Submitting to IRB Workshop

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TAMIU ARC

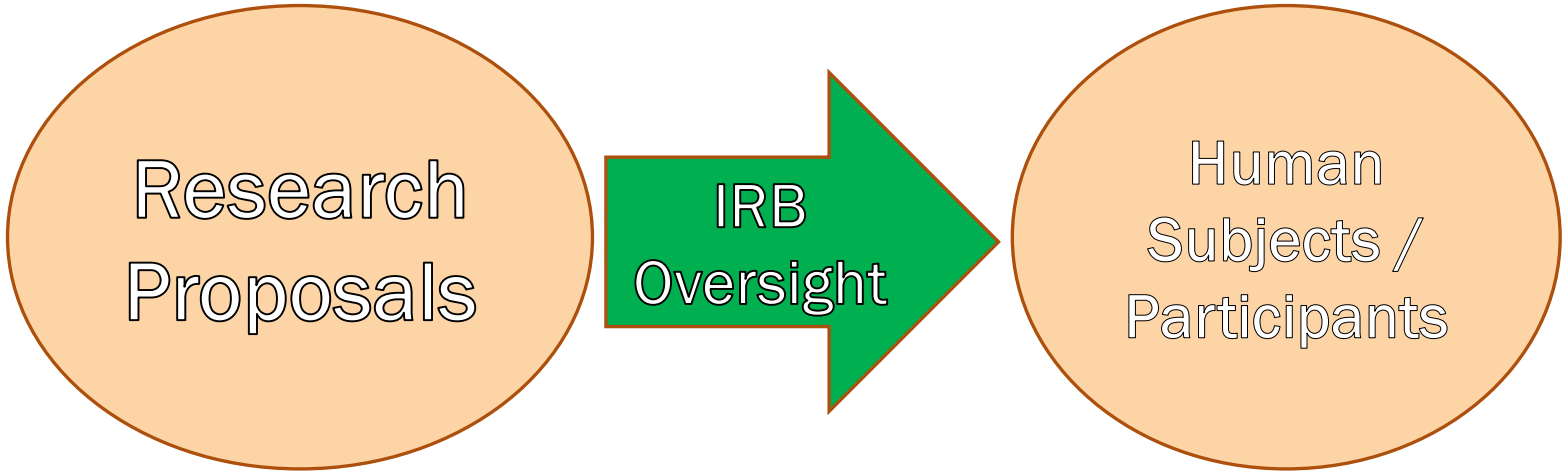
ADVANCING RESEARCH & CURRICULUM

Updated March 2022

This Presentation Will Cover:

- CITI Program Training Course & The Belmont Report
- Determining if Your Research Needs IRB Oversight or is Exempt Category 2
- IRB Protocol Application
- Consent Forms
- IRB Continuing Review Application/Unanticipated or Adverse Event Report
- IRB Completion Report

What is The Institutional Review Board?



Respect people and treat them with the personal dignity and autonomy that best represents academic integrity!

All research done at the university must be sent through IRB and students must have faculty mentors serve as their Principal Investigators and submit the IRB Protocol application.

ALL LINKS AND WEBSITES IN THIS PRESENTATION CAN ALSO BE FOUND AT TAMIU.EDU/IRB

The Institutional Review Board (IRB) is an appropriately constituted administrative body established to protect the rights and welfare of human subjects or patients recruited to participate in research activities conducted under the auspices of the Texas A&M International University faculty, employees, graduate, and undergraduate students or using members of the Texas A&M International community as subjects and regardless of the source of funding. In accordance with the regulations of the Department of Health and Human Services (DHHS,Office of Human Research Protection (OHRP)), the IRB has the authority to review and approve, require modifications in, or disapprove all research activities involving humans that fall within its jurisdiction.

As mandated by our Federal Wide Assurance with the federal government (45 CFR 46) and TAMU System Policy 15.99.01, all research projects involving human subjects, conducted by Texas A&M International University (or other agency of The Texas A&M International University) faculty, employees, graduate students, undergraduate students or postdoctoral fellows or using members of the Texas A&M International University Community as subjects (regardless of the source of funding), must be approved by the University's Institutional Review Board (IRB). Any outside agency performing research using Texas A&M International University facilities and using members of the Texas A&M International University community will first seek approval of the Texas A&M International University IRB.

CITI PROGRAM

CITI Program Training Course & The Belmont Report

CITI Training Course is Required

1. The **CITI program** is a nationally recognized training program, which allows you to self-enroll. Good for three years, this training is needed for all non-exempt projects.
2. The **Belmont Report** is required reading for members of the research community doing human subjects research and is also covered along with other materials in the CITI program training.

