary is implemented.
- (e) Studies using passive deception (described in sections III-a and III-b above) are eligible for expedited review. Studies that use certain forms of active deception described in points III-c, III-d, and III-e above may be expedited, but only for students in upper division courses (300-level or above) or those pursuing independent study. Students who do not meet this requirement need to seek full IRB approval for any proposal involving active deception. Faculty should seek full IRB approval for all proposals involving active deception. Forms of deception described in III-f may only be approved by the full IRB and deception described in III-g is prohibited.

VII. What additional information and materials are required for proposals using deceptive procedures that are submitted for expedited review?

- (a) *Justification of deception.* The project description should explain the nature of the deception and why deception is necessary to conduct the study; the description should also clearly describe the steps taken to safeguard participants.
- (b) *Risks.* The risks and benefits section must identify risks to participants, explain precautions taken to ensure that participants will not be exposed to more than minimal risk, and describe steps taken to minimize risks associated specifically with deceptive procedures (e.g., thorough debriefing).

Consent procedures. The normal informed consent process must be modified to advise potential participants that the information they are given is not complete and that they will be fully informed at the end of the experiment. To do this, a statement similar to the one below must appear in the project description of the consent form:

“Although we have described the general nature of the tasks that you will be asked to perform, the purpose of the research may not be fully explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the methods and purpose of the study. You will also be given an opportunity to ask any questions you might have.” (adapted from University of Connecticut)

- (c) *Debriefing.* The debriefing should describe in detail the ways in which deception was used, why it was necessary, and the true purpose of the study. Because the investigator is responsible for ensuring that the participants leave the research setting with an accurate understanding of these issues, methods of monitoring participants’ understanding should be included in the debriefing process. The

debriefing process should be explained in the protocol, accompanied by a complete debriefing form or script. Studies using active deception must include an oral debriefing.

- (d) *Autonomy*. To restore participants' autonomy and control at the conclusion of the debriefing experimenters must provide participants with an opportunity to withhold the use of their data if they are unhappy with the deception. A statement similar to the one below must appear at the end of the debriefing script:

"Now that we have explained the full intent of the study, we want to provide the opportunity for you to ask any questions you might have about the hypothesis and the procedures used in the study. In addition, if you are unhappy about the use of deception in this study you may withdraw your participation at this time."

Appendix A: Summary of Types of Methods and Reviews

Method	Review
Passive Deception (a) Incomplete disclosure (b) Omission of information	*Expedited review.
Active Deception (c) Deceptive information or instructions that misinform (d, e) Confederate manipulations	*Expedited review for students in upper division courses and independent study. Full review for all others (e.g., faculty and students in lower division courses.)
(f) Concealment and staged manipulations in field settings	Full review.
(g) Withholding information in order to obtain participation	Prohibited.

*Note: Full IRB review is always required for any study involving more than minimal risk.

Office of Institutional Research/Institutional Review Board Memorandum of Understanding

This memorandum of understanding (MOU) lays out the terms under which research conducted by the Office of Institutional Research (OIR) may forego the Institutional Review Board (IRB) process.

The term “institutional research” applies only to data collection, analysis, and reporting performed by the OIR for the primary purpose of providing information for the university. Institutional research projects may include system data, program evaluations, focus groups and surveys requesting student opinions and feedback about aspects of the university, including research for the purposes of program assessment, policy analysis, curriculum review, campus climate evaluation, and any other categories of research exempted from ongoing IRB oversight by 45 CFR 46.101(b), provided they involve only minimal risk to subjects. Institutional research is excluded from IRB review, provided the data are never presented in such a way that individual participants could be identified. For any research that collects qualitative data, the following phrase will be included in the informed consent: “The results of this research are confidential (or anonymous); however, comments that are particularly informative or salient may be excerpted for publication, though all identifying information will be stripped.”. Identity stripped qualitative data and/or aggregate results of research conducted by Institutional Research under this exclusion may be used in scholarly writing for publication, conference presentations, external reporting and institutional publications such as the Admissions Viewbook and the University of Puget Sound Bulletin.

Research done in conjunction external organizations are exempted only if approval has been granted through the IRB at another accredited institution, and OIR abides by that IRB protocol. Reports to external bodies, excluding the university’s accrediting body, must refer to data in the aggregate, without reference to individual responses. If the collection of individual data is done through a national organization affiliated with a college or university (e.g., NSSE and Indiana University, CIRP and UCLA) and that institution will have access to individual data, IRB approval from that institution must be in place.

