

8.6 ATTACHMENT B

(Approved by the Academic Policy Committee 1/17/2012)

St. Thomas University Institutional Review Board Policy

The Office of the Provost is responsible for oversight of the St. Thomas University Institutional Review Board (IRB) for protection of human participants in research. The Provost appoints the Chairperson of the IRB, who is responsible to oversee appointment/election and training of the chairperson and membership of the committee. Committee members are required to undergo training as specified by the Federal Office of Human Research Protection (OHRP). The administrator of the IRB will ensure compliance with registration and Federal Wide Assurance of the St. Thomas University IRB with U.S. Dept. of Health and Human Services

I. The Responsibility of Researchers

Any member of the faculty, staff, or student body at St. Thomas University who is involved in research with human participants has the responsibility to become familiar with and follow University policy regarding the use of human participants in research. This policy applies to all research involving human participants conducted by, or under the auspices of, faculty, staff, or students at St. Thomas University, or individuals/organizations conducting research using facilities, faculty, staff or students of St. Thomas University, unless such research is exempt from review as listed in section III.C. below. At St. Thomas University, research with human participants will be classified as falling into one of three categories:

1. Research Exempt from Institutional Review Board (IRB) Review
2. Research only requiring an Expedited IRB Review
3. Research requiring Standard IRB Review, including proposals involving research with human participants submitted for external agency/organization funding.

(Criteria for each of these categories are explained in section III below.)

- Research proposals that are submitted to an external agency/organization for funding should be submitted for a standard review by the Institutional Review Board, regardless of whether the research would normally qualify for exempt status or expedited review. Additionally, the procedures for protecting human participants stipulated by the funding agency shall be followed in the case of research supported by grants and contracts, but must also receive the approval of the IRB.
- Research to be conducted without external funding, which is not exempt from review according to the criteria listed in section III below, shall be reviewed by the IRB. It is recommended that research involving human participants which is exempt from IRB review be reviewed in consultation with someone other than the project investigators to confirm the project's exempt status and to insure that the welfare of the human participants is protected. IRB members are available to provide this consultation.

- The principal investigator, under whose guidance research is to be conducted, has primary responsibility for determining whether the participants will be exposed to risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (minimal risk). If that determination is affirmative, or if there is reason for uncertainty, or if the research involves any of the circumstances outlined in III.E. below, the investigator shall seek the advice of the IRB committee established for that purpose.
- The principal investigator shall explain to participants, prior to their participation, the objectives of the research, the procedures to be followed and the potential risks and benefits (i.e., informed consent). Investigators shall not use individuals as participants unless satisfied that they, and/or others legally responsible for their well being, consent to participation freely and with understanding of the consequences. The IRB may waive these requirements only when persuaded that the research cannot otherwise be done, that its potential value outweighs the risk to the participant, and that the waiver does not adversely affect the participant's rights and welfare.
- Investigators shall respect the privacy of participants. They shall protect confidential information given them, advising participants in advance of any reasonably foreseeable limits upon their ability to ensure that the information will remain confidential to the extent permitted by law.
- Participants shall not be induced to participate by means or in circumstances that might affect their ability to decide freely. This is of particular concern for faculty wishing to use current students as research participants. Faculty requiring student involvement as participants in research as a part of a course must provide, without penalty, alternate activities worth equal credit in which the students may engage, should they choose not to participate in the research activity.
- It shall be made clear to all participants that they are free to withdraw from active participation in the research at any time. Participants who indicate a desire to withdraw shall be allowed to do so promptly and without penalty or loss of benefits to which the subject is otherwise entitled.
- University faculty or staff who assign or supervise research conducted by students are responsible for ensuring that the students are qualified to safeguard adequately the well-being of the participants. Students who conduct research with human participants under the supervision of one or more faculty members or as a part of a course project or requirement, as well as all students conducting independent research are subject to the policies and procedures outlined in this document.

II. Institutional Review Board

- The Office of the Provost will annually designate a Chairperson of the Institutional Review Board (IRB) of research with human subjects at St. Thomas University. This committee, referred to as the IRB, shall be authorized to review and to approve or disapprove, or state conditions for, the conduct of any research involving human participants, in accordance with the policies stated herein, for the express purpose of protecting the welfare of the university, the researchers and research participants (see III. A. below). The purpose of the IRB

