

AUSTIN PEAY STATE UNIVERSITY
APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

Please read the entire application before completing.

TITLE OF PROJECT:

TITLE ON CONSENT FORM (If different than above):

FUNDING SOURCE:

PRINCIPAL INVESTIGATOR

Name: _____ I have completed CITI Training

Status: Faculty _____ Staff _____ Graduate Student _____ Undergraduate Student _____

Department: _____ Phone: _____

Mailing Address: _____

Email Address: _____

FACULTY SUPERVISOR

Name: _____ Department: _____

Mailing Address: _____

Phone: _____ Phone: _____

All of the questions below should be answered using lay language. The IRB is comprised of individuals from diverse scientific and nonscientific backgrounds. You should avoid all jargon and assume that IRB members have no prior knowledge on the research topic, theoretical or methodological approaches, or measurement techniques or instruments. The best way to avoid unnecessary delays is to provide the IRB with as much information about your study as possible. **You will need to attach a copy of all demographic forms, survey instruments, and other data collection systems.** If you are unable to attach the above please contact the College of Graduate Studies for advice. It is important to remember that informed consent is a process not a document. Informed consent begins with recruitment and ends only after a study is completed.

1. **Describe the purpose of this study.** Be sure to clearly indicate the research question being asked.
2. **Briefly describe the research that has already been conducted in this area.** The IRB needs to understand how this study adds to the knowledge on this topic in order to be able to judge the risks and benefits to participants.
3. **Describe the population from which your research sample will be drawn.** Be sure to indicate if subjects are from a vulnerable population such as infants, children, pregnant women, mentally disabled persons, prisoners, employees, students, economically or educationally challenged persons etc... What additional safeguards will be included to protect the rights and welfare of these participants
4. **Explain the inclusion and exclusion criteria that will be used (e.g., age, race, gender, language, academic abilities, academic major, pre-existing conditions, etc...).**
5. **Indicate how many potential participants will be approached.** The APSU IRB needs to know the maximum number that might be asked to participate, NOT the minimum number needed to adequately ask the research question. It is recommended that you choose a number higher than you expect to need because once the number is approved you will need to apply to the IRB for permission to recruit additional participants. Do not choose an unnecessarily large number however, because sample size may affect the risk/benefit ratio decision that the IRB must make. Please break down your maximum numbers by category (e.g., child, adult, male, female, depressed, non depressed etc...) such that the board can evaluate the risks for different types of participants.
6. **Describe how participants will be identified, approached, recruited and consented.** Who will make the first contact and when and where will it occur. All materials used to recruit participants need to be submitted for review (e.g., media advertisements, brochures, email, poster/signs or sign-up sheets, etc...). If verbal announcements will be made for recruitment purposes please provide a script of how the study will be described or a list of the points that will be made.
7. **Specifically identify all individuals who will describe the study to potential participants. Also, specifically identify all individuals who will obtain consent from potential participants.** Do these individual(s) have a dual relationship with potential participants (e.g., instructor, mentor, employer, caregiver, etc...) that might create the potential for the perception or actual existence

of coercion or undue influence? What procedures will you put in place to reduce or eliminate potential/perceived coercive situations?

- 8. Describe your research procedures.** We need to know all of the procedures that will occur, but in particular we need a description of what the participants will experience. For example, a description of the instructions that will be given to them, activities in which they will engage, the length and timing of involvement, and the circumstances under which they will provide data (i.e., group assessments, one-on-one interview, videotaping, audio taping, phone calls, spending time in an uncomfortable position, etc...).
- 9. If this study involves deception, describe and justify its use.** Deception will require that subjects be debriefed following data collection. The purposes of the debriefing are to explain the true purpose of the study, reduce any negative consequences participants may experience from participation and to provide a clear, easy opportunity for withdrawal of consent. You must include a copy of the debriefing statement in your application.
- 10. Describe any form of compensation that participants will receive (e.g., money, extra credit, toys, food, etc...).** If so, please describe amount, type, when they will receive it. If withdrawal from the study will change the amount or type of compensation please describe how (i.e., prorated, elimination, etc...). Note that academic extra credit can only be awarded at the discretion of the instructor, not the principal investigator.
- 11. Explain if this research might entail psychological, legal, physical, or social harm or discomfort to the subjects.** What steps have been taken to minimize these risks? What provisions have been made to insure that appropriate facilities and professional attention necessary for the health and safety of the subjects are available and will be utilized? How will the participants be informed of these procedures? If an information sheet describing these resources will be provided to participants, please submit. If university or community professionals agree to provide their services, please submit a letter of cooperation from the individuals/agencies that describes the agreement.
- 12. Describe how the potential benefits of this activity to the participants and humankind outweigh any possible risks.** This opinion is justified for the following reasons:
- 13. Describe how the confidentiality of data about participants will be protected.** What steps and procedures will be used? How (hard copy, electronic, etc...) and where (e.g., locked file cabinet in PIs campus office) will data be stored? If data will be destroyed please indicate when and how.
- 14. If data will be anonymous, explain how this anonymity will be achieved.** Note that anonymity requires that at no time can the data be connected to the participant by anyone involved in the research, even the PI. If data will be anonymous, explain how and where the consent document will be stored.
- 15. Explain how any data collected relate to illegal activities.**