In instances when an individual response indicates harm to self or others, OIR policy is to inform the appropriate authority at the University of Puget Sound. Under no other circumstances will OIR report individual quantitative data even if the data are collected as anonymous or are stripped of identifiers after collection. Data regarding subpopulations (e.g., by gender, by ethnicity, by class standing) of a dataset will be considered aggregated data. Under no circumstances may OIR share data that can be used for purposes of financial profit.

The Director of OIR should direct any questions about this MOU to the current Chair of the IRB or, if that person is unavailable, the Associate Deans.

Date: March 2014

Owned by: Office of Institutional Research and Retention

Appendix D: New or updated documents: Protocol Decision Document, coversheet, level of risk assessment, level of review guide, IRB protocol checklist, and consent form guidelines

UPS IRB PROTOCOL #: _____ Review date: __ / __ / ____

Title: _____

Investigator(s) name(s): _____

Level of review (check one): Exempt Expedited Full Board

Decision (check one): Approved
 Minor corrections or clarifications required
 Reconsideration after investigator responds to identified concerns
 Disapproval for reasons specified in writing below

Written feedback for investigator (please use this space to outline what minor corrections or clarifications are necessary, what concerns have been identified, or specific reasons for disapproval):

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: _____

Protocol Title: _____

Principal Investigator: Typed name: _____
Signature: _____
Department or School: _____
Email: _____
Telephone number: _____

Co-Investigator: Typed Name: _____
Signature: _____
Email: _____

Co-Investigator: Typed Name: _____
Signature: _____
Email: _____

Co-Investigator: Typed Name: _____
Signature: _____
Email: _____

<p>Faculty Advisor's Statement (student projects only): I, _____ am the advisor for _____ _____. 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 _____</p> <p>Signature: _____ Email: _____</p>
--

Source of Support (if any):

Level of Risk to Human Participants: _____ Minimal _____ Greater than minimal

Number of Participants: _____

*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

Level of Risk

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy 45 CFR 46.102(i)].

Greater than minimal risk means that the probability and magnitude of harm or discomfort in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. *All research that poses greater than minimal risk requires full board IRB review.*

Examples that constitute minimal or greater than minimal risk by type of harm (physical, psychological/emotional, social/economic) are listed below:

Type of Harm	Minimal Risk	Greater than Minimal Risk
Physical	<ol style="list-style-type: none"> 1) Pain associated with routine medical procedures 2) Exercises considered relatively safe for healthy adults 3) Irritation associated with the electrode gel used with EEG 	<ol style="list-style-type: none"> 1) Pain associated with a medical procedure that can lead to prolonged pain 2) Asking participants with asthma to perform physical exercises 3) Using EEG with people with epilepsy or other seizure disorders
Psychological or Emotional	<ol style="list-style-type: none"> 1) Stress or feelings of embarrassment or guilt from answering questions about sensitive topics that could be encountered in daily life (e.g., questions about body image, self-esteem, selfishness, etc. that could be found in a mainstream magazine) 2) Feelings associated with being observed in a public space while engaging in typical behavior(s) that a participant would likely consider not to be private 3) Negative feelings that are transitory and do not exceed those experienced in daily life 	<ol style="list-style-type: none"> 1) Stress or feelings of embarrassment or guilt from answering questions about sensitive and/or illegal topics (e.g., drug use, sexual practices/orientation, criminal background, violence, etc.) 2) Feelings of invasion of privacy from covert observation of behavior(s) that a participant would likely consider private 3) Negative feelings that are lasting and therefore exceed those experienced in daily life

Social or Economic	<ol style="list-style-type: none">1) Completion of research could result in anonymously providing negative information about a participant's social or business group2) Participation in the research is not likely to result in economic loss	<ol style="list-style-type: none">1) Completion of research could result in embarrassment or harm to the individual participant's reputation within his or her social or business group, loss of employment, or political persecution2) Participation in the research may lead to economic loss (e.g., priming gambling)
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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.

IRB Protocol Checklist

For reference - it is not necessary to include the checklist itself in your submission.

Attach information describing the research project as indicated in the checklist below.

Although there is no limit to the length of the proposal, the ability to describe the relevant issues concisely is appreciated.

Cover Sheet

Completed

Signed

Faculty Advisor's Signature (student protocols)

Project Proposal

Project Description

Purpose

Background

Significance

Research Design/Methodology

Subject Population

Who?

How many subjects, including how this estimate was derived?

How will access to the population be gained? (If outside organizations will participate, their agreement must be documented.)

Will a vulnerable population be used (e.g., children, mentally disabled, prisoners, etc.)? If so, describe any special procedures used to safeguard the subjects.

