

**UNIVERSITY OF ST. THOMAS
HUMAN SUBJECTS COMMITTEE**

Table of Contents

Pages	Contents
2-8	Protocol
9-10	Narrative
11-10	Cover Sheet
12	Expedited Review Checklist
13-14	Guidelines for Informed Consent
15	Continuing Review Form

UNIVERSITY OF ST. THOMAS
HUMAN SUBJECTS COMMITTEE
PROTOCOL

I. STATEMENT OF PURPOSE

- 1) The University of St. Thomas is dedicated to the pursuit of excellence in teaching, research and community service. Since “knowledge is meant to serve the human person, research in a Catholic university is always carried out with a concern for the *ethical* and *moral implications* both of its methods and its discoveries.” The University of St. Thomas accepts its responsibility towards human subjects of research and recognizes that subjects’ legal and ethical rights must not be infringed. As an academic community, we agree that “the cause of the human person will only be served if knowledge is joined to conscience.” (John Paul II, *Ex corde Ecclesiae*, “On Catholic Universities,” 1990 ¶ 18)
- 2) As members of the University community, we must honor institutional standards. As scholars and researchers, we must uphold the highest standards of professional freedom and responsibility. Scholarly research must be competent, demonstrate scientific integrity, promote the best interests of the University and society, as well as consider the safety, health, and welfare of every participant in the research project.
- 3) As members of the University community, we recognize the importance of academic freedom for teaching and research as set forth in UST's Handbook for Faculty and Administrators (9th ed.). The charge and role of the Human Subjects Committee is to review research proposals *in light of the protection of human subjects*.

II. STATEMENT OF PRINCIPLES

The University of St. Thomas affirms that the following principles should be interpreted in the light of *Ex corde Ecclesiae* and in the context provided by the code of medical and general ethics promulgated by the World Medical Association in the Declaration of Helsinki and by the American Psychological Association in the Ethical Principles in the Conduct of Research with Human Participants:

- 1) Since the participation of humans in research and training projects may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, projects carried out on-campus or off-campus, or between projects carried out by members of the University of St. Thomas community* or persons outside this community.

(*all full-time faculty and part-time faculty when they utilize University resources or affiliation with the University, or when they involve any member of the University in data collection; students, administrators and staff)

- 2) All activities involving humans as subjects must provide for the safety, health, and welfare of every individual. Rights, including the right to privacy, must not be infringed.

- 3) No harm should be done to anyone participating in a research project. All foreseeable risks to subjects should be reasonable in relation to the goods, if any, from which they are expected to benefit and the importance of the knowledge that can reasonably be expected to result.
- 4) Participation in projects must be voluntary, and informed consent must be obtained from all subjects unless this requirement is specifically waived by the Human Subjects Committee. If a subject is not legally capable of giving informed consent or is of questionable competence, a legally authorized representative may do so. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Parents may not expose their child to risk except for the child's benefit.
- 5) An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of normal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment.
- 6) Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the principal investigator. Such information shall not be communicated to others unless the following conditions are met:
 - explicit permission for the release of identifying data is given by the individual;
 - information about individuals may be discussed only for professional purposes and only with persons clearly concerned with the project;
 - written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid invasion of privacy; and
 - provisions must also be made for maintaining confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the Human Subjects Committee and carried out by the principal investigator until the records are destroyed. Records that contain private information shall be destroyed as soon as possible in keeping with the long-range goals of the project.
- 7) Investigators external to the University of St. Thomas who wish to petition review from the University of St. Thomas Human Subjects Committee must:
 - provide documentation of review and approval from their local institution's Human Subject Review process;
 - secure the research involvement of a collaborator from the University of St. Thomas faculty who will be locally responsible and accountable for the protection of human subjects; and
 - complete University of St. Thomas standard protocol forms and submit them for review to the Human Subject's Committee.
 - In the case of graduate student studies (for example, dissertations), the application to the University of St. Thomas Human Subjects Committee must include the written endorsement of the chair of the student's faculty committee, verifying the scientific merit of the proposed study.
 - In some cases the Human Subjects Committee may request additional documentation.
- 8) Projects will be given initial and continuing review by the Human Subjects Committee as set forth in these guidelines. All members of the University community involved in

investigation and training are responsible for continual monitoring to assure compliance of their research with these principles.