16. Please indicate by marking Yes or No whether the attached informed consent document includes each of the following elements as required by the Code of Federal Regulations: Title 45, Part 46.116.

- Yes or No** A statement that the study involves research,
- Yes or No** An explanation of the duration of the subjects participation,
- Yes or No** A description of the procedures to be used;
- Yes or No** A description of any reasonably foreseeable risks or discomforts to the subject;
- Yes or No** A description of any benefits to the subject or others which can be reasonably expected from the research; *(Note: compensation is not a benefit)*
- Yes or No** A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- Yes or No** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject; *(Note: should include APSU IRB, PI and if applicable, students' faculty sponsor)*
- Yes or No** A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. *(Note: this statement should be written in language at an appropriate level for the subjects in your study)*

The following may or may not apply to your study. Please carefully read and mark each one Yes or No.

- Yes or No** An explanation of whom to contact in the event of a research related injury to the subject;
- Yes or No** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- Yes or No** For research involving more than minimal risk, and explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- Yes or no** A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;
- Yes or No** Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

Yes or No Any additional costs to the subject that may result from participation in the research;
(Note: This is not limited to monetary costs)

Yes or No The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

Yes or No A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

_____ The approximate number of subjects in the study

17. If your study includes children please provide the committee with information about how you will obtain the child's assent to participate. Children older than 12 are expected to be provided the opportunity to sign to indicate their assent to participate. Children 7-12 should be provided with a written document, which may or may not also be read. Depending on the research to be conducted children 6 years and younger may be read an assent script (please submit). In addition to your procedures to obtain assent, please indicate what dissent behaviors will lead you to decide a child is not providing or has withdrawn his/her assent to participate. Note: child assent can be solicited only after parental consent has been obtained.

18. If you are requesting a waiver of the documentation of informed consent please explain how you would meet the requirements of 45 CFR 46.117.

I have read the Austin Peay State University Policies and Procedure on Human Research (00:002) and Research Misconduct (99:013) and agree to abide by them. I also agree to report to the Austin Peay Institutional Review Board any unexpected events related to this study. I also agree to receive approval before implementing any changes in this study.

Signature

Date

Faculty Supervisor's Signature

Date

EXAMPLE
INFORMED CONSENT STATEMENT

Title of Project

INTRODUCTION

The Department of _____ at Austin Peay State University supports the practice of protection for human subjects participating in research. The following information is provided to help you decide whether you wish to participate in the present study. You retain the right to refuse to sign this form and not participate in this study. You should be aware that even if you consent to participate in this study, you may withdraw from this study at any time without consequence. If you choose to withdraw from this study, it will not affect your relationship with this department, the services it may provide to you, or Austin Peay State University.

PURPOSE

The purpose of this study is to

PROCEDURES

You will be asked to The approximate time required for completion is. . . .

RISKS

(Describe possible risks)

BENEFITS

(Describe possible benefits of participating)

COMPENSATION

(Describe any compensation that will be provided by participating)

PARTICIPANT CONFIDENTIALITY

(Describe how confidentiality will be maintained)

REFUSAL TO SIGN CONSENT

You are not required to sign this Consent form and you may refuse to do so without affecting your right to participate in any programs or events of Austin Peay State University or any services you are receiving or may receive from Austin Peay State University. However, if you refuse to sign, you cannot participate in this study.

CANCELLING THIS CONSENT

You may withdraw your consent to participate in this study at any time. If you choose to withdraw from the study before data collection is completed, any collected data will be destroyed and not used.

QUESTIONS ABOUT PARTICIPATION

If you have any questions about the procedures, you may direct them to the principal investigator, (Investigator's name)

CONSENT

I have read the above information and received a copy of this form. I have had the opportunity to ask questions regarding my participation in this study. I agree to take part in this study as a research participant.

By my signature I affirm that I am at least 18 years old and a student at Austin Peay State University.

Print Participant's Name Date

Participant's Signature Date

RESEARCHER CONTACT INFORMATION

(Provide contact information for principal investigator and faculty advisor if student research)

IRB Contact Information

Dr. Doris Davenport, Chair

davenportd@apsu.edu

(931) 221-7467

P.O. Box 4658