South Texas College
Institutional Review Board
Application for Human Subjects Research

Please follow the Instructions at the end of this document. Fit all responses into the space provided.

☐ New Application ☐ Request for Amendment ☐ Request for Continuation

STUDY TITLE

PRINCIPAL INVESTIGATOR (PI)

Name:

E-mail Address:

Phone Number:

HOME INSTITUTION

Home Institution is the college or university under whose auspices the study is conducted. For graduate students, the home institution is always their program institution, not South Texas College. Include your home institution IRB's approval memo with this application.

Home Institution:

PI's Title at Home Institution:

Location (City, State):

REQUIRED DOCUMENTATION

The following items are necessary for the IRB to make its determination. Use the checkboxes to indicate included items. Your application will not be accepted for review unless all applicable documents are included with this application. Review the Instructions for more information.

This application form, completed, signed and dated	☐	All protocols or instruments in their final form	☐
PI's surname in indicated page headers	☐	All informed consent text(s), or request for waiver	☐
Affirmation on page 9	☐	PI's research ethics certification (CITI, ACRP, etc.)	☐
If applicable:			
Home institution IRB approval memo	☐	All recruitment materials in their final form	☐
Permission to use previously published instrument	☐	Original STC IRB approval memo (for continuation/amendment)	☐

PI'S SIGNATURE

Signature:

Today's Date:

RESEARCH TEAM

Q1. Research Team. Please enter details on your coinvestigators. If more than three, list the senior three only.
Coinvestigators would be those listed as the "authors" of the study, if the study were to be hypothetically submitted to a peer-reviewed outlet such as a journal or conference. This remains true even if there is no intention of formal publication. Do not include the Principal Investigator's name. Do not include business or communications contacts.

Name (include "Ph.D." if applicable):	Title, Affiliation:	E-mail address:

Or select: I am the sole investigator. ☐

Q2. Terminal Degree. Does the Principal Investigator hold the terminal degree in an academic discipline related to the topic of the study? Please select the applicable checkbox.

The Principal Investigator holds the terminal degree. ☐

The Principal Investigator is seeking the terminal degree at an accredited institution. ☐

Neither. ☐

Q3. Applicant Information. Please answer the following questions if applicable.

Degree Sought (if graduate student):

STC Department (if STC employee):

FUNDING & PAYMENTS

Q4. Disclose all forms of funding for the study, if applicable. If the study is funded through a grant, specify the grantor, grant name and project number.

Q5. Participation Incentive for Subjects. Will study subjects receive any kind of incentive for participation? Please describe. Include the amount(s) and the point(s) in the study at which the incentive(s) will be awarded.

And/or select: Subjects in the study will not receive incentives for participation. ☐

Q6. Payments to STC Persons. Will any payments other than participation incentives be provided to any STC student, instructor or employee, from the research team or organizations with which they are affiliated, whether related to the study or not? Describe in detail here. Specify recipients, amounts, and funding source(s).
Payments may include but are not limited to participation incentives, honorariums, gift cards, or other items of cash value.

Or select: STC persons (other than study participants) will not receive payments or inducements of any kind related to the study. ☐

ELEMENTS OF THE COMMON RULE, 45 CFR 46

Q7. Common Rule. Please answer each of the following. Is/does the study….?

'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.

Is/does the study….?	**Yes**	**No**	**N/A**
A systematic investigation involving human subjects designed to develop or contribute to generalizable knowledge?	☐	☐	☐
Involve no more than Minimal Risk to research subjects?	☐	☐	☐
Involve minor children, prisoners or other institutionalized persons, or pregnant women?	☐	☐	☐
Include adequate provisions to protect the privacy of subjects and maintain confidentiality of the data?	☐	☐	☐
Select subjects in an equitable manner?	☐	☐	☐
(Normal Educational Practices) Conducted in established or commonly accepted educational settings, involving normal educational practices (e.g. pedagogical materials in the classroom setting)?	☐	☐	☐
(Survey/Interview) Conducted using only interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior?	☐	☐	☐
(Behavioral Intervention) Involve benign behavioral interventions with adult subjects with their agreement?	☐	☐	☐
(Secondary Research) Involve use of identifiable private information received from a publicly available source (i.e. not collected by the researcher as a part of the study)?	☐	☐	☐
(Public Benefit) Research, evaluate, or examine a state or federal government program?	☐	☐	☐
(Taste & Food) Involve taste or food quality evaluation?	☐	☐	☐
(Biospecimen) Involve the collection, storage or maintenance of biospecimens for research use?	☐	☐	☐
Otherwise take place in any medical or clinical context, or under the supervision or request of a public health authority?	☐	☐	☐
Conducted or supported by, or on behalf of, any department or agency of the federal government?	☐	☐	☐

MINIMAL RISK STANDARD

Q8. Minimal Risk Standard. Could the study involve any of the following risks? Please read the definitions before answering.