9) In all cases the investigator should show practical regard for the University of St. Thomas community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles could impugn the investigator's own name and the reputation of the University. The investigator does not abdicate ethical and legal responsibility merely by complying with these guidelines. When the investigator is a student, responsibility for the conduct of the research and the supervision of human subjects lies with the faculty sponsor. It is always the responsibility of the principal investigator to obtain clearance from the Human Subjects Committee prior to the initiation of any research activity involving the use of human subjects. Failure to obtain permission may endanger all federal funding as well as lead the University to limit further research or to terminate the principal investigator's contract.

10) Investigators must report any significant financial interest held by or for the benefit of the investigator, his or her spouse, or any dependent children that may reasonably appear to be affected by the proposed research. A "significant financial interest" is anything of monetary value, other than salary or remuneration received from the University of St. Thomas, or income from services provided to public or nonprofit entities.

III. MEMBERSHIP

1) The Human Subjects Committee shall consist of eight persons. Upon recommendation of the Committee, the President shall appoint members, usually for three-year overlapping terms. Members can be reappointed by the President for another term.

The Committee shall be composed of:

- one representative of the President, appointed from the administration (non-voting);
- one faculty member from the Cameron School of Business;
- one faculty member from the School of Education;
- one faculty member from the Dept. of Psychology;
- two faculty members from the School of Arts and Sciences;
- one member with a demonstrated expertise in ethics;
- one representative from the community at large.

2) The chair shall be selected from the voting members. A quorum consists of one more than half of the voting members.

IV. FUNCTIONS AND OPERATIONS

The Human Subjects Committee shall have the responsibility to review and the authority to approve, modify, or disapprove any scholarly research project or proposed changes in any research project carried out at the University of St. Thomas which involves human subjects. The Committee understands its responsibility as centered on the protection of human subjects in accordance with the standards recognized by this University.

- 1) All research projects involving the use of human subjects must be submitted to the Human Subjects Committee for approval. If it is unclear whether the proposed research involves human subjects, the principal investigator must seek assistance from the chair of the Committee. Applications shall be submitted to the Committee at least two weeks in advance of the meeting date. Application forms may be obtained from the Office of the Vice President for Academic Affairs. Additionally, the material is available on the UST file server. Copies of applications will be distributed to members of the Human Subjects Committee for review prior to the next scheduled meeting.
- 2) The Human Subjects Committee will meet during the fourth week of each month (September to April), with *ad hoc* meetings called by the chair as necessary. Its meeting schedule will be distributed to all faculty and administrators at the beginning of each semester.
- 3) No applicant involved in the conduct and/or supervision of the research project, who is also a member of the Human Subjects Committee, shall vote on its approval or disapproval. That member, however, may provide information to the Committee for its review.
- 4) A quorum of the membership, including at least one member whose primary expertise is in non-scientific areas, must be present at a meeting in order to conduct business. Decisions reached by the Committee shall then require a majority vote by members present. If the Human Subjects Committee agrees that the proposed research project protects human subjects in accordance with established standards, its decision shall constitute certification of approval. The chair of the Committee is responsible for sending a letter of approval to the investigator.
- 5) The Human Subjects Committee may elect to impose some additional restrictions or recommendations under which the project must be conducted. The principal investigator may be asked to meet with the Committee should it be apparent that clarification or modification in the application is required.
- 6) If the Human Subjects Committee disapproves the application, reasons for this decision will be provided in writing to the principal investigator. At the next scheduled meeting the principal investigator may submit any modifications in accord with the Committee's recommendations and/or request a personal hearing.
- 7) In the case of the Human Subject Committee's second disapproval, the principal investigator may then appeal to the President of the University. Upon the formal request of the principal investigator whose project has been disapproved, the President will conduct an independent review of the disapproved project by appointing an *ad hoc* committee. This committee will consist of three members: one chosen by the President, one chosen by the principal investigator and a third agreed upon by the first two. This review will not reverse the decision of the Human Subjects Committee; however, the results of this Committee's review shall be

made available to the Human Subjects Committee for its reconsideration of the disapproved project.