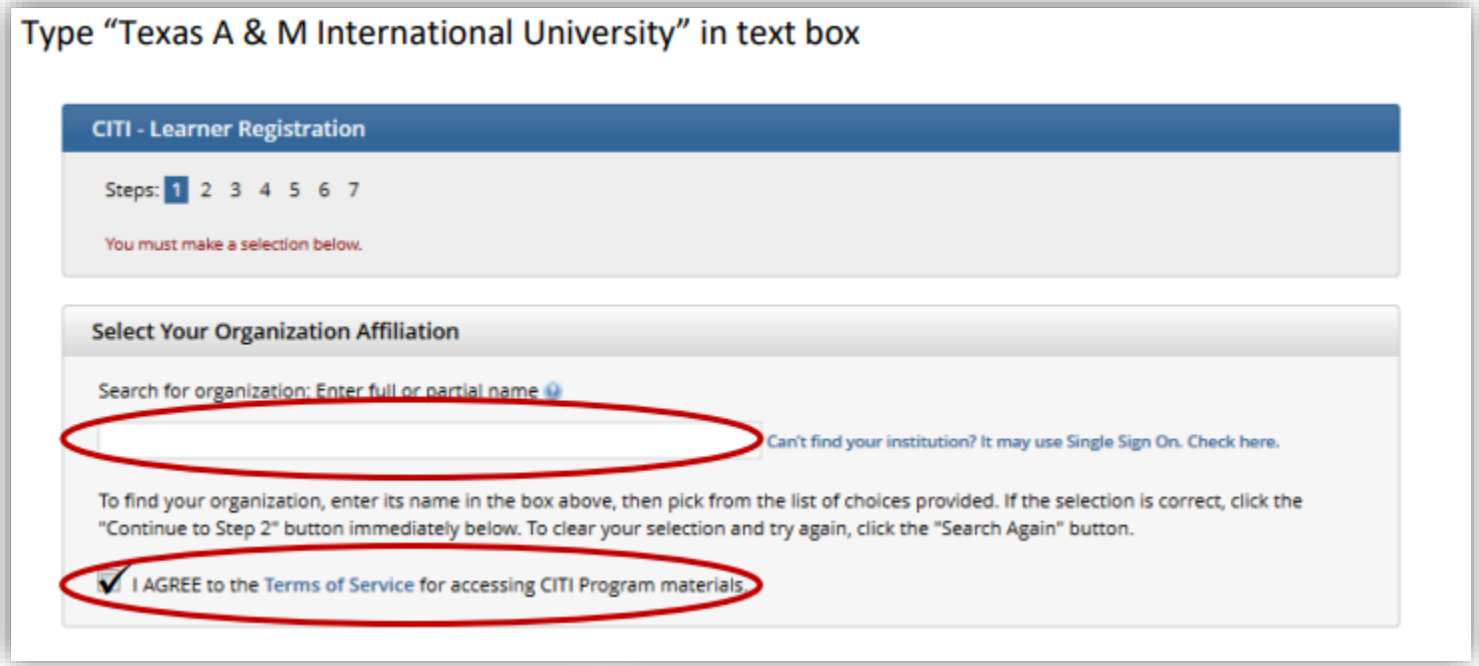
Click Here to Read the Belmont Report

How to Register for CITI Training

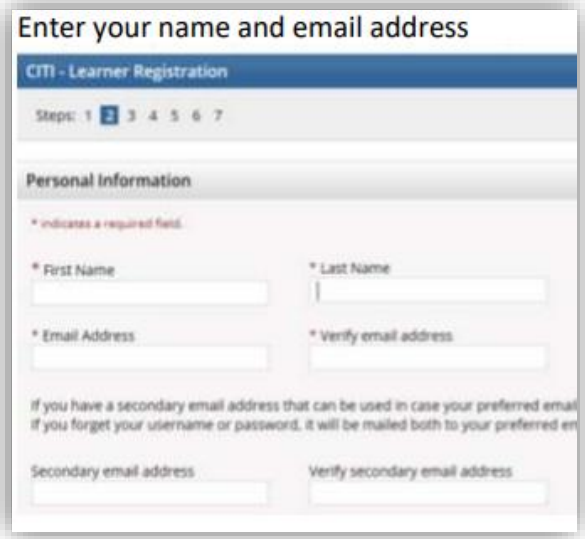
Go to: www.citiprogram.org

Click on "**Register**" to create username

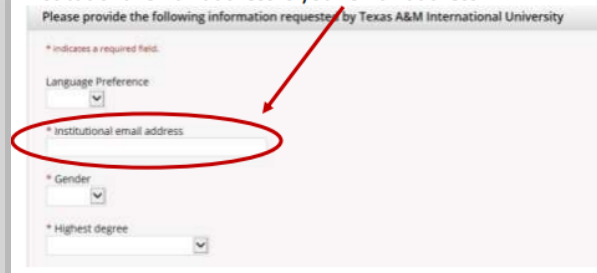
Type "Texas A & M International University" in text box



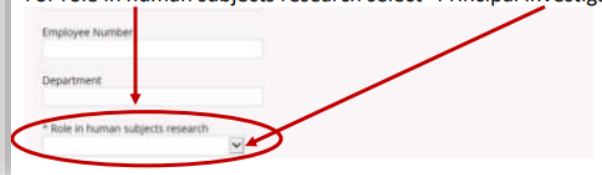
Enter your name and email address



Institutional email address is your email address.

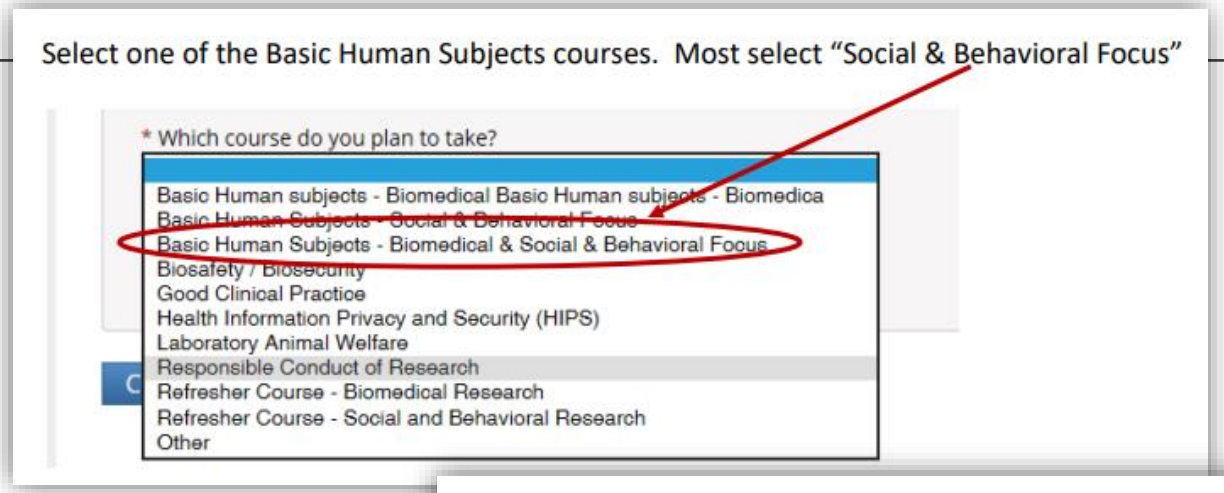


For role in human subjects research select "Principal Investigator" from the drop-down menu

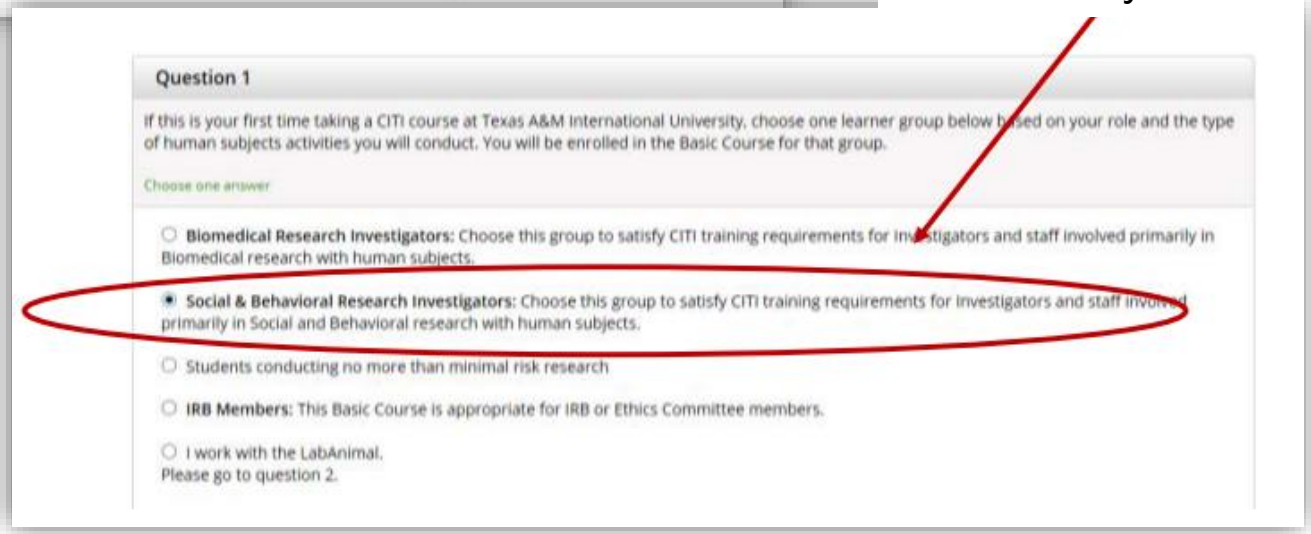


Which Training do I Sign up For?

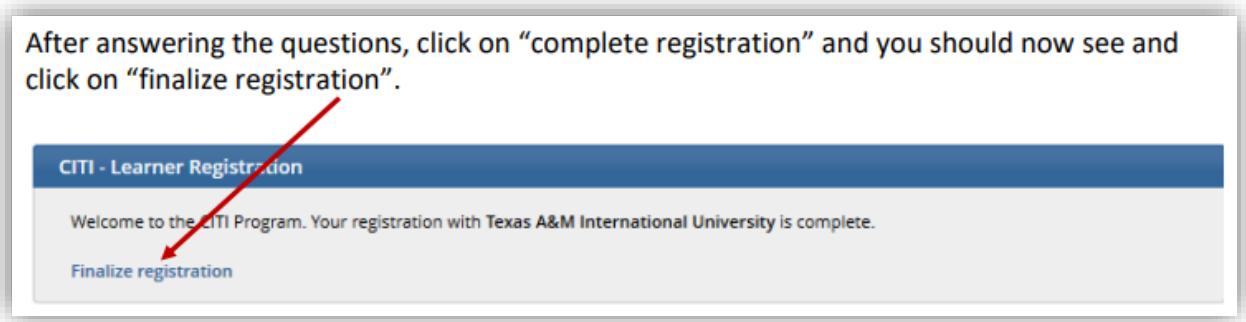
- Course required to conduct human subjects research:
  SOCIAL & BEHAVIORAL RESEARCH COURSE
- Course required to conduct biomedical research:
  BIOMEDICAL RESEARCH COURSE
- Course required if research is funded by the National Institutes of Health (NIH) or National Science Foundation (NSF):
  RESPONSIBLE CONDUCT OF RESEARCH
- Course required if research is funded by the TAMIU University Research Council:
  RESPONSIBLE CONDUCT OF RESEARCH <u>PLUS</u> ANY OTHER NECESSARY TRAININGS ACCORDING TO THE PROJECT