If deception is used, please justify

Discuss possible risks to participants

Discuss benefits to participants

Describe any payments that will be made to participants, the amount and schedule of payments, and the conditions for receiving this compensation.

Treatment of Data

Describe the procedure to be used to maintain confidentiality, especially when using video tapes, etc.

How will informed consent be obtained? Attach a copy of the consent form or verbal statement to be used

Multi-Site Studies

If this study will be conducted at other institutions with investigators who will

be reporting research results to the Puget Sound Principal Investigator, describe the following:

- ___ How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed?
- ___ What provisions are in place for management of interim results?
- ___ What will the multi-site process be for modifications to the protocol?

Attachments

The following items should be included with the cover sheet and project proposal application, as appropriate:

- ___ The written/electronic consent form(s) or verbal statement to be given to the subjects regarding consent/assent. In the case of projects involving children or decision impaired subjects, assent is required from the subject in addition to the consent of their legal guardian.
- ___ Written consent forms must be duplicated on appropriate departmental letterhead
- ___ Letters of consent from the appropriate authorities responsible for access to the subject pool (for example, a letter from the school superintendent or church pastor indicating their willingness to allow participation of their students/parishioners).
- ___ Copies of surveys or questionnaires that the participants will receive.
- ___ Sample recruitment letter or advertisement.
- ___ If survey or interview questions are collected in a language other than English, please provide back-translation certification

Section 6: Elements of Informed Consent and Consent Form Requirements

Consent forms document that the research project has been adequately explained to the subject. Consent forms need to be written in clear, concise, non-technical language, and must follow these guidelines:

- (1) The first page of the consent must be duplicated on institutional or department letterhead.
- (2) The upper margin of the first page must be **at least one inch below the letterhead to allow room for the IRB approval stamp**. (The stamp will go in the upper right hand corner of the first page of the consent form.)
- (3) The consent form must have one of these general titles:

Consent to Act as a Subject in an Experimental Study,

Consent to Act as a Subject in a Research Study, or

Consent to Act as a Subject in a Clinical Research Study

If the consent form is directed for minors then the following title should be used:

Parental Consent for a Child to Act as a Subject in an Experimental Study, a Research Study or a Clinical Research Study

- (4) The consent form must have the same official title as the title listed on the protocol.
- (5) List all investigators with names, the address of the department at the university and a university phone number. Do not include personal phone numbers. University e-mail addresses are acceptable. Personal e-mail addresses are not acceptable. Non-faculty members must list their faculty sponsor(s).
- (6) List the source of external support for the study, if applicable.
- (7) Provide a space for the subject's initials in the lower right corner of each page of the consent form. Pages must be numbered.
- (8) Informed Consent for Competent Adults and Adolescents must be formatted with the following standard paragraph subtitles: (Description, Risks and Benefits, Alternative Treatments, etc.). This format assists the reviewers and the investigator to insure that all required information is included.

DESCRIPTION: The first two sentences should give a brief, non-technical explanation of the study and identify why a particular subject is asked to be in the study. (Example: “The purpose of this study is to determine how people with different types of illnesses solve problems. You have been asked to participate because you have been diagnosed as having one of these illnesses.”)

A brief description of the methods that incorporates the following (if applicable) should also be included:

Duration of participation

Time sequences for stages or steps in participation

Rest periods when indicated

Tests or diagnostic procedures, and/or questionnaires

Volume of blood to be drawn, in terms of tablespoons or ounces (tablespoon=15 ml.); maximum allowable amount-450 ml (if applicable)

Expectation of the subjects for the completion of the experiments

RISKS AND BENEFITS: Include all reasonably foreseeable risks and discomforts associated with participation in the study. Such risks could be physical, psycho-social, or legal. Also mention the specific precautions that will be taken to avoid such hazards. For example, if blood is to be drawn, mention the possibility of a bruise or soreness at the site of venipuncture, or a spasm with loss of blood flow at the site of arterial puncture. Include any potential benefits to the subject or to scientific knowledge. The benefits should be described as **possibly** occurring rather than implying a promise of improvement, benefit, etc.

ALTERNATIVE TREATMENTS: This is only applicable to research in which there is a choice of therapeutic interventions.

NEW INFORMATION: If applicable, the form should include the statement:

New information gained during the time the research is in progress and which is relevant to participation will be provided.

If this statement is used, it should appear in the same type font as the rest of the consent form. (NOTE: Such new information and any change in the project should be sent to the IRB for review and approval prior to discussion with subject.)

