SOUTHWEST
TENNESSEE COMMUNITY COLLEGE

APPLICATION FOR IRB REVIEW OF PROPOSED RESEARCH

- Frequently asked questions concerning this application can be found here.

SECTION 1: BASIC INFORMATION

1.1 Lead Investigator ("LI").

Full Name:
Contact Person (If Different Than Lead Investigator):
Organization:
Department:
Program Name:
Program Level: ___ Associate ___ Certificate ___ N/A
Email Address:
Local Phone Number:

1.2 Faculty Advisor (If Student Research).

Faculty Advisor's Full Name:
Faculty Advisor's Email Address:

1.3 Study Information.

Project title:
Expected start date:
Projected end date:
Co-investigator(s):
# of Participants:

1.4 Sponsorship

Is the research sponsored or funded? ___ Yes ___ No
*If Yes, attach a copy of your proposal. If items 2 through 10 are included in proposal, skip to section 11. If any items are not included in the proposal, complete those sections in the application)
*If No, continue on with the full application

1.5 H.R.4346 - Chips and Science Act – Research Security

Foreign Talent Recruitment Programs (FTRP) are any body organized, managed, or funded by a foreign government, or a foreign government instrumentality or entity, to recruit science and technology professionals or students. Participation in a FTRP **must** be disclosed to this IRB.
Are you or your research sponsored, funded, or connected to an FTRP? ___ Yes ___ No
*If Yes, name the foreign country:_____

SECTION 2: PURPOSE OF STUDY

2.1 Study Goal

Describe the purpose(s) or goal(s) of your study. Include your research question(s) or hypothesis(es) if applicable:

2.2 Literature Review.

Briefly describe how the pertinent body of literature supports the study goal. Include citations and references:

2.3 Possible Contributions.

Describe the potential benefits of the proposed research study to the literature:

SECTION 3: METHODS AND PROCEDURES

3.1 Study Design.

Provide a summary statement of the design methodology used. For example, stating that the study is a randomized clinical trial using a double blind procedure with a placebo control. Another example would be a reanalysis of de-identified archival data.

3.2 Materials.

Provide a concise description of all special equipment, instruments, or measures in this section. Also, label and attach copies of data collection tools at the end of this Initial Review Request.:

Indicate All Research Methods Used with an X:

___ Survey (attach questionnaire)
___ Interviews (attach questionnaire or interview guide)
___ Participant observation
___ Unobtrusive observation
___ Experiment (attach description detailed in a protocol and any instruments used)
___ Analysis of data that have already been collected (i.e., "archival" data) +
___ Other, specify: _____

+: For any non-public data, please include permission from the data holder.

PLEASE NOTE:
1) For any research conducted within an organization, provide documentation from an authorized representative of this organization indicating that you have permission to conduct your research there. If this organization has its own IRB, provide proof of IRB approval.
2) Be aware that the use of copyrighted material has to be authorized by the copyright holder.

Type of instrument used:

___ Paper questionnaire, Survey, interview guide
___ Online questionnaire, Survey, interview guide
___ Pre-post survey
___ Experimental design (protocol must be attached)
___ None (note-taking)
___ Not applicable (use of existing data)
___ Other, specify: _____

Describe the objective(s) of your study. What do you hope to accomplish?

What are the expected benefit(s) of your research to the participants themselves, to society, and/or to the academic community?

3.3 Procedure.

Provide a chronological description of the experience of being a participant in this study.

How long do you anticipate that it will take the participants to complete the research procedure(s)?

Please briefly describe your participants, including the social categories you are drawing from or targeting (race/ethnicity, gender, occupation, age group, military status, etc.), or any other relevant characteristics of your sample:

Sampling strategy:

___ Convenience/availability
___ Random/probability
___ Snow-ball
___ Purposive/judgmental/theoretical
___ Other, specify: _____

Indicate which procedures and treatments are associated with the present study and those which are not part of the study (i.e., pre-existing programs, interventions, or classroom exercises).

For archival data, describe how the data is secured, stored, and used.

Data recording method (Mark all that apply with an X):

___ Written (includes notes, participants filling out a paper questionnaire or survey)
___ Electronic (online survey, email, blog, etc.)
___ Audio
___ Video
___ Photo
___ Other, specify: _____
___ Use of existing data

Will the data be linked to the individual participants' identifying information (such as name, email address, social security number, video, picture, etc.)? This may include identifying information on the data collection instrument, or keeping a list of names matched to codes used in the data.

List source of the data and an explanation of why the data were originally collected.

How long do you anticipate it will take you to collect all your data for this project?

For how long do you plan to keep your data?