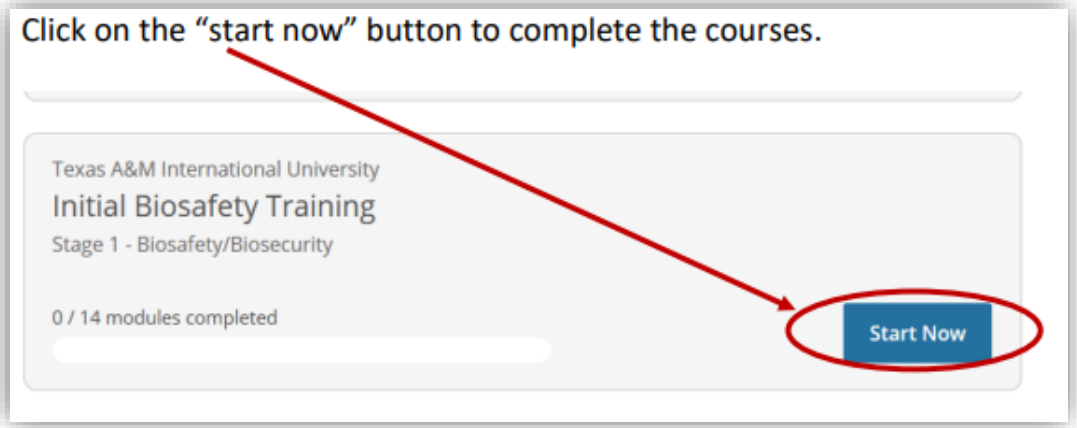
Select the options that are most relevant to you



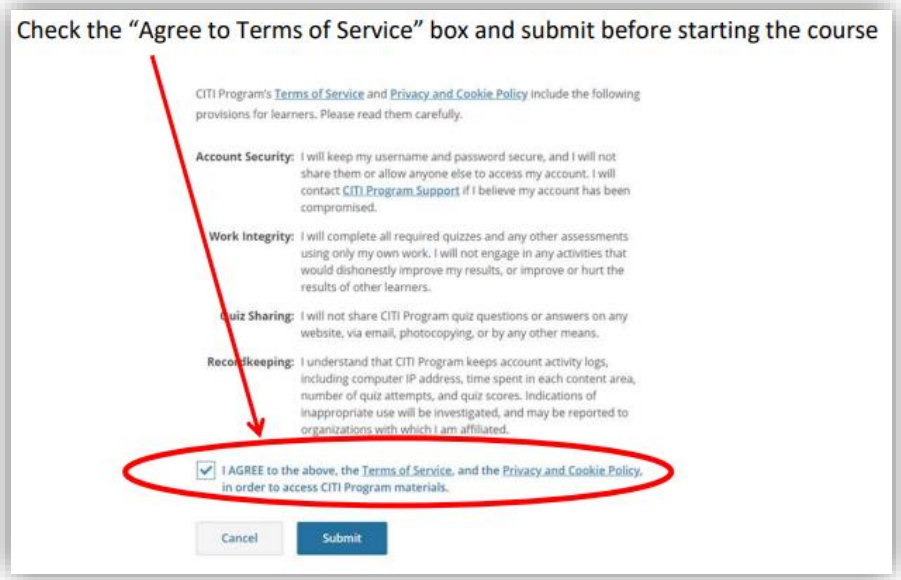
After answering the questions, click on “complete registration” and you should now see and click on “finalize registration”.



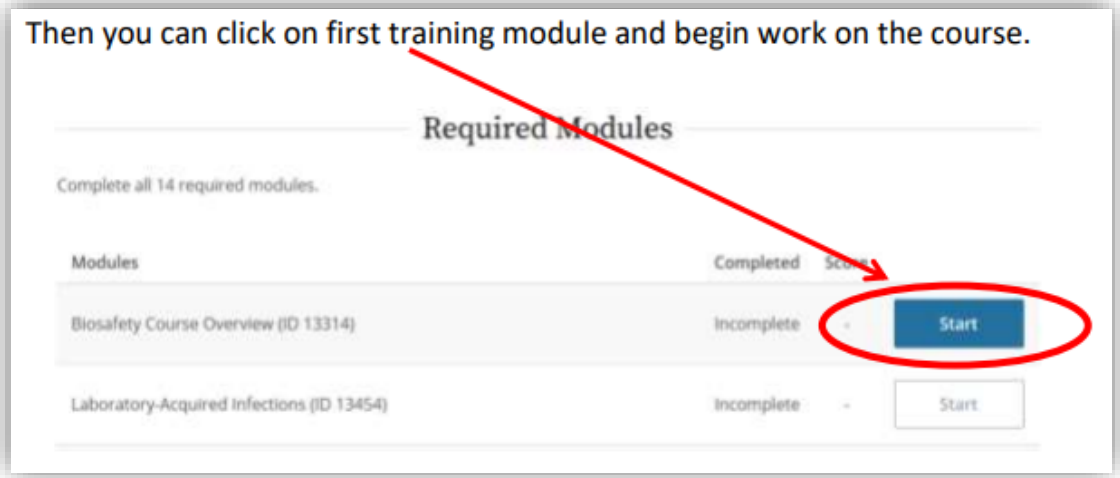
Click on the “start now” button to complete the courses.



Check the “Agree to Terms of Service” box and submit before starting the course



Then you can click on first training module and begin work on the course.



[For Full PDF Instructions Click Here]

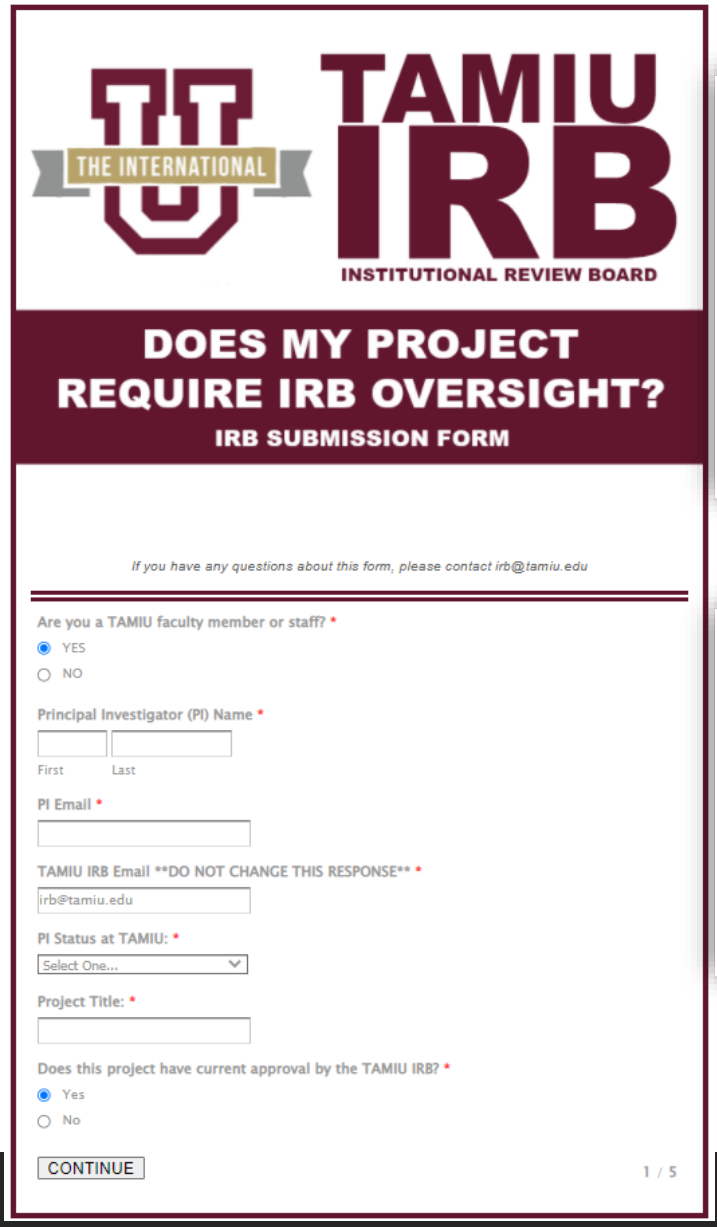
Does My Research Need IRB Oversight?

