

**The University of Tulsa
Institutional Review Board
Procedures for Application
Approval of Use of Human Subjects in Research**

Your application for approval of the use of human subjects should consist of the following:

1. Completed application
2. Description of the study
3. Informed consent form
4. Copies of any questionnaires, test instruments, letters of approval from cooperating institutions and/or organizations

Complete proposals should be submitted to:

Carmen Schaar-Walden
Coordinator of Research Compliance
Office of Research and Sponsored Programs
800 S. Tucker Drive
McClure Hall, Room 205
Tulsa, OK 74104
918-631-3310
carmen-schaar-walden@utulsa.edu

Please allow one week to ten days for review of exempt and/or expedited protocols. Protocols that must go full Board must be submitted by the 1st of the month in which you want the protocol reviewed.

Description of the study:

To assist Institutional Review Board members in conducting their review of your application, please prepare a brief description of the study you plan to conduct, including the following information (please number pages):

- A. Purpose/Objectives
Explain the overall purpose of your study and its primary objectives, including the importance of the knowledge expected to result.
- B. Research Protocol
Describe the study and procedures you will use, including a step-by-step description of the procedures you plan to use with your subjects.
- C. Confidentiality
Briefly describe the procedures you will use to assure confidentiality of the data you collect from your subjects, specifically address whether subjects will be identifiable from raw and/or refined data, how data will be protected from non-project personnel (e.g., stored in locked cabinets), whether the identifiable data will be destroyed when no longer needed, and whether project publications (theses, papers, videotapes, etc.) will allow identification of individual subjects.

If the research is being conducted electronically (on the web, disks, files, etc.), please address how confidentiality will be maintained/handled.

- D. **Subject Benefit/Risk**
Describe both the potential benefits and risks to subjects and society that may result from their participation in this project.
- E. **Application Form**
If the answer to any questions on the Application Form is “yes”, please provide additional information and address any concerns that may exist.

Informed Consent Form:

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject and/or the subject's legally authorized representative. Two copies of the Informed Consent Form should be provided, one for the subject to retain for his/her records and the signed form that is returned to the researcher.

A consent form must be written in **lay language**, easily comprehensible to the person who is being asked to sign it as a legal indication of voluntary participation in the proposed study and every effort should be made to limit the consent form to one page including space for the participant's signature. No informed consent form may include any language through which the subject or the subject's representative is made to waive or appear to waive any of the subject's legal rights, or which releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence. The following outline summarizes the minimum information that must be included in a consent form. Additional elements of informed consent may be requested or required by the Institutional Review Board where appropriate, depending upon the special circumstances of a particular research protocol.

1. **HEADING**
The form should be clearly titled Informed Consent Form for research being conducted under the auspices of The University of Tulsa.
2. **INTRODUCTION**
Begin with a statement that identifies the study by title, sponsor (if any), and principal investigator. Indicate that the document is an individual's consent for participation in that research project.
3. **DESCRIPTION OF THE STUDY**
Describe the purposes of the research in language that is appropriate considering the age, educational level, etc. of the subject pool. Provide a straightforward, easily understandable description of the procedures to be followed in the study; identifying any procedures that are experimental. Specify the amount of time required for the subject's participation.
4. **POTENTIAL RISKS AND BENEFITS OF PARTICIPATION**
 - a. **Risks**
Identify any reasonably foreseeable risks or discomforts to the subject as a result of participation in the study, and describe measures that will be taken to minimize any risk or discomfort. If no

foreseeable risks beyond those present in normal everyday life are anticipated, a statement to that effect should be included.

b. Benefits

Describe any benefits to the subject or to others that may reasonably be expected from the research, including therapeutic benefits, new knowledge that leads to improved conditions, payment for participation in the study, etc.

5. SUBJECT'S ASSURANCES

a. Conditions of Participation

Include a statement that the subject's 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.

For studies involving only adults, include a statement such as: *To participate, you must be 18 years of age or older.* For studies involving minor children, a parental consent form must be included in addition to the participant's assent form.

b. Confidentiality

Include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Avoid use of the term anonymous if there is any reasonable possibility that subject's identities can be established. If the research is anonymous (i.e., a survey returned in pre-addressed postage paid envelope with no way of identifying the participant), a cover letter which clearly addresses all the components of informed consent may be substituted for a signed consent form. In the case of a telephone survey, a script clearly addressing all the components of informed consent should be submitted for review.

c. Compensation for Injury

For research involving more than minimal risk, explain whether or not any compensation or medical treatment is available if injury occurs. If compensation or treatment will be provided, describe the nature of the compensation and/or treatment. If no compensation will be available, make that clear in the consent form. Explain how the subject can obtain additional information if necessary.

d. Course Credit/Compensation for Participation

If the subject is to receive course credit/compensation for participation, state clearly the amount of credit/compensation to be received and what level of participation is required to receive credit/compensation. Include the statement: *If I am participating in this research project to obtain course credit and I decide to withdraw from participating, I might not get the course credit associated with the research project.*

e. Video/Audio Taping of any Research Activities

If any activities are to be audio/video taped, state such. Include statements regarding the subject's right to refuse to allow such taping without penalty or prejudice.

6. **Contacts for Questions about Research Subject's Rights**
Include a statement identifying by name and phone number of the person whom the subject may contact with questions about the research. A statement directing inquires about rights, as a research participant to be made to the Office of Research and Sponsored Programs, Carmen Schaar-Walden, 918-631-3310 (or carmen-schaar-walden@utulsa.edu) is a required component of informed consent.

7. **Signatures/dates**
Include the statement: *I hereby agree to participate in the above-described research. I understand my participation is voluntary and that I may withdraw at any time without penalty or loss of benefits.*

Informed consent must be documented by the signature of the subject on subject's informed consent form. When necessary, a separate form also should be provided for the subject's legally authorized representative or guardian. A space to indicate the date signed should be included on all informed consent documents.

A copy of all instruments to be used in the study should be attached to the application form and the description of the study.

If you have any questions, please contact Carmen Schaar-Walden, Coordinator of Research Compliance, Office of Research and Sponsored Programs, The University of Tulsa, 918-631-3310 or via e-mail at carmen-schaar-walden@utulsa.edu .