- 8) Any changes in the proposal or any unanticipated risks for the human subjects must be reported immediately to the Human Subjects Committee by the principal investigator. The amended proposal must then be approved by the Committee before the research may continue.
- 9) Committee approval of a proposal will be renewed annually, or sooner, contingent upon the level of risk involved. Projects may also be re-evaluated if subjects involved in the research lodge a complaint with the Human Subjects Committee. The President of the University, not the Human Subjects Committee, shall be responsible for reviewing any complaints and must report his/her decision to the Human Subjects Committee.
- 10) Each faculty investigator is responsible for submitting a copy of the Human Subjects Committee's letter of approval for any covered research in the portfolio compiled for Faculty Self-Evaluation. Department Chairs should refer any failure to comply with this requirement to the Dean as part of the Faculty Evaluation. Deans should refer cases of non-compliance to the VPAA, who may convene a committee to hear and recommend action. An appeal from the decision of this committee and the VPAA may be made to the President.

V. CRITERIA FOR APPROVAL OF RESEARCH

1) Informed Consent

Our common belief in the dignity of human persons and the need to guard against their abuse or exploitation lead us to insist that an investigator secure and document the voluntary, informed consent of every research participant. Indeed, no UST faculty member or student may conduct research without the legally effective informed consent of the subjects involved. If research involves children or those unable legally to provide informed consent for themselves, then the consent of the subject's legally authorized guardian must be obtained. Investigators must follow the *Guidelines for Informed Consent Documents*, which are included in the Human Subjects application materials. The implementation of informed consent, however, often runs into practical difficulties. *Insuring informed consent is the responsibility of investigators and involves an ethical mandate to inform potential subjects of what we are asking them to consider when we invite their participation.*

2) Confidentiality and Rights of Privacy

Adequate provisions to protect the privacy of subjects and to maintain the confidentiality/information of the data must be addressed in the research proposal submitted to the Human Subjects Committee for review.

3) Evaluation of Potential Risks.

The project will be evaluated to determine: 1) whether any harm will be done to anyone participating in the research; 2) whether the foreseeable risks to subjects are reasonable in relation to the goods, if any, from which they are expected to benefit and the importance of the knowledge which may reasonably be expected to result.

4) Expedited Review.

Applications which do not involve *vulnerable subjects*, have guaranteed adequate protection for *students and others in subordinate positions*, pose *minimal risk* to subjects, do not involve *deception of subjects*, do not have *identifying information* on the protocol, and present no *potential conflict-of interest* will be considered for expedited review. (See Human Subjects Application for further information.)

VI. RECORDS AND REPORTING

The University is responsible for preparing and maintaining adequate documentation of the Committee's activities, including the following:

- 1) Copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; annual review forms submitted by investigators; and reports of injuries to subjects.
- 2) Minutes of Human Subjects Committee meetings in sufficient detail to show attendance at the meetings; actions taken by the Committee; the vote on these actions, including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controversial issues and their resolution; dissenting reports and opinions; and non-participation by a Committee member in attendance with a conflict of interest in the project.
- 3) Records of continuing review activities.
- 4) Copies of all correspondence between the Human Subjects Committee and the investigators.
- 5) A list of Committee members identified by name; earned degrees; representative capacity; indications of experience, such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to Committee deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.
- 6) Copies of the Committee's written procedures. The records required by the regulation shall be retained by the Office of the Vice President for Academic Affairs for at least 3 years after completion of the research.

Expedited Review Procedures (rev. 2000)

Proposals that collect anonymous data, that do not use vulnerable participants, and that involve only minimal risk to participants are eligible for expedited review. Researchers would need to prepare a full proposal according to the guidelines. However, in expedited review, researchers can submit proposals at any time between August and May, and receive a review within 10 days (barring holiday conflicts).