IRB ONLINE FORM

Is Exempt Category 2?

CATEGORY 2 ONLINE FORM

IMPORTANT REMINDER: Students cannot serve as the Principal Investigator (PI) on an IRB protocol. Their faculty mentor must be listed as the PI and submit the protocol application.


THE INTERNATIONAL

TAMIU IRB

INSTITUTIONAL REVIEW BOARD

DOES MY PROJECT REQUIRE IRB OVERSIGHT?

IRB SUBMISSION FORM

If you have any questions about this form, please contact irb@tamiu.edu

Are you a TAMIU faculty member or staff? *
- YES
- NO

Principal Investigator (PI) Name *

First Last

PI Email *

TAMIU IRB Email **DO NOT CHANGE THIS RESPONSE** *

irb@tamiu.edu

PI Status at TAMIU: *

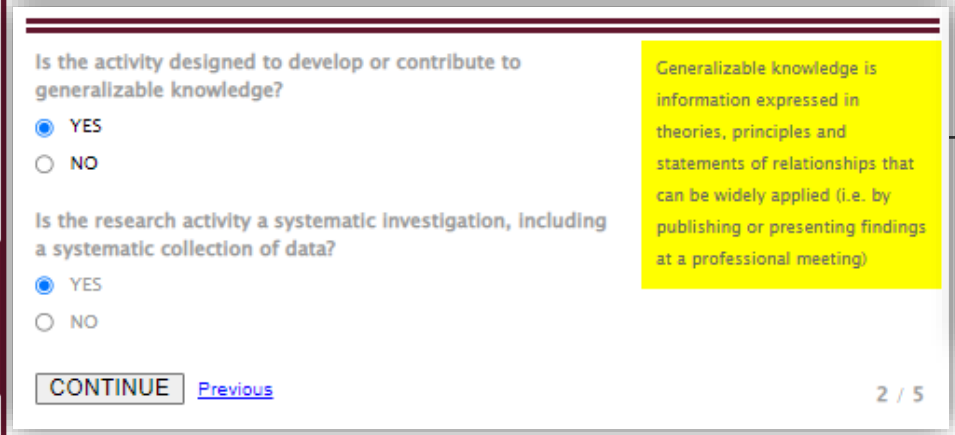
Select One...

Project Title: *

Does this project have current approval by the TAMIU IRB? *
- Yes
- No

CONTINUE

1 / 5

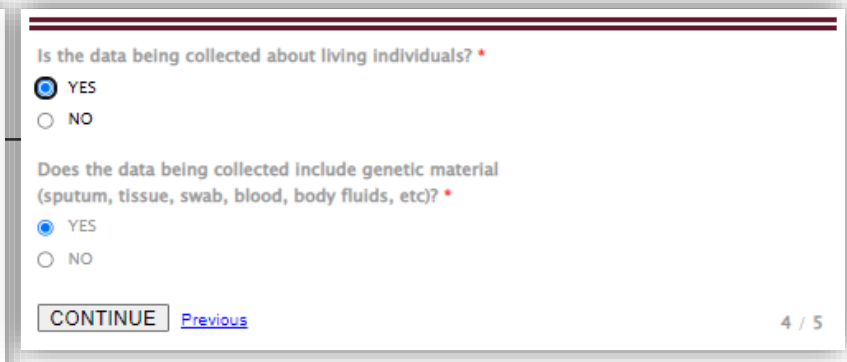

Is the activity designed to develop or contribute to generalizable knowledge?
- YES
- NO

Is the research activity a systematic investigation, including a systematic collection of data?
- YES
- NO

CONTINUE Previous

2 / 5

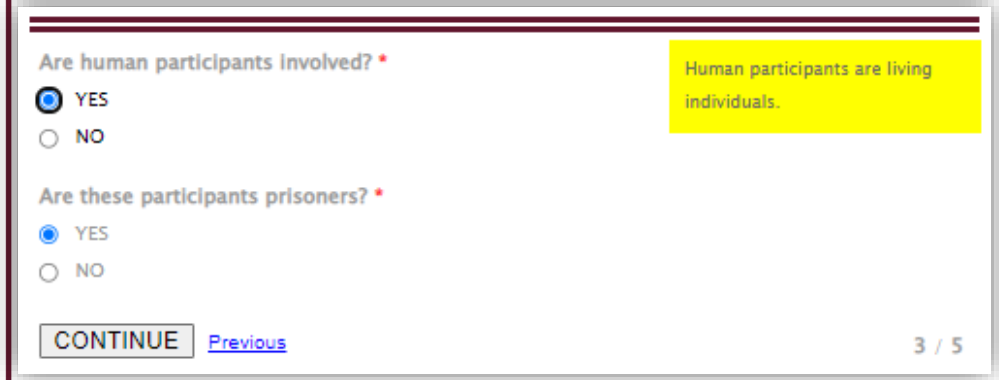
Generalizable knowledge is information expressed in theories, principles and statements of relationships that can be widely applied (i.e. by publishing or presenting findings at a professional meeting)


Is the data being collected about living individuals? *
- YES
- NO

Does the data being collected include genetic material (sputum, tissue, swab, blood, body fluids, etc)? *
- YES
- NO

CONTINUE Previous

4 / 5

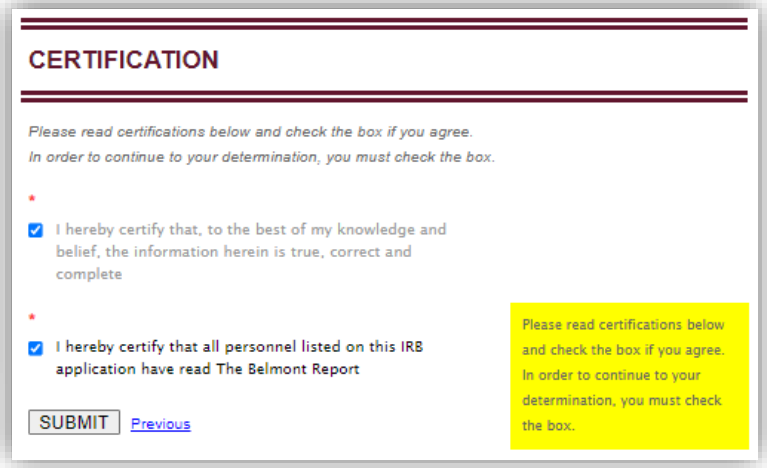

Are human participants involved? *
- YES
- NO

Are these participants prisoners? *
- YES
- NO

CONTINUE Previous

3 / 5

Human participants are living individuals.


CERTIFICATION

Please read certifications below and check the box if you agree.
In order to continue to your determination, you must check the box.

*
- [x] I hereby certify that, to the best of my knowledge and belief, the information herein is true, correct and complete

*
- [x] I hereby certify that all personnel listed on this IRB application have read The Belmont Report

SUBMIT Previous

Please read certifications below and check the box if you agree. In order to continue to your determination, you must check the box.

