IRB Proposals in Psychology

1. Overview

IRB. IRB stands for "Institutional Review Board." The mission of the IRB is to protect the rights and welfare of human research subjects by minimizing risks, ensuring that people are fully informed before they participate in research, and promoting equity in research participation. At TTU, all research involving human subjects is reviewed by the IRB. At TTU, the IRB has more than 1,700 active proposals. The IRB is housed administratively in the Human Research Protection Programs (HRPP) office, Office of the Vice President for Research. The office itself is in Administration, Room 357. Rosemary Cogan, Ph.D., is the IRB Chair and Donna Peters is the HRPP Manager.

Training. Training regarding the protection of human subjects is required for federal research proposals and is strongly recommended for all investigators before beginning human research. Several training programs are available on-line and can be reached at www.vpr.ttu.edu.

Health Sciences Center. If you plan a research project that involves the TTU Health Sciences Center, usually only HSC IRB approval is needed. Information about TTU HSC IRB procedures and forms can be found at www.ttuhc.edu/research/hrpo/irb.

Find forms. Instructions and forms are on-line at www/depts.ttu.edu/vpr/irb/

Reviewers in psychology. Psychology has several IRB reviewers who can approve Exempt and Expedited proposals. Put your proposal in the mailbox of one of the reviewers in the department. Your in-the-department reviewer will then send the material to the IRB office. We recommend that proposals for the Full Board also be given to a departmental reviewer.

Our IRB reviewers are Rosemary Cogan, Ph.D., and Ken DeMarree, Ph.D. You are welcome to visit with either of us if you have IRB questions. Darcy Reich, Ph.D. has been on the IRB for several years and is an alternate member at this time.

PI. The Principal Investigator for an IRB proposal must be a TTU faculty member or a full time staff member at TTU with the terminal degree in his or her field. Students are Co-investigators. The Principal Investigator is responsible for the proposal and for the conduct of the research.

Proposals, revisions, or amendments that do not follow the instructions or that have not been reviewed by the Principal Investigator will be returned for revision before a complete review will be carried out.

Format. Please single space materials. Please number the pages. Please do no*t* staple or paper clip separate parts of the proposal and please do not staple the entire proposal. Print the material on one side of the paper only.

2. Type of proposal

Exempt proposals. Many psychology proposals are in the Exempt category. Exempt research involves a) educational tests, surveys, or interviews, or observing public behavior and b) data recorded so that individual participants cannot be identified. For Exempt projects, no consent form is needed. Participants do need to be given the information they need to make an informed decision to participate in the research. This is often an information sheet and this is part of the IRB proposal. This means that participants need not be given a copy of a consent form and researchers need not store signed consent forms for the required three years after a project is complete. Project renewals are also simpler with Exempt proposals.

Research involving people under the age of 18 almost always moves a project to an Expedited proposal. The exception to this is that university students under the age of 18 can be part of the department's participant pool.

Expedited proposals. Sometimes the identification of the individual participants cannot be avoided. Other features of research may require an Expedited proposal. Research involving children is almost always in the Expedited category and requires review by two IRB members, arranged by the primary reviewer.

Full Board proposals. Some proposals must be reviewed by the Full Board (the complete IRB committee). These proposals might involve special populations (e.g., prisoners) or procedures involving significant risk (e.g., maximally intensive exercise). The Full Board meets from 3:00 to 5:00 on last Tuesday of each month.

3. IRB proposals follow a five-point template.

I. Rationale.

Include a clear statement of the problem, present knowledge related to the problem, and the aims of the proposed study. The rationale should be brief (usually a few paragraphs and usually no more than one single spaced page). Include references to the most salient background literature and include a reference section.

II. Subjects[1].

Describe the population of human subjects involved and how they will be recruited. For a variety of reasons, do consider research participants other than students. What follows has to do with the special situation of student research participants.

Department participant pool. If you plan to work with students in the Psychology Participant Pool, please say in your proposal that you *will follow standard procedures on file with the IRB.* Because understanding something about research is essential in psychology, students earn credit

[1] In psychology, we generally use the word "participant." In the guiding federal regulations, the word for people who participate in research is "subject." Whether or not people who participate in research are co-equal partners with investigators is an interesting issue. For IRB proposals, either word can be used except in the 5-point template.

in PSY 1300 for research participation. An alternative assignment which is equal in time and can contribute to understanding more about research is available to students in PSY 1300.

Under 18. We will always have a few students in the Psychology Participant Pool who are under 18. Minors have special protections. For Exempt or Expedited research – research with minimal risks – with students in the Participant Pool, include a *Waiver or Alteration of the Elements of Consent* form in your IRB proposal, available in the IRB web material. In your proposal, include the following statement:

> Because a small number of student volunteers may not be of age to give legal consent, a waiver of the requirement to obtain informed written consent is requested for these participants only. Except that the signature of such subjects will not constitute legal consent, the consent process will be exactly the same as for all other subjects. Thus, the rights and welfare of these subjects will not be affected. Because of the difficulty of verifying age and obtaining parental consent, the research could not practically be carried out without the waiver.

When students from the Psychology Participant Pool are research participants, it is very helpful to provide debriefing information, perhaps in the form of a debriefing hand-out, that tells students what the research was about in a way that connects the information to the material they are learning in Psychology 1300.

If you might want to recruit participants from classes other than PSY 1300, you can include this option in your IRB proposal. Students in other classes can volunteer. If any kind of credit is given, there must be an alternative way to earn the credit. You do not need to explain the equivalent alternative but you do need to say that an alternative with approximately the same effort, time, and benefit will be available.