Could the study involve any of the following risks to subjects? Use the checkboxes to answer each.	**Yes**	**No**
Physical risk, i.e. the possibility of physical injury to the subject?	☐	☐
Legal risk, i.e. any disclosure of a subject's participation or responses could result in attention from law enforcement agencies, or legal or criminal liability?	☐	☐
Coercion risk, i.e. the researcher is in a position of authority over the subject?	☐	☐
Power risk, i.e. the researcher's position or reputation is such that the subject may feel compelled to participate and/or provide favorable responses?	☐	☐
Privacy risk, i.e. the data collected includes identifiable information about the subject? Answer no if the Informed Consent is the only document that can link a subject's identity to his or her responses.	☐	☐
Stressors, i.e. elements of the study could cause negative emotional responses in subjects?	☐	☐
Are there safety procedures in place to mitigate the above risks?	☐	☐
Does the research team have a plan for addressing adverse reactions?	☐	☐

STUDY OVERVIEW

Q9. Research Objective. Please summarize the objective of the study and/or your research question. Be concise and fit your answer in the space provided.

Q10. Key Variables/Concepts. If not specified above, what are the key variables or concepts of interest? Be as concise as possible.

Q11. Time Frame. What is the expected time period in which data will be collected? Acceptable answers include a specific semester, or a date before which all data collection is finished.

STUDY FORMAT

Q12. Key Methodology. Among the following, select checkbox(es) to indicate all data collection methods to be used in the study. Select all that apply.

- ☐ Surveys initiated by the researcher
- ☐ Focus groups
- ☐ In-depth interviews
- ☐ Instructional or classroom activities, such as tests or journaling
- ☐ Analysis of educational data created and/or collected by South Texas College
- ☐ Existing records, other than the above
- ☐ Observation in public places, including classrooms
- ☐ Observation in a controlled environment
- ☐ Treatment or randomized control experiment
- ☐ Collection of biospecimens (blood, saliva, etc.)
- ☐ Other (be sure to specify in answers elsewhere in this form)

Q13. Data Requests. Do you plan to request records or data of any type from offices of South Texas College? Briefly describe your intentions below, specifying the request and to whom you expect to make it.
Examples would include but not be limited to contact rosters and student grades. Please note that data request procedures are not under the purview of the IRB, and IRB approval does not guarantee the provisioning of data.

Or select: The study does not involve data requests to offices of South Texas College. ☐

STUDY SUBJECTS

Q14. Subjects. Describe the study subjects. Please select the general category from the checkboxes (all that apply), and then provide further detail in the space provided. What specific criteria will be used to determine eligibility? For example, student age, student major, students in a specific STC course, employees in a specific department, faculty teaching a specific course, etc. Also provide criteria of exclusion if any.

☐ STC Students ☐ STC Faculty and/or Staff ☐ Non-STC Persons or Members of the Public

Q15. Number of Subjects. Answer below. This refers to the *maximum* number of subjects. A range is acceptable.

Q16. Recruitment Summary. Provide a description of the procedure for selecting and recruiting subjects (when, where, how) including whether any STC community members (like instructors) be asked to assist in recruitment.

Q17. Benefits to Subjects. Will subjects receive any benefit from the study? Do not include incentives previously mentioned, or general knowledge.

Or select: Subjects will receive no benefit (other than any participation incentives). ☐

Q18. Deception. Are subjects deceived, misled or misinformed in any way as a part of the study? Describe.

Or select: The study in no way deceives, misleads or misinforms subjects. ☐

METHODOLOGY & PRECAUTIONS

Q19. Research Design. Please briefly describe your study procedures, step by step, in the space provided. You will be asked to provide details on data collection and records storage later on.

Q20. Experimental Methods. Does the research design include experimental methods? Describe.

Or select: The study does not use experimental methods. ☐

Q21. Previously Published Instrument. Is your survey or interview instrument wholly or partially derived from another author's peer-reviewed work? Specify the source here. The best answer is an APA- or MLA-style citation from Google Scholar.

Or select: The instrument is the research team's own work in its entirety. ☐

Q22. Permission to Use Previously Published Instrument. Have you received consent or permission from the original author(s) to use their work? Include this permission among your materials. If the original work was distributed under a license that allows free academic use, check the appropriate box. If not applicable, please skip.

	Yes	No
I have permission, and I have included this permission among my materials for this application.	☐	☐
Or select: The original work's license allows free academic use.	☐	

Q23. Safety Procedures & Adverse Reactions. Describe in detail the safety procedures that mitigate any risks to subjects. Include procedures that will address adverse reactions in subjects.