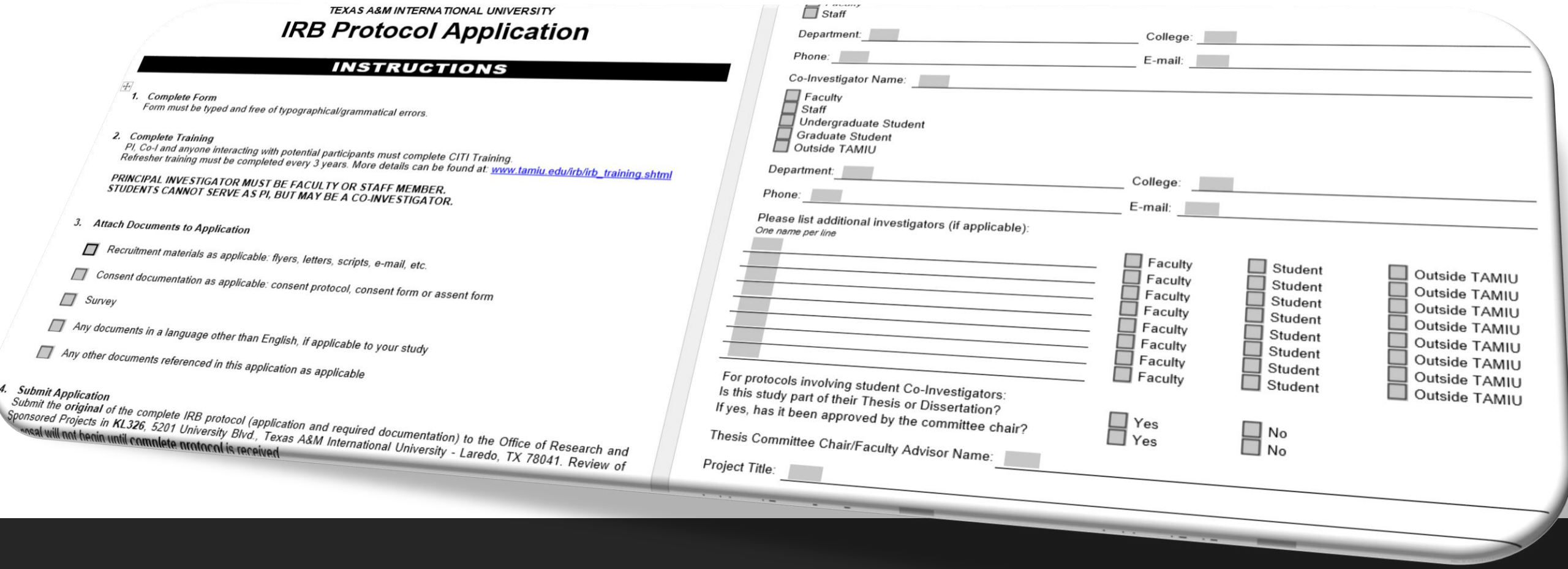
Exempt Category 2

All exempt protocols must still be submitted to the IRB.

Does your research include:

1. The identity of the human subjects that cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk
3. The identity of the human subjects that can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination.

Answered yes to any of these? Click here → CATEGORY 2 ONLINE FORM



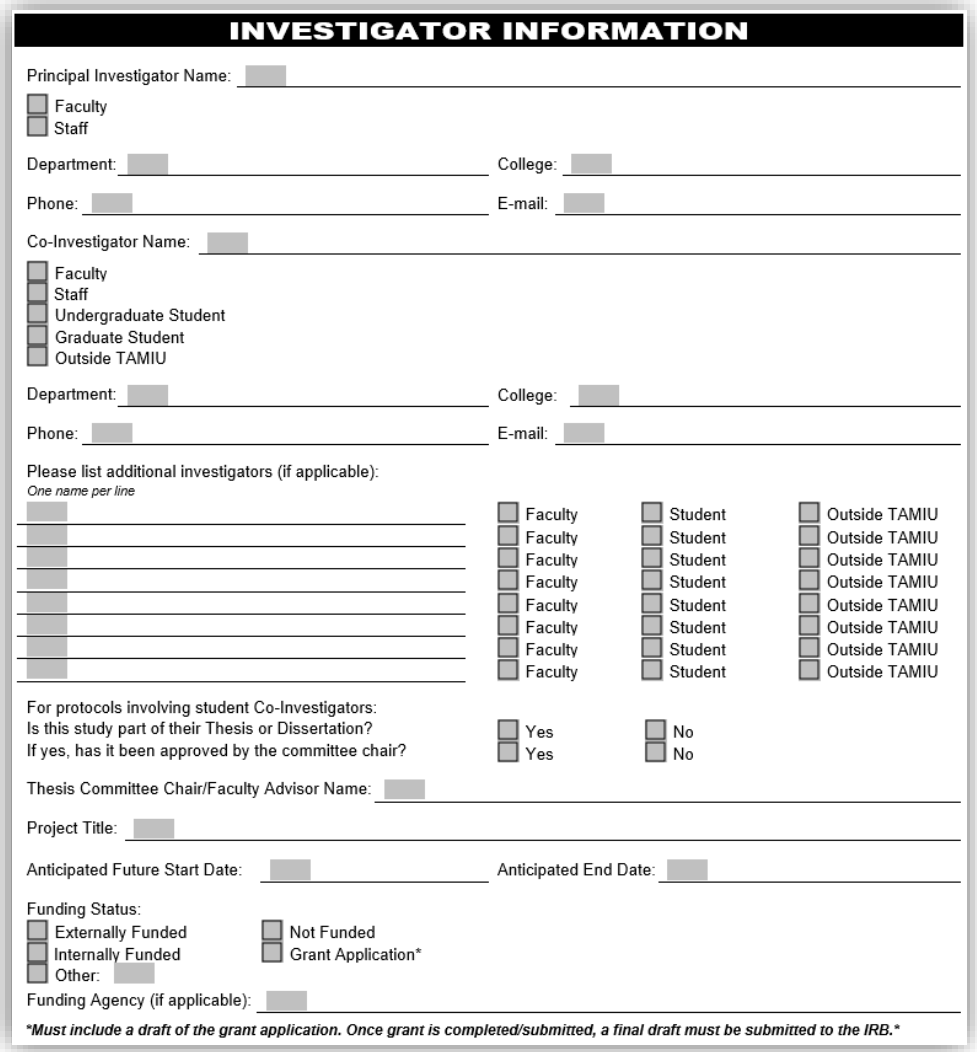
IRB Protocol Application

DO NOT BEGIN COLLECTING DATA UNTIL AFTER IRB APPROVAL

Ensure that all investigator info is correct

Be sure that your principal investigator is a faculty mentor if you are a student.

List any other faculty, students, or outside of university contacts and make sure they have completed CITI Training.



INVESTIGATOR INFORMATION

Principal Investigator Name: _____

☐ Faculty
☐ Staff

Department: _____ College: _____

Phone: _____ E-mail: _____

Co-Investigator Name: _____

☐ Faculty
☐ Staff
☐ Undergraduate Student
☐ Graduate Student
☐ Outside TAMIU

Department: _____ College: _____

Phone: _____ E-mail: _____

Please list additional investigators (if applicable):
One name per line

_____	☐ Faculty	☐ Student	☐ Outside TAMIU
_____	☐ Faculty	☐ Student	☐ Outside TAMIU
_____	☐ Faculty	☐ Student	☐ Outside TAMIU
_____	☐ Faculty	☐ Student	☐ Outside TAMIU
_____	☐ Faculty	☐ Student	☐ Outside TAMIU
_____	☐ Faculty	☐ Student	☐ Outside TAMIU
_____	☐ Faculty	☐ Student	☐ Outside TAMIU
_____	☐ Faculty	☐ Student	☐ Outside TAMIU

For protocols involving student Co-Investigators:
Is this study part of their Thesis or Dissertation? ☐ Yes ☐ No
If yes, has it been approved by the committee chair? ☐ Yes ☐ No

Thesis Committee Chair/Faculty Advisor Name: _____

Project Title: _____

Anticipated Future Start Date: _____ Anticipated End Date: _____

Funding Status:
☐ Externally Funded ☐ Not Funded
☐ Internally Funded ☐ Grant Application*
☐ Other: _____