Class time cannot be used for research unless the experience is directly related to the work of the class.

At TTU, a post in TechAnnounce can be very helpful for recruiting participants.

Information for participants. Even without a consent form, participants still need information about the research so they can make an informed decision about whether to participate. Do include a consent conversation script or information sheet for participants with your IRB proposal if there is no formal consent form. (Consent forms are described below.)

III. Procedures

Describe all procedures involving the participants. Identify any risks beyond those of everyday life. If there are no risks beyond those of everyday life, say this clearly. If there are potential risks, say so. Include any precautions you will take to minimize risks. Describe any benefits to the participants.

IV. Adverse events and liability

Very few projects in psychology have more than minimal risks. Asking people about their lives, history, or feelings, for example, does not create risks. There is an annotated bibliography about research on reactions to research participation in studies of sensitive on the IRB web site:

http://www.depts.ttu.edu/vpr/irb/downloads/Reactions-to-Research-Participation.pdf

If there are no more than minimal risks beyond those of everyday life there will be no liability plan and you will simply say:

Since there are no risks beyond those of everyday life, no liability plan is offered.

If there are more than minimal risks beyond those of everyday life, explain how you will deal with unexpected adverse events and how you will handle liability for potential problems. If a research project involves liability issues, Risk Management may need to be consulted.

V. Consent form.

If your project does need a consent form, write simply and clearly so that participants can understand the information. For college students, a Flesch-Kincaid grade level of 8 or lower is recommended. The number is in Microsoft Word's Spell Check. If consent forms are difficult to understand, participants simply do not read the material and thus lose some of the benefits of the process. Headings make a consent form easier to read. The consent forms need to be written in the second person ("You" form). For example, a sentence might begin, "You will …" This way of writing consent forms is mandated by federal regulations.

The very last line of the consent form – below the signature line – must be: "This consent form is not valid after (expiration date)." The expiration date is one year from the last day of the month before the IRB proposal is approved (e.g., a proposal approved on July 18, 2013 will expire on June 30, 2014).

An example of a very simple consent form that meets federal regulations is available on the IRB web site and a copy is attached here (Appendix B, page 6).

Attachments to your proposal

- *Waiver of the Elements of Consent form* for Exempt proposals with undergraduate students. The element being waived is parental consent. This form is also used when the research involves deception.
- *Waiver of Consent form* for Expedited proposals where there will be no written consent (e.g., some on-line projects).
- *Other materials:* Include copies of recruiting materials questionnaires, interview protocols, a copy of any grant proposal related to the IRB proposal and any other relevant materials. Please put the attachments in the order in which they will be used (e.g., a recruiting flyer, then a consent form, then the interview protocol, then the measures, then a debriefing sheet).

Appendix A
Checklist for IRB consent forms and information sheets

This checklist is included for your convenience. It is not part of your proposal but may be helpful. Research that involves potential risks often requires additional statements and these can be found in the IRB materials available on-line.

√	Element
	A statement that the study involves research
	A statement of who is responsible for the research including the name and phone number of the Principal Investigator
	An explanation of the purpose of the research
	A description of the procedures to be followed
	The expected duration of the subject's participation
	A description of any reasonably foreseeable risks or discomforts to the subject. If there are no such risks or discomforts, the consent form should so state
	A description of any benefits to the subject or to others which may be reasonably expected from the research. If there are no such benefits, the consent form say so.
	A statement describing the extent to which confidentiality of records identifying the subject will be maintained
	A statement that says in this or in similar language, "You do not have to be in this research. You can leave any time you wish. You can keep all the benefits you have earned even if you stop."
	The following statement about subjects' rights: "This study is being run by Dr. (name) from the Department of (name) at Texas Tech University. If you have questions, you can call her at (phone number). TTU also has a Board that protects the rights of people who participate in research. You can call 806-742-2064 to ask them questions. You can also write them at the Human Research Protection Program, Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409."
	A statement about the expiration date of the project's approval: "This consent form is not valid after (expiration date)." The expiration date is the anniversary of last day of the month preceding the approval. The letter informing the investigator of the approval of a proposal specifies the date of expiration.

Appendix B

Consent Form Example

Please share your thoughts in our research project.

What is this project studying?
The study is called "Thinking about things in college." This study will help us learn how students' thinking relates to their lives. What we learn may help people, and we hope to publish this study widely to make it as beneficial as possible.

What would I do if I participate?
In this study, you will be asked to complete surveys. Some questions will be about you. Some questions will be about your thoughts. Some will be about how you feel and what you do.

Can I quit if I become uncomfortable?
Yes, absolutely. Dr. Researcher and the Protection Board have reviewed the questions and think you can answer them comfortably. However, you can stop answering the questions at any time. You can leave any time you wish. You will keep all the benefits of participating even if you stop. Participating is your choice.

How long will participation take?
We are asking for 45 minutes of your time.

How are you protecting privacy?
The questionnaires will not request any personal information to protect your privacy.

I have some questions about this study. Who can I ask?

- The study is being run by Dr. Researcher from the Department of Phrenology at Texas Tech University. If you have questions, you can call her at 806-742-XXX #XXX.
- TTU also has a Board that protects the rights of people who participate in research. You can ask them questions at 806-742-2064. You can also mail them at Institutional Review Board for the Protection of Human Subjects, Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409.

How will I benefit from participating?
You will learn something about research. You will get credit for a class requirement. You will receive half a credit for each 30 minutes you spend participating.

_____ _____

Signature Date

_____

Printed Name

This consent form is not valid after Month/Date/Year.