How will you store your data? (Check all that apply):

___ Locked file cabinet
___ Password-protected computer
___ Locked office
___ Locked safe
___ Other, specify:_____

SECTION 4: SECONDARY ANALYSIS OF EXISTING DATA (IF RELEVANT)

The specific information is necessary when identifiable data about human subjects will be obtained. Data are identifiable if they include direct or indirect identifiers such as name, e-mail address, UID Number, race, gender, nationality, age etc.

List source of the data and an explanation of why the data were originally collected.

Describe in detail the data you plan to access and analyze.

Indicate the requirements of the data supplier and how access to the data will be granted or obtained.

Agencies involved with recruitment or data collection (indicate any funders or organizations from which you obtain participants or their data):

If access to the data is governed by a data use agreement, provide a copy of the agreement.

Describe procedures that will protect data you are given access.

SECTION 5: INVESTIGATOR QUALIFICATIONS

Describe the lead investigator's qualifications and experience in conducting this particular type of research.

If physical or psychological assessments are being administered who will administer the assessment and score the results and what are their qualifications for doing so? Is the training in human subject protection of those administering assessments adequate?

Number of prior research projects completed as LI:

SECTION 6: HUMAN SUBJECTS AND RECRUITMENT

Insert a document in the appendix describing the population and recruitment strategies. Items to consider for inclusion:

- Include characteristics of the participant population including the age range(s), gender, ethnicity, health status, any physical, mental, cognitive or emotional limitations, and any other relevant variables.
- Indicate if subjects include students, prisoners, pregnant women or any other class of subjects that might be especially vulnerable and require special consideration. Certain Populations will require additional permissions after approval of the IRB. IRB approval does not guarantee approval by the appropriate STCC administrators.
- If subjects are students, describe the relationship between students and researcher. If there is a pre-existing relationship between the researcher and the subject pool, please describe that relationship in detail.
- Recruitment strategy
- **Attach all materials to be used in recruitment.** Provide detailed description and example where relevant of any material presented to potential participants prior to their receipt of the informed consent/assent documents. Include advertisements, postings on social media, posters, scripts for radio/TV, other electronic ads, scripts for verbal recruitment, copies of email recruitments, and any text that will be provided to potential participants. It should be clear in all recruitment materials that you are conducting research. See Sample Recruitment flyer on IRB website

SECTION 7: SUBJECT PAYMENT

Insert a document in the appendix describing the cost or payment made to the participants. Items to consider for inclusion:

- Describe any economic or other incentives for participation including reimbursement for time and travel.
- If study participation requires subject to complete multiple sessions, payments must be pro-rated over the course of the study. (Example: In a study where subjects are paid $50 per session, Tom completes only two sessions, then he should be paid $100 for his participation)
- Does the research involve any cost to participants?
- If the study incentive involves earning course credit, list alternative ways to earn the same credit.

SECTION 8: POTENTIAL RISKS.

Insert a document in the appendix describing the potential risks and potential benefits. Items to consider for inclusion:

- Describe all potential risks: physical, psychological, social, legal or other associated with each procedure. Assess the probability, severity, potential duration and reversibility of each risk.
- Identify those risks that are minimal and those which are more than minimal.
- Describe the procedures used to minimize any potential risks.
- Describe the direct potential benefits to the subject. If there are none, this should be so stated.
- Describe the potential societal benefits of the study in terms of human health/welfare, the advancement of knowledge or the good of society.
- Justify the research study based on your evaluation of the risk/benefit assessment. When composing this section, imagine you are standing in front of a panel of researchers who are all skeptical about your research. Your task is to reassure them that the benefits of your research outweigh the risks.
- How will you minimize the existing risk(s)?

SECTION 9: PRIVACY AND CONFIDENTIALITY

Insert a document in the appendix describing the privacy and confidentiality strategies. Items to consider for inclusion:

- Outline strategies to protect privacy, including how the investigator will access participant information.
- Identify those risks that are minimal and those which are more than minimal.
- Describe the procedures used to minimize any potential risks.
- Outline in detail the strategies to maintain confidentiality of identifiable data, including controls on storage, handling, sharing of data as well as eventual destruction of identifiable data including signed consent forms.
- How long do you anticipate it will take you to collect all your data for this project?
- Will the data be linked to the individual participants' identifying information (such as name, email address, social security number, video, picture, etc.)? This may include identifying information on the data collection instrument, or keeping a list of names matched to codes used in the data.
- For how long do you plan to keep your data?
- Who will have access to the data? For what purposes?
- How will you store your data?

SECTION 10: COLLABORATION, ENGAGEMENT & SPONSOR RELATIONSHIPS .