Funding Agency (if applicable): _____

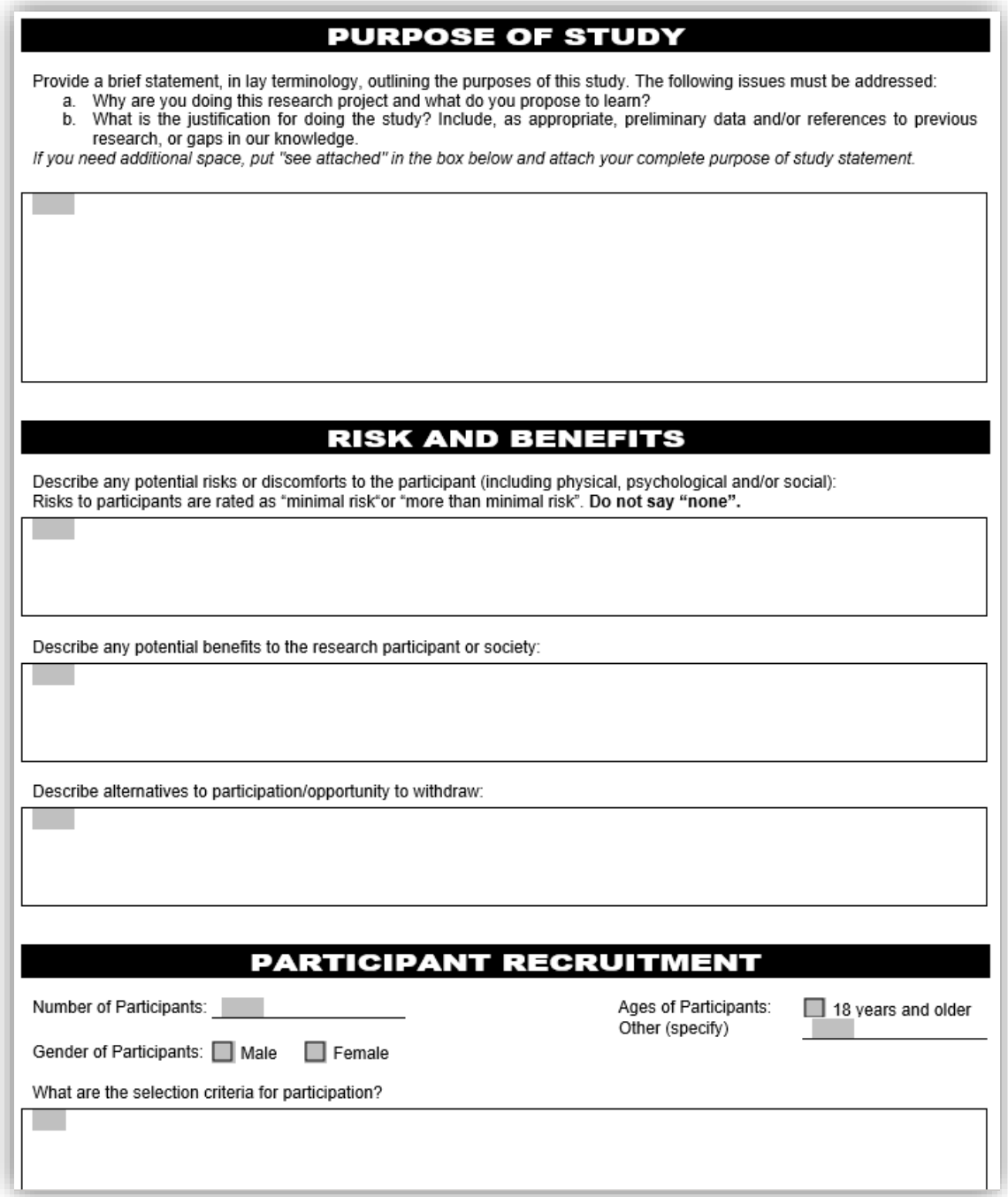
Must include a draft of the grant application. Once grant is completed/submitted, a final draft must be submitted to the IRB.

Click Here to Download this Form

Be clear and direct with your intentions

The purpose of your study should include as much relevant information as needed for the IRB to have a full understanding of your research.

*You can attach additional documents if needed.



PURPOSE OF STUDY

Provide a brief statement, in lay terminology, outlining the purposes of this study. The following issues must be addressed:

a. Why are you doing this research project and what do you propose to learn?
b. What is the justification for doing the study? Include, as appropriate, preliminary data and/or references to previous research, or gaps in our knowledge.

If you need additional space, put "see attached" in the box below and attach your complete purpose of study statement.

RISK AND BENEFITS

Describe any potential risks or discomforts to the participant (including physical, psychological and/or social):
Risks to participants are rated as "minimal risk"or "more than minimal risk". **Do not say "none".**

Describe any potential benefits to the research participant or society:

Describe alternatives to participation/opportunity to withdraw:

PARTICIPANT RECRUITMENT

Number of Participants: _____

Ages of Participants: ☐ 18 years and older
Other (specify) _____

Gender of Participants: ☐ Male ☐ Female

What are the selection criteria for participation?

Ensure you are getting appropriate consent to your participants

CONSENT

LOCATION

Describe the setting where the consent process will take place (*i.e. classroom, office, park, personal computer, etc.*):

PERSONNEL

Name individuals or group of individuals who will be speaking directly to potential participants during the consent process:

CONSENT TOOLS

Please check all that apply and **attach to the application**:

- ☐ Cover letter
- ☐ Information sheet
- ☐ Telephone script
- ☐ Consent form
- ☐ Minor assent form
- ☐ Parental consent form

WAIVER

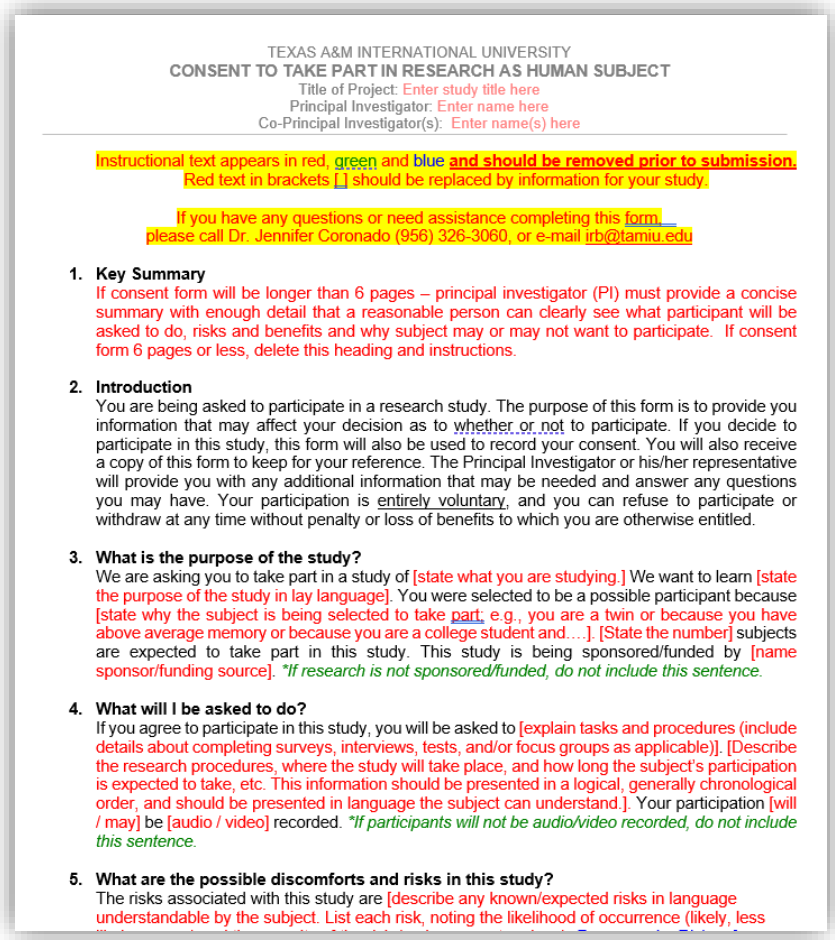
Request for waiver of documentation of informed consent:

- ☐ Yes
- ☐ No

If yes, explain below and submit information sheet:

Note: For almost all electronic surveys, PI should request a waiver of documentation of informed consent, documenting actual signature isn't usually possible.

