

## **ATTACHMENT B**

(Approved by the Academic Policy Committee 5/10/16)

### 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 membership of the committee. Committee members are required to undergo training as specified by the Federal Office of Human Research Protection (OHRP). The chairperson 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 subjects has the responsibility to become familiar with and follow University IRB policy. This policy applies to all research involving human subjects 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 subjects will be classified as falling into one of three categories:

1. Research Exempt from Institutional Review Board (IRB) Review
2. Research requiring an Expedited IRB Review
3. Research requiring Standard IRB Review, including proposals involving research with human subjects 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 subjects 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 required that research involving human subjects which is exempt from IRB review be reviewed by the IRB chairperson to confirm the project's exempt status and to insure protection of the welfare of human subjects.
- 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-below, the investigator shall seek the advice of the IRB committee.
- The principal investigator shall explain to these individuals, 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 to 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) 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 membership will include at least four St. Thomas University faculty members with earned doctorates who are willing to serve on the IRB in a year-round capacity, and one individual who is not otherwise affiliated with the institution, in compliance with 45 CFR 46.107. All members of the IRB, including the Chair and the outside affiliate, will have full voting rights pertaining to submitted IRB materials. 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. Under appropriate circumstances, the IRB shall solicit advice from others especially qualified to represent the views of a particular participant population.
- The selection and term of the IRB chair will be at the sole discretion of the Provost. 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 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 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 human subjects 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 human subjects as participants as set forth in the report 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 fully outline the anticipated research process. 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. It is the responsibility of the IRB to determine whether or not a research protocol qualifies for IRB exemption. STU requires all Principal Investigators to submit their research to the IRB to confirm exemption. 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, and/or 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 the guidelines noted 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.

- 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 the exemption or expedited guidelines noted 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 and are not eligible for expedited review.

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

**St. Thomas University also has an approved “Federal Wide Assurance” (FWA) with the U.S. Department of Health and Human Services—STU agrees to oversee research with human subjects to comply with all aspects of 45 CFR Part 46, #FWA00011912.**

## ***Principal Investigator Eligibility Policy***

### **Background**

The title of Principal Investigator (PI) identifies the individual responsible for the conduct of a sponsored project or non-sponsored project requiring registration with one or more STU compliance committees, including the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACUC). This responsibility includes the intellectual conduct of the project, fiscal accountability, administrative aspects, and the project's adherence to relevant policies and regulations. For that reason, PIs must have a reasonable prospect of long-term employment at St. Thomas University.

### **Automatic PI Status**

The policy of St. Thomas University is that only full-time academic faculty members with earned doctorates (as defined in the STU Faculty Handbook) may routinely serve as PIs. Certain other titles are allowed to serve as PIs within the limitations described below. Exceptions to this policy may only be made with the prior approval of the Provost. The University will not submit proposals for external funding or approve requests requiring compliance committee oversight without adherence to this policy.

Full-time members of the academic faculty, for the purposes of this policy, include the following personnel titles:

- Professor
- Associate Professor
- Assistant Professor
- Professor Emeritus

Whenever there is a question as to the eligibility for automatic PI status, the applicable definitions in the STU Faculty Handbook shall apply. For the purposes of this policy Co-PI and Co-Investigator are synonymous.

### **Individuals not currently employed by STU**

An individual who is not currently employed by St. Thomas University can serve as a PI or a Co-PI on a project if a department chair and dean of the unit in which the work will be conducted provides documentation that an appointment to one of the eligible titles listed above has been offered to and has been accepted by the individual.

### **Graduate Students**

A graduate student cannot serve as a PI. A full-time faculty member, who is eligible to be a PI, must serve as the principal investigator for all graduate student research projects, including thesis or dissertation research.

### **Adjunct Faculty**

PI status will not be granted to adjunct faculty or staff. Exceptions to this policy may only be made with the prior approval of the Provost per the exceptions criteria described in this policy.

## **Exceptions**

Exceptions can be granted and PI status conferred on a case-by-case basis.

## **Deemed Exceptions**

The Provost may deem that certain positions, other than those listed above, are granted PI status for the term of the position at STU.

## **Requested Exceptions**

Adjunct faculty, instructors, lecturers, visiting scholars and professional staff involved in projects that contribute to the University's mission may also request PI status from the Provost. Requested exceptions may be granted when the following conditions apply:

1. An application to serve as PI is to be submitted on the basis of a specific proposal idea or concept. Approval to be a PI is granted for a specific proposal idea only, and should not be construed to permit the applicant to submit other proposals for unrelated ideas or concepts.
2. The individual must have the necessary experience and independence to compete for his or her own sponsored program and/or to administer the project. They must have previous experience with similar types of research projects and the ability to comply with all requirements of the award or project.
3. The individual must obtain written commitments of sponsorship from the department chair and dean, and any other individual required to guarantee necessary laboratory space or other resources or support.
4. The department chair and dean must agree to assume responsibility for an awarded sponsored program should the individual leave STU.

## **Procedure for Requesting an Exception**

Requests for PI eligibility should be directed to the Provost prior to the submission of an IRB proposal to permit adequate time for review of the request. The request must include written (or emailed) approval by the proposed PI's department chair and dean. The request must also include the curriculum vitae of the proposed PI. The Provost will inform the proposed PI and the chair of the STU IRB of the decision.

## **Decisions**

Serving as a PI at STU is a privilege and responsibility, therefore the ultimate decision regarding PI eligibility exceptions rests with the Provost (or designee in his/her absence). No other individual on campus can designate PIs. PI eligibility status for deemed or granted exceptions may also be revoked by the Provost at his/her discretion.