For IRB Use Only	
File Number:	
Approval	

Exempt Review Application

Institutional Review Board IRB), Texas A&M University-Commerce

Section I: Filling Out and Saving the Form

Save this file as a Word document on your computer, answer all questions completely within Word, and submit it along with all supplemental documents to ResearchCompliance@tamuc.edu. For Mac Users: To select your response for each check box, click on the appropriate check box and then hit the space bar to place an "X" in the box to indicate your answer.

Section II: Does this Form Apply?

Please click the box indicating your answer to **each** of the following questions.

1. Will your research study involve any vulnerable populations such as children, prisoners, and individuals with impaired decision-making abilities?	☐	Yes
	☐	No
2. Could public disclosure of any identifiable data you collect place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation?	☐	Yes
	☐	No
3. Will your study involve data collection procedures other than surveys, educational tests, interviews, or observation of public behavior?	☐	Yes
	☐	No
4. Will your study involve any sensitive subject matters such as: abortion, criminal activity, sexual activity, sexually transmitted diseases, prior diagnosis for mental health disorders, or victims of violence?	☐	Yes
	☐	No
5. Will your study involve audio-recording or video-recording the participants?	☐	Yes
	☐	No
6. Will your study involve obtaining individually identifiable information from health care plans, health care clearinghouses, or health care providers?	☐	Yes
	☐	No

If you answered YES to any of the above questions, your study will not meet the criteria for Exempt Review. Please fill out the Expedited or Full Board Application for your study.

Section III: General Information

Type only in the blue fields, and closely follow all stated length limits. Handwritten forms will not be accepted. Please include each part of the application as a separate doc file.

1. Title of Study

Must be identical to the title of any related internal or external grant proposal.

2. Investigator ☐

Must be a full-time TAMUC faculty member or a full-time staff employee whose job responsibilities include conducting human subjects research.

First Name	Last Name	TAMUC Email Address

TAMUC Dept.	TAMUC Building & Room Number	Office Phone Number

College

Title

3. Co-Investigator (if applicable)

First Name

Last Name

TAMUC E-mail Address

TAMUC Department or University

Title

4. Additional Personnel

List the names & emails of all other Additional Personnel (including students) who are responsible for the design, conduct, or reporting of the study (including recruitment or data collection).

CITI IRB Training

Have all Additional Personnel completed the CITI IRB training course ("Human Subjects Research") and (*Responsible Conduct of Research*)? Please attach the completion certificate.

☐ Yes

☐ No

If you answered "No," this training is required for all Personnel before your study can be approved. The CITI IRB course may be accessed by visiting: https://www.citiprogram.org/.

6. Funding Information (if applicable)

Has external or internal funding been proposed or awarded for this project?

☐ Yes

☐ No

If yes, please submit the statement of work or a project summary and provide the proposal number or project ID number for any external funding or the number for any internal funding for this project.

7. Purpose of Study and Methodology

Briefly state the purpose and methodology of your study in **lay language,** including the **research question**(s) (or hypotheses) you intend to answer. A brief summary of what you write here should be included in the informed consent form. **Methodology should include name of all instruments and data analysis as well as procedures.**

8. Recruitment of Participants

Describe the projected number of subjects.

Describe the population from which subjects will be recruited (including gender, racial/ethnic composition, and age range).

Describe how you will recruit subjects (face-to-face, e-mail, flyer, classroom announcement, etc.).

Have you attached a copy of all recruitment materials such as flyers, e-mails, and scripts for classroom announcements?

☐ Yes

☐ No

9. Location of Study

Identify **all locations** where the study will be conducted (Please be specific (e.g. school, room number, lab.)

For data collection sites other than TAMUC, have you attached a signed and dated letter on the cooperating institution's letterhead giving approval for data collection at that site?

☐ Yes

☐ No

10. Informed Consent

Describe the steps for obtaining the subjects' informed consent (by whom, where, when, and how written documentation of informed consent will be obtained. If subjects are being recruited from a classroom or other group, please specify how you will maintain the participants' confidentiality regarding who does or does not participate.)