1. The HSC chair will verify that the proposal is eligible for expedited review.

2. The chair will distribute the proposal to two other committee members, avoiding same-department conflicts (by 2nd day). The chair will pass the proposal to three other members if the proposal originated in the committee chair's department. The chair will rotate reviewer duties.
3. Expedited reviewers will respond within five days of receipt of the proposal as:
 - a. Approved without changes
 - b. Approved pending changes, with rationale based on HSC criteria
 - c. Not approved, with rationale based on HSC criteria
4. The chair will examine the reviews, and if they agree, pass on the verdict to the researcher. If the researchers disagree, the chair will share the comments and rationale of each reviewer to pursue consensus.
5. A telephone call and written notification will communicate the committee's decision.

UNIVERSITY OF ST. THOMAS
HUMAN SUBJECTS APPLICATION
NARRATIVE

1. Please give a brief (50 words or less), non-technical summary of the proposed research.
2. Please detail all procedures that relate to the participation of human subjects in your research.
 - a. How are subjects recruited? Are any inducements to participation offered?
 - b. What are the salient characteristics of the subjects: (e.g., number who will participate, age range, sex, institutional affiliation or other criteria.)
 - c. Are any of your participants: (Check all that apply.)
 - _____children
 - _____pregnant women
 - _____unborn children
 - _____prisoners
 - _____mentally disabled persons
 - _____economically or educationally disadvantaged persons
 - d. Are any of your participants students enrolled in your class or members of any other group over whom you exercise authority?
 - e. Describe what you will ask subjects to do as participants in this study and how long you will anticipate subjects will be involved in study activities. Describe any experimental manipulations you are employing and how subjects will be assigned to experimental conditions. How will the study be conducted? Will any observations, tests, be taken more than once?
 - f. Describe how permission has been obtained from any cooperating institution--- school, hospital, corporation, prison or other relevant organization. Is the permission of another Institutional Review Board Required? If so, how has this permission been obtained?
3. List any assistants who will be working with you. What experience with this kind of research do you and your assistants have?
4. Do subjects risk **any** harm by participating in the research? Are the risks necessary? What safeguards do you take to minimize the risks? Does your debriefing letter suggest remedies for any harm subjects may experience? The investigator is expected to consider the physical, psychological, moral and spiritual, legal and social dimensions of human life when making the risk-assessment.
5. How will participation in this research benefit subjects? If subjects will gain no direct benefits, explain how the importance of the knowledge gained through this research is commensurate with the risks to which the subjects are exposed. Do subjects receive any information about the research when they are `debriefed' or after the conclusion of the project?
6. Are subjects deliberately deceived in **any** way, that is, will their experience as research subjects be significantly different from what you have led them to expect? How will you explain this deception to subjects following their participation?

7. How are confidentiality and/or anonymity assured? Do you have identifying information on your protocol (e.g. name, male/female, ethnicity and age)? At what stage are identifiers removed from the data? If identifiers must be retained, please explain why.
8. How will the study materials and research data (written or otherwise recorded) be stored at the end of the study? Who will have access to them? To what uses—research, demonstration, public performance, archiving—might they be put in the future? How will subjects' permission for further use of their data be obtained?
9. How do you explain the research to subjects and obtain their informed consent to participate? If subjects are children, mentally disabled or otherwise not legally competent to consent to participation, how is their assent obtained and from whom is proxy consent obtained? How is it made clear to subjects that their participation is voluntary and that they can quit at any time? Is there a clear statement that no penalty will result from non-participation? Is there a clear statement concerning anonymity or the degree of confidentiality that a subject can expect?
10. List any significant financial interest held by or for the benefit of you, your spouse, or your dependent children that may reasonably appear to be affected by the proposed research. A "significant financial interest" is anything of monetary value, other than salary or other remuneration you receive from the University of St. Thomas, or income from services provided to public or nonprofit entities.

Append copies of all supporting materials: letters of recruitment or advertisement; letters seeking and obtaining permission from cooperating institutions or other IRBs; all study materials used with subjects, e.g. tests, surveys, copies of verbal or visual stimulus materials; all debriefing materials and communications to subjects about research results; documents relating to informed consent; documents relating to potential conflicts-of-interest.