General Consent Form Templates are Available online!



TEXAS A&M INTERNATIONAL UNIVERSITY
CONSENT TO TAKE PART IN RESEARCH AS HUMAN SUBJECT
Title of Project: Enter study title here
Principal Investigator: Enter name here
Co-Principal Investigator(s): Enter name(s) here

Instructional text appears in red, green and blue **and should be removed prior to submission.**
Red text in brackets [] should be replaced by information for your study.

If you have any questions or need assistance completing this form, please call Dr. Jennifer Coronado (956) 326-3060, or e-mail irb@tamiu.edu

1. **Key Summary**
   If consent form will be longer than 6 pages – principal investigator (PI) must provide a concise summary with enough detail that a reasonable person can clearly see what participant will be asked to do, risks and benefits and why subject may or may not want to participate. If consent form 6 pages or less, delete this heading and instructions.

2. **Introduction**
   You are being asked to participate in a research study. The purpose of this form is to provide you information that may affect your decision as to whether or not to participate. If you decide to participate in this study, this form will also be used to record your consent. You will also receive a copy of this form to keep for your reference. The Principal Investigator or his/her representative will provide you with any additional information that may be needed and answer any questions you may have. Your participation is entirely voluntary, and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

3. **What is the purpose of the study?**
   We are asking you to take part in a study of [state what you are studying.] We want to learn [state the purpose of the study in lay language]. You were selected to be a possible participant because [state why the subject is being selected to take part; e.g., you are a twin or because you have above average memory or because you are a college student and….]. [State the number] subjects are expected to take part in this study. This study is being sponsored/funded by [name sponsor/funding source]. **If research is not sponsored/funded, do not include this sentence.*

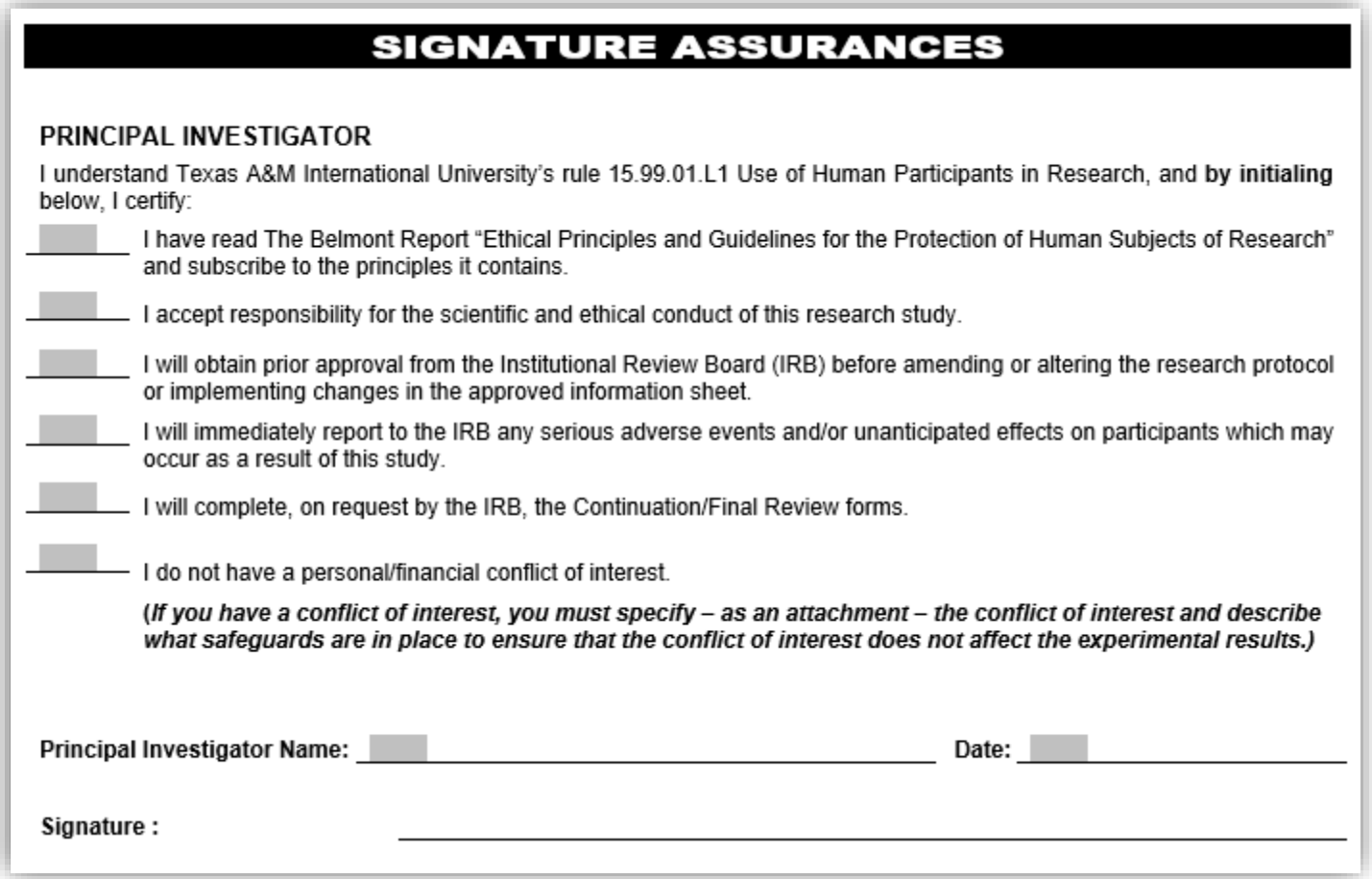
4. **What will I be asked to do?**
   If you agree to participate in this study, you will be asked to [explain tasks and procedures (include details about completing surveys, interviews, tests, and/or focus groups as applicable)]. [Describe the research procedures, where the study will take place, and how long the subject's participation is expected to take, etc. This information should be presented in a logical, generally chronological order, and should be presented in language the subject can understand.]. Your participation [will / may] be [audio / video] recorded. **If participants will not be audio/video recorded, do not include this sentence.*

5. **What are the possible discomforts and risks in this study?**
   The risks associated with this study are [describe any known/expected risks in language understandable by the subject. List each risk, noting the likelihood of occurrence (likely, less

Click Here to Download this Template

Signature Assurances

These certifications mention the Belmont Report, IRB Approval before collecting data, reporting of changes in your study, and submittal of continuation/final review forms.



SIGNATURE ASSURANCES

PRINCIPAL INVESTIGATOR

I understand Texas A&M International University's rule 15.99.01.L1 Use of Human Participants in Research, and **by initialing** below, I certify:

_____ I have read The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles it contains.

_____ I accept responsibility for the scientific and ethical conduct of this research study.

_____ I will obtain prior approval from the Institutional Review Board (IRB) before amending or altering the research protocol or implementing changes in the approved information sheet.

_____ I will immediately report to the IRB any serious adverse events and/or unanticipated effects on participants which may occur as a result of this study.