Insert a document in the appendix describing any collaboration, engagement and sponsor relationships. Items to consider for inclusion:

- Describe all collaborative relationships necessary to complete your research. Include letters of support from the collaborator(s). This letter must come from a person with director-level authority within the collaborating institution. When the collaborator has an Institutional Review Board, please include a copy of the IRB application sent to collaborating institution.

- Does the collaborator require STCC IRB approval before they will commit to the study?
- Specify what data will be provided to the collaborator(s) and sponsor(s).

SECTION 11: INFORMED CONSENT.

Does the research involve any deception of the participants?

___ Yes
___ No

What type of consent process will you use? (Mark all that apply with an X)

___ Implied consent (attach template implied consent statement)
___ Consent form (attach template consent form)
___ Assent (attach template consent form or statement)
___ Not applicable (research on publicly available data)
___ Other, specify: _____

SECTION 12: AFFIRMATIONS

PI statement of responsibility

I, the Principal Investigator, certify that I have followed the guidelines as outlined in this application and in the instructions available on the IRB webpage at [Insert Policies Link]

___ I have provided an answer to every single question of the application, leaving none blank. I understand that incomplete applications will be returned without review.
___ I am submitting this application, including all supplemental documents, as ONE Word document. I understand that any other type of submission will be returned without review.
___ I have answered all questions truthfully. I understand that failure to do so will result in immediate revocation of any IRB approval, with the potential for further disciplinary action through my home institution.
___ I have obtained the required ethics training certification, as described on the IRB webpage at [Insert Link]
___ If a student, I have received guidance from my faculty advisor and obtained his/her signature
___ If a first time undergraduate Principal Investigator, my research involves no risk greater than those encountered in daily life

I also certify that I have included all necessary supplemental documentation, as applicable to my research (check all that apply):

___ Data collection instrument(s), such as survey, interview questionnaire(s), or protocols for experiments
___ Consent form template(s)
___ Assent form template(s)
___ Implied consent statement template(s)
___ If using Southwest Tennessee Community College students and/or a vulnerable population, recruitment materials (email announcements, flyers, etc. to match the recruitment methods listed)

___ Authorization from outside agency
___ Proof of approval from outside agency IRB
___ If not a member of the Southwest Tennessee Community College, proof of approval from my organization's IRB
___ Proof of completion of ethical training with at least 6 months' validity, to be renewed if the study extends beyond that date.
___ If I am submitting this application as a student, proof of completion of ethical training for my faculty advisor

I accept the following responsibilities (please check each after reviewing):

___ I will not start collecting any data for this project before obtaining IRB approval of the proposal.
___ I will obtain approval from the STCC IRB prior to instituting any change in the project protocol.
___ I will bring to the attention of the STCC IRB the development of any unexpected risks or ethical concerns.
___ I understand that the approval period is for exactly one year, and that all study activities will either cease prior to expiration, or I will submit a request for an extension prior to the expiration date.
___ I have read, understand and acknowledge the IRB bylaws.
___ I will keep signed informed consent forms (if required by the project) from each participant for five years after the completion of the project and will ensure proper storage.

PI's signature: _____ Date: _____

(***Student research only***) Faculty advisor statement of responsibility

I, the faculty advisor for this research project, certify the following:

___ I have reviewed this entire application and assisted the PI in designing his/her research project
___ I have ensured that the PI has followed all instructions to fill out this application according to the guidelines provided by the STCC IRB
___ I approve the research project as outline in this application
___ I will assist the PI in making any revisions requested by the Saint Leo IRB
___ I will assist the PI in the completion of the research and will continuously monitor all study related activities throughout the research period.
___ I will ensure that the PI submits a modified application for review, should any modifications to the research plan occur.
___ I will ensure that the PI submits a request for continuation in a timely fashion, should the research be extended beyond the one-year IRB approval.

___ My ethics certification is valid for at least another 6 months and is attached to this application.

___ I will renew my ethics certification at expiration, if it expires before the PI's research project is completed.

___ I understand that I will be held legally responsible in case of any violation of the IRB regulations by the research team.

Faculty Advisor's Signature: _____ Date _____

****

FOR IRB USE ONLY:

Verification of ethics training certification

PI: ❑ Valid certification (Expiration date: / /) ❑ Certification expired ❑ No certification

Faculty Advisor: ❑ N/A ❑ Valid certification (Expiration date: / /) ❑ Certification expired ❑ No certification

Type of review: ❑ Exempt ❑ Expedited ❑ Full

Decision: ❑ Approved

❑ Minor Revisions Required

Minor revisions required:

_____

_____

_____

❑ Revise and resubmit

Revisions required:

_____

_____

_____

_____

❑ Not approved

Justification for non-approval:

_____

_____

_____

IRB representative's signature: _____ Date:_____

[Start inserting required supplemental documents here on the next page, after deleting this statement]