COST AND PAYMENTS: Include any cost or payment to the subject, or reimbursement for related expenses. Mention any conditions affecting payment and time of payment. If there are no costs or payments associated with participation in the study include a statement such as:

There are no costs for participating in this study. You will not be paid for your participation.

If this statement is used, it should appear in the same type font as the rest of the consent form.

APPROVAL TO USE AND DISCLOSE HEALTH INFORMATION: Any study that involves the use of protected health information (PHI) needs to include the following statement.

Federal and state laws require care providers to protect the privacy of your health information. Volunteering to participate in this study means that your health information that relates to this study may be collected, used and disclosed to carry out the study. This includes health information about you that was collected prior to, and in the course of the study. Information may be collected from you by interviews or from your medical records. Examples of the health information that may be collected include, but are not limited to, personal information (such as name, address, gender, age, etc.), your medical history, personal habits, and physical tests and measures.

By signing this consent form, you are authorizing the research team to have access to your study-related health information. The research team includes the investigators listed on this consent form only. Your health information will be used only for the study purpose(s) described in this research consent form. Your health information will be shared, as necessary, with any other person or agency as required by law. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

By signing this study consent, you are authorizing the research team to use and share your study-related health information until the end of the research study. The study records will be confidentially shredded for your security when storage is no longer required.

You may withdraw your approval to use and share your study related health information at any time by contacting the Principal Investigator (insert investigator's name here) in writing, email or phone. If you withdraw this approval, you may no longer participate in this study. The study related health information that has already been collected may still be used to preserve the integrity of the study, including a disclosure to account for your withdrawal from

the study. However, the use or sharing of future health information will be stopped.

If this statement is used, it should appear in the same type font as the rest of the consent form.

Use asterisks to separate the sections of the consent form using the pronoun "you" from those using the pronoun "I".

CONFIDENTIALITY: Assurance of protection of confidentiality must be included in the consent form.* Describe your plans, and include the *appropriate* sections of the following statement:

I understand that any information about me obtained from this research, including answers to questionnaires, history, laboratory data, findings on physical examination, or audio or videotapes will be kept strictly confidential. Information that will carry personal identifying material will be kept in locked files. 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.

NOTE: If this statement is used, it should appear in the same type font as the rest of the consent form. **This statement is only applicable to those studies that do not require the PHI statement above.**

*Modification of this basic rule may be made in the case of deception studies and other extraordinary circumstances. It is not yet clear whether the courts will allow researchers to keep research records confidential in criminal proceedings.

RIGHT TO REFUSE OR END PARTICIPATION: The following is a suggested paragraph which should be adapted to your specific protocol.

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. If this is for a course assignment, students who are participating should be made aware that they will not be penalized for withdrawing from the study.

NOTE: If this statement is used, it should appear in the same type font as the rest of the consent form.

When a subject is unable to understand a research project due to age, maturity, psychological state, or brain disease or injury, such a project should not be undertaken unless it provides a reasonable expectation of benefit to the subject and does not interfere with a treatment program. When incompetent adults are sought as subjects for research, the spouse, parent or legal guardian must give informed consent. The consent form should be similar to that for competent adults with appropriate blanks for insertion of the subject's name and for indicating the relationship of the subject's representative to the subject. Make certain that necessary changes are made, recognizing that the signer is not the subject (i.e., a revised right-to-refuse paragraph).

ADDITIONAL INFORMATION REGARDING INFORMED CONSENT

The subject or legal representative has the right to withdraw consent at any time prior to or during the study. The term "legal representative" refers to the person who substitutes judgment and consents to participation in the best interest, and on behalf of the subject, and may include the subject's spouse, parent or legal guardian of a minor or incompetent individual. The exact relationship of the subject's representative shall be entered on the form.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the standard elements of informed consent, or waive the requirement to obtain informed consent, only if the IRB determines that the research could not be done without the waiver or alteration.

In addition, the Board must find and document either (1) that the purpose of the research is to demonstrate or evaluate (a) federal, state, or local benefit or service programs which are not themselves research programs; (b) procedures for obtaining benefits under these programs; or (c) possible changes in or alternatives to these programs or procedures; or (2) that the research involves no more than minimal risk to the subjects; that the waiver or alteration will not adversely affect the subjects; rights and welfare; and that whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If deception is a significant element in the research, the investigator must provide a detailed explanation in the protocol and assurance that adequate debriefing will be carried out as soon as possible after completion of deception.

A signed "long" consent form to document consent is generally required. In specified circumstances, the requirement of a signed written consent form may be waived altogether. The investigator must establish the need for departure from usual informed consent.