- is to assist researchers in the proper conduct of research projects by making suggestions to prevent any ethical/legal issues or harm. The IRB also serves as an institutional review body that will document that ethical standards are followed by faculty seeking external funding.
- The membership of the IRB shall be nominated by the chair with names forwarded to the Provost for consideration. The committee will be comprised of four faculty members, one student member, and the University Director of Institutional Research. The Director of Institutional Research will serve in an Ad Hoc, non-voting capacity only. The four faculty members will each be appointed for two-year terms. However, two of the four faculty members will each serve one-year terms during the first year of the Committee's activity. This will provide some measure of continuity as faculty members rotate on and off the IRB in subsequent years. One student (an undergraduate, a graduate, or a Law School student) will be selected each year for a one-year term to serve on the IRB in a voting capacity. Under appropriate circumstances, the IRB shall solicit advice from others especially qualified to represent the views of a particular participant population.
 - A chair of the IRB will be chosen from among the faculty members during the second year of his or her two-year term. Members of the University community will be informed each year as to the identity of the IRB Chair and will be directed to obtain needed forms from and send research review requests to this individual. The chair will call meetings of the IRB as needed, and in a timely manner so as not to unduly delay investigators. Investigators should submit review requests at least 3 weeks prior to their planned date of the beginning of data collection. The REC must respond within three weeks.
 - The Chair alone, or in consultation with one other committee member, will review research proposals that have been submitted under the "Exempt from Review" classification to verify that they meet the "Exempt" criteria.
 - Two to three of the committee members (two of whom must be faculty members with full voting rights) will review research proposals that have been submitted under the "Expedited Review" classification.
 - The full committee will be convened to review research proposals that have been submitted under the "Standard Review" classification.

III. The Review Process

- The purpose of the review process is to determine whether the use of human participants in research is in compliance with University principles and policies and is not incompatible with the University's mission. Protection of the participants from undue harm is of paramount importance. The purpose of the review process is not to critique or evaluate the quality of the research proposed, to determine eligibility of proposed research for internal funding, or to evaluate the methodology of the research except as it relates to the welfare of the research participants.
- The IRB is guided by ethical principles regarding research with humans as participants as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"), Ethical Standards of the American Educational

Research Association, and the American Psychological Association's Ethical Principles in the Conduct of Research with Human Subjects.

- Before human participants are involved in research, proper consideration will be given to:
 1. the informed consent process and confidentiality procedures to be employed, and
 2. the risks to participants.

When the research involves more than minimal risk to the participants, consideration will be given to:

1. the anticipated benefits to the participants and others,
2. the importance of the knowledge that may reasonably be expected to result,
3. the fairness of the procedures and outcomes in the selection of research participants, and
4. procedures to be employed at the completion of the research (or during the research, if necessary), to ameliorate any harm caused to the participants as a result of having participated in the research.

To facilitate review, investigators are asked to complete the IRB submission forms and description of the research. This entails including a copy of questionnaires/surveys/interview questions/tests or measures to be used in the research, and including a copy of the consent and debriefing forms to be used for Expedited and Standard Reviews.

- Research Activities Exempt From Review. Research activities in which the involvement of human subjects is confined to one or more of the following categories are exempt from review by the IRB:
 1. Research conducted whereby individuals or groups evaluate a class, professor, administrator, service, or program provided by some entity under the auspices of St. Thomas University as long as the participants are not identifiable or identified (Example: in-class anonymous survey). Routine assessment of students and instructional activities are not research, and are exempt from IRB review.
 2. Research involving the observation of public behavior, except where: a) the observations are recorded in such a manner that the human subjects can be identified, either directly or through identifiers linked to the participants, or b) the observations recorded about the individual, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability, or (c) the research deals with sensitive aspects of a participant's behavior including illegal conduct, drug/alcohol use, highly private or sexual behaviors.
 3. Research involving observation, survey or interview procedures is exempt when the participants are elected or appointed public officials or candidates for public office and the interview or survey concerns the responsibilities of the office.
 4. Research involving the collection or study of existing or archived data, documents, records, or existing pathological or diagnostic specimens, if these sources are publicly available, or if information, data, test scores, or observations

- are recorded by the investigator in such a manner that participants cannot be identified directly or through identifiers linked to the subjects.
5. Research whereby one STU faculty or staff member (e.g., program coordinator) or the University as an entity is solicited to respond to a survey or questionnaire by some outside individual/agency/or accrediting body. The solicited individual or University, as an entity, is under no obligation to respond to such surveys except when doing so is required by state or federal laws or by SACS or ABA requirements or by the requirements of similar accrediting bodies.
- Research Activities Requiring an Expedited IRB Review
 1. Research involving a survey, observation or interview procedure NOT conducted to evaluate a class (i.e. not exempt under III-C.1 above) as long as the respondents are not identifiable or identified. (Ex: anonymous survey)
 2. A duplication of a previously approved research protocol, or a minor change in research procedures, for research projects previously reviewed by the IRB and approved within the last 12 months and conducted without any problems.
 - Research Activities Requiring Standard Committee Review. Review and approval of the proposed research by the IRB is required if any of the following are involved, unless the research is specifically covered under III.C. or III.D. above.
 1. Procedures that involve more than minimal risk; or
 2. Procedures that deprive the subjects of necessary, or normal/ordinary resources; or
 3. Hypnosis, untested procedures, or procedures involving an unusual degree of mental stress; or
 4. The use of subjects who are not able to give free and fully informed consent; (e.g., young children, individuals with developmental or mental disabilities, participants who are institutionalized or incarcerated)
 5. Explicit, or implicit, deception of the subjects about any aspect of the research likely to be significant;
 6. The use of subjects who are available because of the need for professional services, or
 7. Activities that may be illegal, or are likely to offend prevailing standards or morality, or.
 8. Any research proposed by an outside individual group or agency where by STU faculty, staff or students will be the research participants, or
 9. Any research activities that are not exempt from IRB review (III-C) and are not eligible for expedited review.

