Use of Human Subjects in Research

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General Description

Purpose:

USE OF HUMAN SUBJECTS IN RESEARCH

When a research project involves human subjects and also involves the use of federal grant funds, it is subject to policies described primarily in the Code of Federal Regulations, 45 CFR 46, entitled “Protection of Human Subjects.” The policy of Trinity University is to comply with these regulations in all cases of research involving human subjects. These regulations provide for the creation of a human subjects review committee known as the “Institutional Review Board” (IRB).

Considerations
Trinity University has established the IRB in order to consider research protocols that involve human subjects and to approve, disapprove, or require modifications in such research. In its review,the IRB ensures that risks to subjects are minimized and that these risks are reasonable in relation to anticipated benefits. It also ensures that selection of subjects is equitable and not coercive and that informed consent will be sought and documented from each prospective subject. It also ensures that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

I. INSTITUTIONAL REVIEW BOARD PROCEDURES

A. Types of Research that Need IRB Approval

In general, any research conducted by faculty, staff, or students that involves living human beings is subject to IRB review. Research involving survey or interview procedures or involving observation of human behavior should be submitted for IRB review. Even though 45 CFR 46 exempts some research of this type, Trinity University policy requires its submission to the IRB. Notable exceptions are:

1. Research conducted in educational settings involving normal educational practices such as research on regular and special educational strategies or research on the effectiveness of or the comparisons among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
3. Research involving existing data or records or human artifacts if they are publicly available or are used in such a manner that subjects cannot be identified.

B. Information that Should Be Submitted to the IRB

An investigator should always feel free to make an informal inquiry to the chair of the IRB. Persons submitting research for review should supply information that will allow the IRB to weigh those considerations described above.

Proposals should be submitted to the Chair of the IRB through the IRB website. All proposals must be submitted with a title and a completion date.

When proposals are being submitted as part of an academic course, if multiple projects are proposed, it is preferred that proposals be submitted in batches to the Chair of the IRB, by the course instructor, and after his/her review of the proposals.

“Risk” should be interpreted in a broad sense to mean not just physical risk but also legal, psychological, social, and economic risk. Discomfort, pain, and embarrassment should be minimized and justifiable in terms of anticipated benefit(s). (“Minimal risk” is quite explicitly defined in 45 CFR46. Designating a project “minimal risk” does not diminish the responsibilities of either the IRB or the investigators, nor does it eliminate the requirement for obtaining informed consent.)

If a survey, interview, or test is involved, the investigator should include a copy of the exact form that will be used. A description of the informed consent process and a copy of the consent form(s) must be submitted. Items submitted to the IRB will, in general, be kept in IRB files and will not be returned.

C. The Review Process

Research involving minimal risk and that is not exempt from review may receive an “expedited review” by the IRB Chair or by some other IRB member designated by the chair. Most of the human subjects research at Trinity University either is exempt or can be expedited, and the

expedited review process normally takes less than one week. Research involving more than minimal risk requires approval at a convened meeting of the IRB, and this process could involve a month or more.

Proposal authors should consider and plan for the IRB approval when scheduling the preparation of a proposal. If a meeting of the full board is needed, applicants are typically expected to attend that meeting.

It is expected that the applicant will simultaneously submit a copy of the request to the IRB and the chair or supervisor of the applicant's department, or appropriate supervisor in the case of a request from an administrative office. The chair or supervisor will inform the IRB and the applicant of any concerns they have about the proposal.

D. Monitoring of Projects

All projects approved by the IRB must be monitored. When the project has been completed, or at the end of the period in which a project has been approved (typically 12 months), investigators must inform the IRB (1) whether the project is continuing or terminating, and (2) whether or not there were any adverse effects experienced by participants in the study. If continuing, the project proposal must be resubmitted to the Chair of the IRB for further consideration for the next year.