Applications which do not involve vulnerable subjects (see 2c above), have guaranteed adequate protection for students and others in subordinate positions (see 2d above) pose minimal risk to subjects (see 4 above), do not involve deception of subjects (see 6 above), do not have identifying information on the protocol (see 7 above), and present no potential conflict-of interest (see 10 above) will be considered for expedited review. In addition, applications that have been approved by other Institutional Review Boards (IRBs) are eligible for expedited review.

All application materials: cover sheet, narrative and supporting documents which have been generated by investigators should be submitted on disk in Microsoft Word or Word Perfect. A single hard copy of any other materials, e.g. letters from cooperating institutions, is sufficient.

**UNIVERSITY OF ST. THOMAS
HUMAN SUBJECTS APPLICATION
COVER SHEET**

PRINCIPAL INVESTIGATOR(S) _____

DEPARTMENT _____

CAMPUS PHONE _____ E-MAIL _____

CO-INVESTIGATOR(S) _____

CAMPUS PHONE _____ E-MAIL _____

FACULTY SPONSOR'S NAME AND TELEPHONE NO. *(for student applicants)*

TITLE OF PROJECT _____

DURATION OF ENTIRE PROJECT APPROVAL REQUESTED (max. 1 yr.)
from _____ to _____ from _____ to _____

APPLICATION FOR EXTERNAL SUPPORT?
Name of Sponsor _____

Application Deadline _____

All scholarly research (that which is aimed at presentation or publication) involving human subjects carried out by faculty, administrators, staff, or students affiliated with the University--- whether conducted on campus or elsewhere---must be reviewed and approved by the Human Subjects Committee. This policy applies to both funded and non-funded research activities. Any research involving Human Subjects performed without the review and approval of the Human Subjects Committee gravely violates UST's explicit policy and ethical standards. Such a breach of conduct places the investigator in serious jeopardy and could be considered sufficient cause for dismissal from the University.*

*all full-time faculty and part-time faculty when they utilize University resources or affiliation with the University, or when they involve any member of the University in data collection

**UNIVERSITY OF ST. THOMAS
HUMAN SUBJECTS COMMITTEE**

Expedited Review Checklist

Your research is eligible for expedited review if it involves only minimal risk to participants. "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102).

More than minimal risk describes research that includes vulnerable participants, sensitive research topics, or intrusive methods. Vulnerable participants include children (under 18) and prisoners, fetuses, and pregnant women; some institutionalized groups without the ability to make uncompromised decisions about consent also are considered vulnerable. Sensitive research topics include any information about illegal activities or other topics whose disclosure would harm a participant's reputation; examples include: sexual topics (attitudes, behavior, or preferences); drug or alcohol use; illegal behavior; or information pertaining to an individual's mental health.

Answer Yes or No to the following questions.

1. ____ Do you have identifying information on your protocol?

2. Are your participants:
____ children (under 18 years old)?
____ fetuses?
____ institutionalized?
____ pregnant women?
____ prisoners?

3. Is your research about:
____ sexual topics (attitudes, behavior, or preferences)?
____ drug or alcohol use?
____ illegal behavior?
____ participants' mental health?

4. Do your methods pose any risk for participants?
____ Are participants asked to ingest any nonfood substance?
____ Are measurement methods risky (e.g., draw blood)?

If you answered No to all of the above questions, your proposal is eligible for expedited review by University of St. Thomas' Human Subjects Committee. Submit two copies of your proposal (one on paper and one on disk) to the chair of the committee; review should be completed within 7-10 days.

HUMAN SUBJECTS APPLICATION
GUIDELINES FOR INFORMED CONSENT DOCUMENTS

A. *If in your study*

- 1) **no** subject-identifying information is attached to the study materials (i.e., subjects do not give their names and cannot be identified);
- 2) **no** vulnerable subjects are participants (see Application 2c);
- 3) **no** participant is exposed to more than minimal risk (see Application 4);
- 4) **no** procedures are involved for which written consent is normally required outside the research context;

then the informed consent may be adequately communicated to potential subjects in a letter of information and oral exchanges between investigators and potential subjects.