11. Informed Consent Forms

Written informed consent forms to be signed by the subject after IRB approval are required for most research projects with human participants (exceptions include telephone surveys, internet surveys, and other circumstances where the subject is not present; an informed consent notice may be substituted.) Written consent includes electronic signatures of consent. Templates for creating informed consent forms are located on the IRB website at http://www.tamuc.edu/research/compliance/humanSubjectsIRB.aspx. **Final drafts of all informed consent documents you plan to use must be submitted before IRB review can begin.**

12. Languages other than English

Will your study involve the use of any language other than English for informed consent forms, data collection instruments, or recruitment materials?

☐ Yes

☐ No

If "Yes," after the IRB has notified you of the approval of the English version of your forms, you must then submit the other than English language versions along with a back-translation for each. Specify all Languages other than English below:

13. Data Collection

Which methods will you use to collect data? Please check all that apply. Include copies of all data instruments in addition to any online links.

☐ Interviews

☐ Surveys (Please provide active link if online survey)

☐ Focus Groups

☐ Review of Existing Records

☐ Observation

☐ Other – Please list below.

If "Focus Groups" and/or "Interviews" were checked above, please include your questions, detail the procedure or protocol for asking the questions and describe how you will record the data from the focus group. Explain what research question(s) this data will be used to answer and what type of data analysis will be done.

If "Review of Existing Records" and/or "Observation" are checked above, please describe below the records you plan to review and/or the observations you plan to make for your study. Include your observational rubric and detail why this is an appropriate instrument. Explain what research question(s) this data will be used to answer and what type of analysis will be done.

Have you attached a copy of all data collection instruments, observation rubrics, interview scripts, and focus group topics, and intervention protocols to be used?

☐ Yes

☐ No

What is the estimated time for a subject's participation in each study activity (including time per session and total number of sessions)? Be specific. If participants are completing more than one task, write each data instrument and time required. Then add up total time involved. Explain what research question(s) or hypotheses this data will be used to answer and what type of data analysis will be done.

14. Compensation

Describe any compensation subjects will receive for participating in the study. Include the timing for payment and any conditions for receipt of such compensation. If extra credit for a course is offered, an alternative non-research activity with equivalent time and effort must also be offered.

15. Risks and Benefits

Describe any foreseeable risks to subjects presented by the proposed study and the precautions you will take to minimize such risks.

Describe the anticipated benefits to subjects or others (including your field of study).

16. Confidentiality

Describe the procedures you will use to maintain the confidentiality of any personally identifiable data.

Please specify where your research records will be maintained, any coding or other steps you will take to separate participants' names/identities from research data, and how long you will retain personally identifiable data in your research records. Federal IRB regulations require that the investigator's research records be maintained for 3 years following the end of the study. **If this study is being performed by a TAMUC student, the data must be placed in the major advisors' office (or secure departmental location) after the thesis/dissertation is completed.** After 3 years, all identifiable data should be destroyed.)

17. Publication of Results

Please identify all methods in which you may publicly disseminate the results of your study.

- ☐ Academic Journal
- ☐ Academic Conference Paper or Public Poster Session
- ☐ Book or Chapter
- ☐ A Thesis or Dissertation for One of Your Students
- ☐ Other – Please list below. (Website, blog, etc.)

Principal Investigator

☐ By checking this box and e-mailing this application to the OSP from my TAMUC e-mail, I am certifying that the information in this application is complete and accurate. I agree that this study will be conducted in accordance with the

IRB Guidelines and the study procedures and forms approved by the IRB.

Electronic Submission Checklist

1. Attach all supplementary documents, including:

    a. Copies of all CITI IRB Training completion certificates;
    b. A copy of the statement of work or project summary for any internal or external funding for this study;
    c. A copy of all recruitment materials;
    d. A copy of the approval letter from each data collection site (other than TAMUC);
    e. A copy of all informed consent forms or notices; and
    f. A copy of all data collection instruments, interview scripts, focus group topics, intervention protocols and active internet link, if using website.

2. The application and all supplementary documents must be **e-mailed from the Investigator's TAMUC e-mail to researchcompliance@tamuc.edu** . Please insert "Exempt Review" in the subject line of your email.