Or select: I am an STC instructor or employee and will refer students to the STC Counseling Center. ☐

Q24. Safeguards for Protected Classes. If the study involves classes of subjects protected under the Common Rule, what specific safeguards exist in your protocols to minimize risk among these groups? Protected classes under the Common Rule include minor children; prisoners or other institutionalized persons; pregnant women; or persons with health or developmental disabilities such that the ability to consent is impaired.

Or select: The study does not involve protected classes of subjects. ☐

Q25. Special Topics. Does the study involve topics such as religious belief, sexual orientation, public safety, or immigration status? If yes, please specify.

Or select: The study does not involve the listed topics. ☐

CONFIDENTIALITY & DATA PROTECTION

Q26. Study Records. How will data be recorded? Specify both the mode of collection (e.g. paper, Word document, online form, survey software, focus group audio recordings, etc.) and the mode of retention (e.g. the researcher's laptop, file cabinet, shared drive, etc.).

Q27. Data Access. Other than the research team, does anyone else have access to study records? Specify.

Or select: Only the research team has access to any records. ☐

Q28. Protection. Describe provisions to keep study records secure (e.g. password-protected drive, locked cabinet).

Q29. Identifying Records. Other than the informed consent, will any records include information that could identify the individual subject? If yes, please describe.

Or select: No identifying records are collected. ☐

Q30. Confidentiality. Describe provisions in your study to maintain confidentiality for subjects, i.e. the separation of subjects' identity from any data collection associated with them.

Q31. Retention. How long will records be stored? These records include but are not limited to raw data, audio or visual recordings and/or any materials with identifying information. When are they destroyed? Please be precise.

INFORMED CONSENT

Q32. Describe how informed consent will be obtained, by whom, and in what specific format (online survey, paper forms, Google Forms, etc.). Please note that you must include your informed consent documents with this submission. The IRB provides sample texts upon request.

Q33. Elements of Informed Consent. All of the following items must be present in the text of an informed consent in order for a study to be approved by the IRB. Affirm that each are included. Applicants requesting waivers may skip this question.

Are the following elements of informed consent present in the consent materials?	**Yes**
A notice that the study is voluntary.	☐
A notice that subjects have the right to withdraw from participation at any time.	☐
General information about the study, its purpose, and the research team.	☐
A general explanation of the study procedures, from the subject's perspective.	☐
An explanation of any kind of inducement or participation incentive.	☐
Reasons why subjects should not be included in the study (i.e. exclusion criteria), and/or circumstances in which the subject's participation may be terminated by the researcher.	☐
Number of subjects expected to take part.	☐
Duration of the study period, from the subject's perspective.	☐
Disclosure of any possible risks or discomforts.	☐
Contact information for the study team and the STC IRB, in case of questions from subjects.	☐
If any subjects are likely to participate in a language other than English: Non-English language informed consent materials will be available, and these materials are included in this application.	☐

Q34. Request for Waiver. The IRB can wave or alter elements of the informed consent process under certain conditions. To apply for such a waiver, check the following box and then answer the supplemental questions. The answer to the other questions on this page should clearly support the need for a waiver or modification. If not requesting a waiver, skip this question.

I request a waiver of informed consent and/or the documentation of informed consent. ☐

Supplemental: Does each of the following describe the study or its waiver of informed consent?	**Yes**	**No**
The study presents no more than Minimal Risk to research subjects.	☐	☐
The data collection could not practicably be carried out without a waiver for informed consent, and/or a waiver for the documentation of informed consent.	☐	☐
The only record linking subjects to their study data would be the informed consent documentation.	☐	☐
Waiving documentation of informed consent will not adversely affect the rights and welfare of the subject.	☐	☐
The subjects or their legally authorized representations will be provided pertinent information after participation (as opposed to beforehand as part of the consent documentation).	☐	☐
The subjects or their legally authorized representatives are members of a distinct community in which signing forms is not the norm, and an alternative method of documenting consent is provided.	☐	☐

AFFIRMATION

Below we ask you to affirm that your application is truthful, and that you understand certain policies covering human subjects research at South Texas College. Please check each box and then initial at bottom.

- ☐ The information in this application is a truthful representation of my study.
- ☐ I have not failed to include any details that are relevant to judgments of risk, research ethics, conflicts of interest or payments to STC persons.
- ☐ I understand that IRB approval relates to research ethics alone, and does not constitute a blanket approval to conduct research at South Texas College. I understand the study may require approvals from other offices of STC.
- ☐ I understand that my submission must include the final drafts of all protocols or instruments, including survey questionnaires, focus group protocols, or similar.
- ☐ Should there be any changes to these protocols or instruments, I understand that I must come back to the IRB to seek approval for the new materials before any data is collected.
- ☐ I agree to safeguard any data produced by STC, and to ensure its protection, confidentiality, and security.
- ☐ I understand that any data security breach, of any kind, must be reported to the IRB.
- ☐ After the study, I agree to delete permanently all copies of STC data and such identifying information unnecessary to the study.
- ☐ After the study, I understand that I should provide a copy of the final report to the IRB.
- ☐ The IRB's approval is valid for one year. If the study is not completed within one year, I understand that I must file for a Continuation.