- B. *If **any** of conditions 1-4 is not met, then a written and signed consent document is essential. In the case of vulnerable participants, consent may have to be obtained from the legally authorized representative of the subject, e.g. where children are involved, parental consent must be obtained, in addition to the assent of the child.*

The consent process has three elements:

A. *Information.*

Letters of Information shall contain:

- 1) A statement that the project is a research one and an explanation of its scope, aims and purposes.
- 2) A statement regarding the amount of time a subject will have to spend in order to participate and a description of the research procedures.
- 3) A description of any reasonably foreseeable risks or discomforts subjects may incur and actions taken to minimize such risks.
- 4) A statement regarding any payment or reimbursement for expenses. If there is more than minimal risk, a statement as to whether any compensation and/or medical treatment is available if injury occurs.
- 5) A statement describing the potential benefits to subjects or others.
- 6) A statement of what incentive (e.g., extra course credit), if any, is available to subject and information regarding any alternative means of obtaining the incentive.
- 7) A statement describing the extent to which confidentiality of records identifying the subject will be maintained or whether subjects will be anonymous. This should include, where applicable, information concerning the storage and disposition of any recordings.

- 8) A statement that participation is voluntary and that a subject may discontinue participation at any time. Non-participation will not result in penalty or loss of benefits to which the subject is otherwise entitled.
- 9) An offer to answer any questions, which should include the principal investigator's name, phone number and mailing address; the faculty sponsor's name and phone number if the investigator is a student; the name of any sponsoring or funding source.
- 10) A statement that a copy of the informed consent form must be given to subjects or their legally authorized representative.
- 11) Where applicable, a statement that the investigator has "Right to Publish" research results should be included.
- 12) The following statement must be placed at the end of ALL consent documents immediately after the signature lines. "THIS RESEARCH STUDY HAS BEEN REVIEWED AND APPROVED BY THE HUMAN SUBJECTS COMMITTEE AT THE UNIVERSITY OF ST. THOMAS. For additional information concerning your rights as a human subject please contact Dr. Kurt Geisinger, Vice President of Academic Affairs, (713) 525-2164."

B. *Comprehension.*

Information given to the subject must be stated in simple, easily understood language. While there is always a moral and professional obligation to ascertain that information is complete and adequately comprehended by a subject, this obligation increases when **any** of the above conditions (1-4) obtains. Special provisions may need to be made to insure comprehension, particularly where there is significant risk or where a subject is immature, mentally disabled or incompetent.

C. *Voluntariness.*

Principal investigators must provide opportunities for the potential subject freely to consider whether or not to participate. Particular attention should be paid to minimizing the possibility of coercion. Therefore, subjects must be informed that participation is voluntary and that choosing not to participate will result in no cost or negative consequences to the individual. Nor should any undue influence in the form of an offer of an excessive, unwarranted or inappropriate reward be used in order to obtain participation. On this account, the investigator has the responsibility to avoid:

- utilizing UST instructional (class) time for data collection;
- mandating participation of a research subject as a requirement for a course; and
- maintaining dual relationships with subjects. Individuals employed by the researcher may not be asked during work time to participate in a study as a subject. If extra credit is afforded potential subjects to encourage participation, options commensurate in time and involvement must be provided so that research participation is not the only extra credit option available.

University of St. Thomas
Human Subjects Committee
Continuing Review Form

This material is due by _____, and should be returned to the Chair of the University of St. Thomas Human Subjects Committee (UST-HSC).

UST-HSC approval of this project will expire on the date listed above. This form must be completed by (a) those wishing to extend data collection for another 12 months, and (b) those whose research is inactive or has been terminated/completed.

Please discuss the following, using continuation sheets as necessary.

1. Request extension of data collection until _____. Yes No
If No, provide date of completion/termination. _____
If Yes, provide reason for requesting continuation until _____.

2. Changes have been made in study design, subject population, consent materials, or study instruments during the past approval period. Yes No

If yes, list any changes and explain why such changes were made. Include the date of UST-HSC approval of the changes.

3. Please enclose a summary of your experience with the study with regard to human subjects. You must explicate any difficulties encountered by subjects who may have experienced harm or risk in relation to your research. Also explain how you attempted to ameliorate these difficulties, without using subjects' names.

Signatures:

Principal Investigator

Faculty Sponsor, if student PI

Date: _____