Information about the St. Thomas University IRB

Code of Federal Regulations 45 CFR Part 46 §101...124.

TITLE 45 (PUBLIC WELFARE)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46 (PROTECTION OF HUMAN SUBJECTS)

Subpart **A**, known as **the Common Rule**, relates to human subjects research in general. The other subparts (B, C and D of the DHHS version) relate to special research populations and have been adopted by some agencies. (See <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>)

Subpart **B** relates to research on fetuses, neonates, and pregnant women;

Subpart **C** relates to research with prisoners, and in general stipulates that the IRB include a prisoner or prisoner representative (among other requirements);

Subpart **D** relates to research with children, and in general mandates that adequate provisions be made for soliciting the assent of children and permission of their parents or guardians.

St. Thomas University has registered its IRB with the U.S. Dept. of Health and Human Services. # IRB00006131

Institutional Review Boards (IRBs)				
IRB Number	IRB Name	City	State	
IRB00006131	Saint Thomas University IRB #1 - Main	Miami Gardens	FLORIDA	

St. Thomas University has also an approved “Federal Wide Assurance” (FWA) with U.S. Dept. of Health and Human Services - STU agrees to oversee research with human participants to comply with the common rule and all subparts **45 CFR Part 46 §101-124**.

#FWA00011912

Assurance	Institution/Component	Type	City	State or Country	
FWA00011912	St. Thomas University	FWA	Miami Gardens	FLORIDA	

EXEMPTION FROM IRB REVIEW:

The Common Rule states that there are 6 categories of research that are exempt (from full IRB review). The first 4 are most appropriate for social science research:

1. Research in educational settings involving educational practices. (§ 101 (b) (1))
2. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior, unless subjects are identified and disclosure of responses would involve more than reasonable risk. (§ 101 (b) (2))
3. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior not exempt under preceding exemption if human subjects are elected public

officials, and if federal statutes require confidentiality of identifiable information. ((§ 101 (b) (3))

4. Research involving the collection or study of existing (archived) data if publicly available or unidentifiable. ((§ 101 (b) (4))
5. Research and demonstration projects designed to study public benefit or service programs. ((§ 101 (b) (5))
6. Taste and food quality evaluation and consumer acceptance studies. ((§ 101 (b) (6))

Exempt research is free from continued oversight by the IRB although the institution (either a designated IRB representative, the entire committee, or some other institutional authority), not the researcher, must determine that the project is exempt in the first place. Usually this is accomplished through a brief review process.

All questionnaire, educational tests, and interviews are NOT exempt
Such studies are exempt UNLESS:

- 1) Specific individual human subjects can be identified directly or through identifiers linked to them (i.e., their names, telephone numbers or other unique identifiers are recorded in the data)
- 2) disclosure of their responses could place them at risk of:
criminal/civil liability, or damage to their financial standing, employability, or reputation

Research on vulnerable populations may not be exempt. IRB will decide each case.

When the subjects are public officials or candidates for public office, the research is exempt even when identifiers are included.

IN MOST OTHER CASES, the IRB will review the research protocol for ethical issues involving the use of human participants. An EXPEDITED review can be requested, and is appropriate when there is only minimal risk involved in the research. Otherwise, a full review meeting of the IRB committee will be conducted.



APPENDIX: IRB SUBMISSION FORM
St. Thomas University
16401 N.W. 37th Ave., Miami, Florida 33054
Institutional Review Board - Research Proposal Submission Form

[DO NOT WRITE IN THIS SPACE]

Date Received _____

Protocol Qualifies for: Full Review _____ Expedited Review _____
 Exemption _____

Instructions: The principal investigator or faculty supervising a student project should submit this form and research proposal (including consent forms and research instruments) to the chairperson of the University IRB committee. The IRB web page can be consulted for policy and procedures information.

A. Project Title: _____

New proposal _____ Continuation/Renewal _____ Revision _____

Proposed Start Date _____
 Proposed Duration of Research _____
 Performance Site(s) _____

B. Principal Investigator _____

Faculty Project _____
 Supervised Student Project _____
 Class Data Collection _____

Department _____

Email Address _____ Phone Number _____

Co-Investigators _____

Are there any special populations participating (children, handicapped, mentally ill etc.)

_____ No
 _____ Yes (if YES, please describe in the attached research proposal)

Will any payment or course credit be awarded to participants?

_____ No
 _____ Yes (if YES, please explain in attached proposal, and indicate what alternative means of obtaining course credit will be available to students who do not wish to participate)

In the attached proposal:

1. Describe the nature of the research/project being proposed
2. Explain if any physical, psychological or other risks to human participants are associated with the project, or if the project deals with "sensitive" subject matter (see IRB Guidelines)
3. Attach copy of the consent form and be sure it includes:

_____ Description of project	_____ Contact information
_____ Statement of right to withdraw	_____ Statement of risks/benefits
_____ Statement of confidentiality	_____ Description of any costs, credit or payments
_____ Explicit statement of consent	_____ Line for Signature and Date

Investigator/Faculty Supervisor Signature: _____

Date: _____

Student Researcher Signature: _____

Date: _____