Initials of Principal Investigator: Date:

Typed initials are acceptable.

South Texas College
Institutional Review Board
Application for Human Subjects Research
Instructions

Thank you for your interest in conducting research at South Texas College. STC considers support for academic research to be a key component of its pledge to the people of the Rio Grande Valley.

South Texas College accepts only completed applications that it deems sufficient for the Institutional Review Board to make its decision. Upon receipt of materials, the Institutional Review Board (IRB) staff will notify the Applicant whether the submission is sufficient or if further clarification is required.

THE IRB PROCESS AT SOUTH TEXAS COLLEGE

From the Applicant's perspective, the IRB process at South Texas College proceeds as follows:

1. *Submission*. The Applicant submits all elements of this application, including all supplementary materials.
2. *Staff Pre-Review*. The IRB staff reviews the submission for completeness. If incomplete, the staff specifies what specific additional materials are necessary.
3. *Acceptance*. After submitting a complete application, the Applicant receives an e-mail receipt. The IRB's formal review begins at this point.
4. *IRB Review*. The IRB applies the criteria of the Common Rule and makes a determination.
    - In general, the IRB tries to make an initial decision within two weeks after acceptance. However, this timeframe is only an estimate. Circumstances such as college breaks, staff requirements, or the convening of the full Board may cause the IRB to take additional time for its review.
5. *IRB Outcome*. The IRB provides a written memo of its decision to the Applicant.

REQUIREMENTS FOR COMPLETE APPLICATIONS

- Be concise in your responses in this application, and use only the space provided. Applicants may modify their responses in order to fit in the space provided, e.g. shortening the title of the study,
    - Please note that the title of your study (as submitted) and the name of your home institution will be published on the STC IRB Web page. Please ensure the study title is appropriate for this venue.
- All materials, including all fields in this form, must be clearly legible. The standard the IRB applies is, if the submission materials were printed out, would all responses be legible on the page?
- Precisely define the population for the study.
- Submit only the final drafts of all survey questionnaires, focus group protocols, or similar study instruments.
- Ensure that any required Informed Consent notices are included with the application and contain all necessary elements required.
- Include verification of the Principal Investigator's successful completion of research ethics training, e.g. by CITI, ACRP, PHRP, or some other provider acceptable to the US Department of Health & Human Services.

REQUIREMENTS FOR COMPLETE APPLICATIONS (CONTINUED)

- Researchers conducting their studies under the auspices of another institution, whether faculty or graduate students, should apply to their home-institution IRB first, and then apply to STC for "Site Approval." Applicants must include their home-institution approval memo with their STC application.
    - For those researchers whose home institutions require approval from research sites before the IRB will act, the STC IRB can issue "Site Acknowledgment." This document constitutes neither site approval nor final determination, but should be acceptable to the home institution IRB.
- Be sure to sign or initial as required. Be sure to place your surname in the indicated page headers.

REQUIREMENTS WHILE CONDUCTING THE STUDY

- Should there be any changes to survey questionnaires, focus group protocols, or similar study instruments, Applicants must come back to the IRB to seek approval for the new materials before any data is collected.
    - The study must halt until the new materials are approved by the IRB.
- After completion of the study, the Applicant must deposit a final copy of the report or paper with the STC IRB.
- The IRB's approval is valid for one year. If the study is not completed within one year, Applicants must file for a Continuation.
- Any data security breaches must be reported to the IRB immediately.

CONTINUATION OR AMENDMENT

- If this is an application for amendment or continuation, Applicants must include the original STC IRB Approval Memo with their materials.
- Applicants may submit only those aspects of their materials that differ from the initial approved application. Include the required signatures.

This document may not specify all written policies adopted by the IRB in their entirety.

US HHS APPROVED RESEARCH ETHICS TRAINING SUPPLIERS

- CITI <http://about.citiprogram.org> (cost: ~$300)
- PHRP <http://phrptraining.com> (~$50)
- ACRP <http://acrpnet.org/courses/ethics-human-subject-protection/> ($0 w/o contact hours)

IRB CONTACT INFORMATION

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SOUTH TEXAS COLLEGE BOARD POLICY #3840

"All parties wishing to conduct human-subject research involving the college, its students or its personnel, at or on behalf of the College, must comply with all IRB guidelines, submit a request to the IRB for permission to conduct their study and obtain IRB authorization prior to conducting their studies." – adopted by the Board of Trustees, July 2005