



IRB Application

Principal Investigator	<input type="checkbox"/> CITI <input type="checkbox"/> NIH Certificate Date(s)*	School/Discipline
E-mail		Telephone
Position: <input type="checkbox"/> Full-time faculty or staff <input type="checkbox"/> Adjunct faculty or <input type="checkbox"/> Student Other _____		
Project Title		
Co-Investigator(s)/Faculty Supervisor	<input type="checkbox"/> CITI <input type="checkbox"/> NIH Certificate Date(s)*	School/Discipline
E-Mail		Telephone
Will this project involve Research Assistants in direct contact with participants and/or identifiable data? <input type="checkbox"/> YES <input type="checkbox"/> NO If YES: Please list the name of each assistant.		
Will this research involve collaboration with other organizations? <input type="checkbox"/> YES <input type="checkbox"/> NO If YES: Attach documentation of approval to conduct research from each organization – either IRB approval or an administrative letter if no IRB exists at the site. If working with minors in the schools or other institutions, provide copies of necessary clearances of each investigator.		
Indicate the type of review that is being sought <input type="checkbox"/> Exempt <input type="checkbox"/> Expedite <input type="checkbox"/> Full Note: Final determination of the type of review is at the sole discretion of the St. Thomas Aquinas College IRB.		

* Please check the name of the completed training course.

Assurances

PRINCIPAL AND CO-INVESTIGATOR(S):

I understand that as an Investigator, I have responsibility for the protection of the rights and welfare of human subjects and the ethical conduct of the research project. I agree to comply with all St. Thomas Aquinas College (STAC) policies and procedures, applicable federal, state and local laws, and the ethical principles of my profession.

I will obtain necessary review by the IRB if changes are made in the project. One month prior to the end of the approval period of one year I will apply for project continuation if needed. I understand that failure to apply for continuation will result in termination of the project and require resubmission as a new protocol.

I will report any unexpected or adverse events immediately to the IRB.

I certify that the information provided in this request is complete and correct.

Signature

Printed Name

Date

Signature

Printed Name

Date

Signature

Printed Name

Date

SUPERVISOR/ADVISOR (required for adjunct faculty, part-time staff, students, and outside researchers) must be a full-time STAC faculty or STAFF member:

I have reviewed this application and agree to provide supervision for this project. I agree to comply with all STAC policies and procedures, applicable federal, state and local laws, and the ethical principles of my profession. I will report any unexpected or adverse events immediately to the IRB.

Signature

Printed Name

Date

Position

Department

Applicants must submit one signed, printed copy of this application to the Provost and Vice President for Academic Affairs. Electronic copies of the application must be sent to the PVPAA. Review will not take place until both the printed and electronic copies have been received.

NARRATIVE

Please provide a response for each item listed below. If the answer is “none” or “not applicable” that should be indicated in the space provided. Guidelines for each item can be found in the instructions section of the website and are linked to this form.

Applications with missing responses will be returned as incomplete.

I. Overview: Brief description of the current project. Indicate the purpose, rationale and hypothesis/question being addressed.

Expected start date and completion date for data collection.

II. Benefits to Research Participants: Describe the potential benefits of this study to the research participants.

III. Potential Risks: Describe any physical, psychological, social, legal, economic or other risks you can foresee, both immediate and long-range. Include those aspects of the procedure that might cause unusual discomfort or inconvenience to the research participants, including any effect on their self-esteem or self-image. Indicate the steps that will be taken to minimize these risks.

IV. Participants:

A. Expected Number.

B. Expected participant characteristics including whether participants are: (a) younger than 18 years of age, (b) prisoners, (c) members of a special group such as institutionalized individuals whose ability to give free, informed consent is likely to be compromised, (d) individuals with impaired ability to give informed consent, and/or (e) pregnant women.

C. Method of recruitment, including who will be recruiting the participants and whether participants will be affiliates of STAC or outside the college population.

D. Estimated time commitment for each participant.

E. How will participants be compensated for their participation?

V. Procedures:

A. Will deception be used? If so, please describe the nature of the deception involved and describe why it is necessary to the research project.

B. Description of the methods and procedures to be used with the participants including what the participants will be expected to do, and the investigator(s) interactions with the participants, and information gathered.

C. Will this project involve collecting raw data from a) prison records, b) school records, c) medical records? If so, please describe the type of record, the nature of the information drawn from the records and how this information will be used.

D. Will standardized instruments (surveys, tests, questionnaires) be used? If so, has copyright permission been obtained for their use?

VI. Informed Consent: (Attach a copy of the consent form, if applicable.)

A. The Informed Consent Statement should be read to the Participant(s) as he or she reads along. Is there any reason this cannot be done? Explain why and what procedure(s) you will use to ensure participant understanding. If participants cannot give **FREE** and **INFORMED** written consent, explain why and indicate what alternative procedure you will use to guarantee his or her rights (e.g., parent, guardian, or institutional consent). If you are administering an online survey, please explain your consent process.

All signed Informed Consent Statements must be retained for a minimum of three (3) years.

B. Describe the storage location for signed consent statements and the methods that will be used to assure their security.

VII. Confidentiality:

A. Will any personal identifying information be recorded? If yes, please describe.

B. Describe the necessity for recording personal identifying information.

C. Will identifiable information be obtained pertaining to persons other than the participants, e.g., family, friends, co-workers?

D. Describe the steps that will be taken to secure any personal identifying information obtained.

VIII. Debriefing: (Attach a copy of the debriefing script, if applicable.)

A. Describe how debriefing will take place (e.g., when, where, individually, in groups). If debriefing is NOT going to be used, please explain the reason.

B. If deception was employed, describe what you will do to restore the participant's trust.