E. Informed Consent

The main purpose of the informed consent process is to ensure that prospective research subjects are presented, in understandable language, the information that might influence the decision of giving or withholding consent to participate in the research project. Another qualification of the consent process is that the subject exercise free choice and not be subject to coercion or excessive inducement. Articles 46.116 and 46.117 of 45 CFR 46 contain descriptions of informed consent and its documentation, including conditions under which the process may be waived. For much of the research conducted at Trinity University, an appropriate informed consent process (and consent form) would include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subjects' participation, and a description of the procedures to be followed.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.
4. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
5. An explanation of whom to contact for answers to pertinent questions about the research and about research subjects' rights.

6. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
7. A statement that participants must be 18 years of age or older to participate in the study.

Other considerations in obtaining informed consent may be appropriate in certain cases; for example, when an experimental treatment is involved, when the true purpose of the research cannot be divulged to the participants, or when the research involves children or prisoners. The consent form may not include any language that releases, or appears to release, the investigator or his/her institution from liability, or that waives, or appears to waive, any of the subjects' legal rights.
A copy of the consent form should normally be given to the person signing the form.

F. IRB Membership: Duties of the Board and the Chair

The Trinity University Institutional Review Board consists of nine persons: five faculty, a representative from the administration, an undergraduate student, and two persons from the community with no other affiliation with Trinity University.

Members of the board are appointed by the Vice President for Academic Affairs and do not serve set terms. Once appointed, members remain on the board until removed by the Vice President.

The board elects one of its members to serve as Secretary to create minutes of IRB meetings.
At least once per semester, the Chair provides a written report to the board of his/her activities (exempted and expedited proposal decisions).

The Chair reviews all outcome reports submitted by investigators as part of the monitoring process, and brings any information about adverse outcomes back to the board as needed.
If the Chair is unavailable for more than two weeks, s/he may designate a member of the board to serve as Acting Chair for that period of time. Typically, the member serving as Acting Chair must have at least two years of experience on the board prior to this designation.
Archives of previous proposals and decisions will be maintained by the Office of Academic Affairs.

II. SAMPLE CONSENT FORM

We are seeking your participation in a research project involving a study of the burden borne by persons providing home care to victims of an immobilizing stroke. It is our understanding that you have provided the primary home care to a stroke victim, either a spouse, a parent, or a parent-in-law, for at least one year. This study will involve about forty persons who, like yourself, provide such care.

If you agree to participate, you will be interviewed about the care you provide to the stroke victim and about your feelings toward him or her. The interview will last about one hour. Your participation will not subject you to any physical risk or pain, but, because some of the interview questions are very personal, you may be subject to some stress or embarrassment. Your name will not be recorded on the interview sheets: an anonymous code will be used, and your replies will be known to at most two persons, the interviewer and Dr. _____, the director of this study. You may be assured that any reports of this research will contain only data of an anonymous or statistical nature: your name, or the name of the stroke victim, will not be used.

The goal of this research is to determine what burdens, physical and psychological, are borne by those who provide home care of immobilized stroke victims. It is hoped that stroke support groups and the medical community will be able to use our research to ease the burdens of persons such as yourself. We cannot promise that your participation in this study will be of any direct benefit to you. You may find some therapeutic value in discussing the problems you encounter in caring for the stroke victim. You will receive no monetary compensation for participating in this study.

We are planning a follow-up study to take place about one year from now, and you may be asked, at that time, to agree to another interview. However, giving your permission to participate in the present study in no way obligates you to participate in the follow-up study.Any questions you have regarding this research may be directed to the interviewer or to Dr. _____ at _____. Information involving the conduct and review of research involving humans can be obtained from the following member of the Trinity University Institutional Review Board: _____ at 999-____.
Your signature below indicates that you agree to participate in this research and further indicates that:

1. You have read and understand the information written above;
2. You understand that participation is voluntary and that refusal to participate will not penalize you in any way; and
3. You understand that you are free to withdraw from participation at any time without penalty.

III. AMENDMENT

The IRB is responsible for proposing any changes necessary to maintain compliance with federal law. Other changes may be proposed by any member of the academic faculty. All changes must be recommended by the IRB and approved by the Vice President for Academic Affairs.

Revision Management

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Vice President Approval:

Enter Vice President(s) that are responsible for approving this document

Name:	Title:
Deneese Jones	Vice President for Academic Affairs