Institutional Review Board
October 8, 1996
Minutes

Members present: A. Ekes, E. Graham, P. Hansen, R. Preiss
Visitors: C. Weisz

The meeting began with a request by Weisz that the IRB approve an alternative IRB application for approval of research form to be used by the psychology department. The form would be used in lieu of the alternate form previously approved by the IRb and now in use by the department. She then discussed the details of the differences between the two alternative forms.

1. The heading now includes "Psychology Department Form."
2. Spaces for the Protocol and UPS/IRB numbers will appear in the top right corner.
3. The project title will now precede the investigators names.
4. An item for indicating risk level (minimal, moderate, high) will now appear on the front page.
5. Students will now indicate the course number associated with their project on the first page (if the project is for a course).
6. A category for other will be added to the "Attachments" checklist.
7. The second page of the form will now include responses concerning the use of special populations (Section #1),the exemption request section (Section #2),and the affirmation of compliance with signatures of investigators and faculty advisor (Section #3). This information previously appeared later (middle and end) in the proposal.
8. Due to the changes listed in above and a desire to improve the organization of the proposal, the remaining sections of the proposal have been renumbered as follows: #4 Project Description; #5 Subject Recruitment; #6 Confidentiality of Data; #7 Risks to Subjects; #8 Benefits; and #9 Informed Consent Procedures.
9. The headings and instructions for the sections above have remained the same except as follows:

A. In the Benefits section, the phrase "anticipated benefits to subjects and to society" will become "anticipated benefits to subjects, science, and society." Investigators will now be able to use this section to describe the anticipated importance of the study to advancing knowledge in their discipline.

B. In the Informed Consent Procedures section, the phrase "Completion of the task implies consent" following the option to waive written consent was removed because it was unclear what this meant. Investigators checking this option must provide a detailed justification for requesting the waiver, and can address this point in their justification.

10. The template will now include suggested "Standard Statements" for the Confidentiality of data section and for Part B of the Subject Recruitment section. These statements are intended to be appropriate for many, but not all studies. Investigators will adjust the statements as needed.
11. A new document has been created to describe guidelines for preparing a standard consent form. These guidelines are consistent, except as noted below, with those set forth in the UPS IRB's own guidelines, but are abbrieviated to assist students in preparing a consent form to be used with competent adults. In addition to these guidelines, a template of the consent form has been created to assist investigators. The template includes sample "Standard Statements" for various parts of the consent form. The guidelines explain that the standard statements should only be used if they are appropriate for a particular study and that alternative versions of the consent form may be required for studies involving special populations and therapeutic interventions.

Guidelines for the consent form that vary from the UPS IRB guidelines are as follows:

A. Letterhead stationary is not required. Instead, the term "Psychology Department" will appear at the top left corner of the form.

B. The guidelines for the Description section of the consent form has been abbreviated to read: "Brief and nontechnical. Include aims, if appropriate, and description of activities and duration of participation."

C. Standard versions of the Right to Refuse or End Participation and Voluntary Consent sections have been created. The Voluntary Consent section includes the name and phone number of the Psychology Department IRB representative.

D. Spaces for both the subject and research staff person's signatures (with dates) appear on the bottom of the form. A formal statement preceding the staff person's signature has been excluded. The primary purpose of the signature is to provide a witness to the subject's signature so the text seems unnecessary. It is also redundant with text in the Voluntary Consent section which reads, "Any questions I have pertaining to the research have and will be answered by __(Research staff member's name)___." Finally, the IRB's suggested statement is inconsisent with procedures used in many studies. The nature of the research is often described in the consent form itself and not orally by the experimenter.

Weisz will present the revised forms to the Psychology Department faculty for additional feedback. She requests that the IRB members convey any additional suggests and concerns as well. The Psychology Department will request formal approval of the forms by the IRB after revisions have been completed.Changes to the IRB Proposal

The committe then considered and approved research protocols numbered 9394-95 (protocol renewal); 9697-01; and, 9697-02

Ekes distributed the charges for the Faculty Senate:

1. Complete guidelines for conducting research using animals.
2. Conduct a formal outreach program.
3. Develop a system for processing bodily fluids.
4. Simplify and adapt various forms.

With respect to the second Senate charge, Ekes distributed:

1. Universal Precautions from the Centers for Disease Control and Occupational Safety and Health Administration
2. University of Puget Sound Bloodborne Pathogen Exposure Control Plan and Policy

The meeting was adjourned at 5:00

Respectfully submitted

Ernest S. Graham