**Expedited or Full Board Review Application**

File Number:

Approval Date:

**For IRB Use Only**

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

***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.***

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 Department | 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 and email addresses of all other Additional Personnel (including students) who are responsible for the design, conduct, or reporting of the study (including recruitment or data collection).  |
|  |
|  |
| **5. CITI IRB Training** |
| Have all personnel completed the CITI IRB training course (“Human Subjects Research”) and (“Responsible Conduct of Research”)? Please attach the completion certificates. |
| [ ]  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)** 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. Previous Research** |
| Brieflysummarize previous research leading to the formulation of this study, including any past or current research conducted by the Investigator that leads directly to the formulation of this study (including citations and references.) |
|  |
|  |
| **9. 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 |
| **10. Vulnerable Populations** |
| Please Identify any vulnerable populations who will be participating in this study: |
| [ ]  Children (under 18 years of age)[ ]  Prisoners | [ ]  Individuals with impaired decision-making ability |
| If any boxes are checked, describe any special precautions to be taken in your study due to the inclusion of these populations. |
|  |
|  |
| **11. Location of Study** |
| Identify all locations where the study will be conducted. |
|       |
|  |
|

|  |
| --- |
|  |
|  |

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 |

|  |
| --- |
| **12. 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 classroom or other group, please specify how you will maintain confidentiality regarding who does or does not participate.) |
|  |

|  |
| --- |
| **13. 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/humanSubjectsIRB.aspx>**. Final drafts of all informed consent documents you plan to use must be submitted before IRB review can begin.**[ ]  **Yes**[ ]  **No** |

|  |
| --- |
| **14. 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: |
|  |
| **15. Data Collection** |
| Which methods will you use to collect data? Include copies of all data instruments in addition to any online links. Please check all that apply: |
| [ ]  Interviews[ ]  Surveys[ ]  Focus Groups[ ]  Assessment Instruments | [ ]  Internet Surveys (please provide URL link in Other  space below)[ ]  Review of Existing Records[ ]  Observation[ ]  Other - Please list below |
|  |  |
|  |
| 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. |
|  |
|  |
| Will your study involve **audio-recording** the participants?[ ]  Yes[ ]  NoWill you study involve **video-recording** the participants? |
| [ ]  Yes[ ]  No |
| Have you attached a copy of all data collection instruments, interview scripts, observation rubrics, 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)? |
|  |

|  |
| --- |
| **16. 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. |
|  |
| **17. 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). |
|       |

|  |
| --- |
| **18. Confidentiality** |
| Describe the procedures you will use to maintain the confidentiality of any personally identifiable data. If you are audio or video-recording the participants, please outline in detail how you will protect the participants’ identities through management of the recordings. |
|       |
|  |
| 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. If you are audio or video-recording the participants, please detail how you will maintain and when you will destroy the recordings. Federal IRB regulations require that the investigator's research records be maintained for 3 years following the end of the study.  |
|       |
|  |
| **19. 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 Certification**

[ ]  By checking this box and e-mailing this application to Research Compliance 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:
	1. Copies of all CITI IRB Training completion certificates;
	2. A copy of the statement of work or project summary for any internal or external funding for this study;
	3. A copy of all recruitment materials;
	4. A copy of the approval letter from each data collection site (other than TAMUC);
	5. A copy of all informed consent forms or notices; and
	6. 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 “Expedited or Full Board Review” in the subject line of your email.