_____ I will complete, on request by the IRB, the Continuation/Final Review forms.

_____ I do not have a personal/financial conflict of interest.

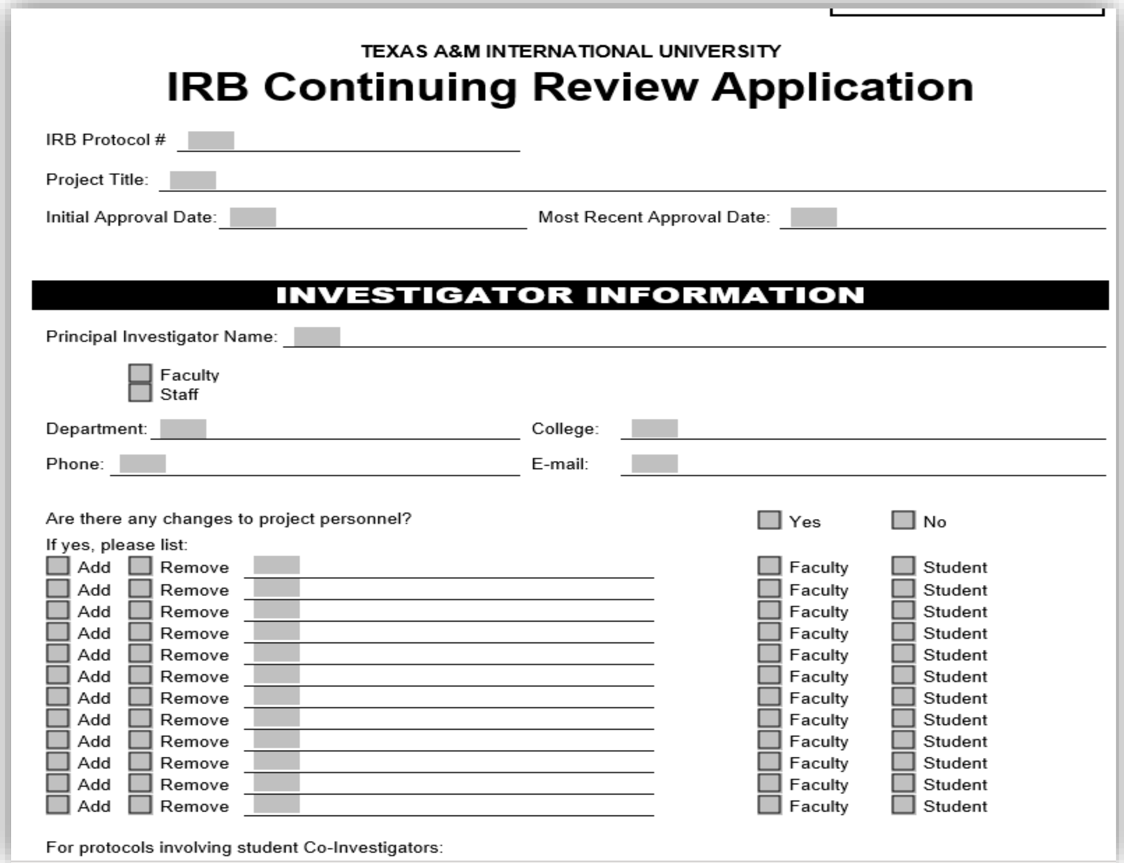
(If you have a conflict of interest, you must specify – as an attachment – the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)

Principal Investigator Name: _____ **Date:** _____

Signature : _____

9 months after you receive your determination letter, the IRB will start emailing the principal investigator listed on the protocol to request a status update on whether the protocol will remain active beyond the initial year.

No paperwork will be required to keep protocols active for more than 1 year of use, excepting those protocols that were reviewed at the Full Review level. For those studies, a **Continuing Review Form** will still need to be submitted.



TEXAS A&M INTERNATIONAL UNIVERSITY

IRB Continuing Review Application

IRB Protocol #

Project Title:

Initial Approval Date: Most Recent Approval Date:

INVESTIGATOR INFORMATION

Principal Investigator Name:

☐ Faculty
☐ Staff

Department: College:

Phone: E-mail:

Are there any changes to project personnel? ☐ Yes ☐ No

If yes, please list:

☐ Add	☐ Remove		☐ Faculty	☐ Student
☐ Add	☐ Remove		☐ Faculty	☐ Student
☐ Add	☐ Remove		☐ Faculty	☐ Student
☐ Add	☐ Remove		☐ Faculty	☐ Student
☐ Add	☐ Remove		☐ Faculty	☐ Student
☐ Add	☐ Remove		☐ Faculty	☐ Student
☐ Add	☐ Remove		☐ Faculty	☐ Student
☐ Add	☐ Remove		☐ Faculty	☐ Student
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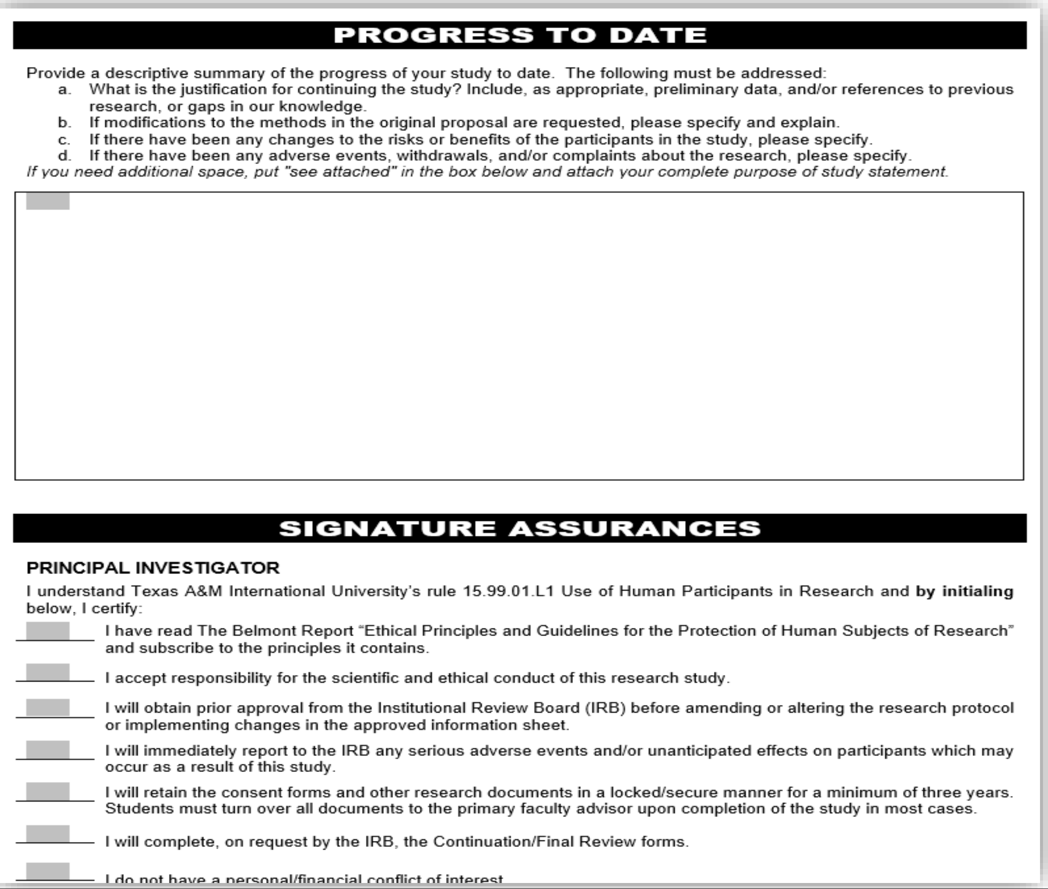
☐ Add	☐ Remove		☐ Faculty	☐ Student

For protocols involving student Co-Investigators:

Download Form



PROGRESS TO DATE

Provide a descriptive summary of the progress of your study to date. The following must be addressed:

a. What is the justification for continuing the study? Include, as appropriate, preliminary data, and/or references to previous research, or gaps in our knowledge.
b. If modifications to the methods in the original proposal are requested, please specify and explain.
c. If there have been any changes to the risks or benefits of the participants in the study, please specify.
d. If there have been any adverse events, withdrawals, and/or complaints about the research, please specify.

If you need additional space, put "see attached" in the box below and attach your complete purpose of study statement.

SIGNATURE ASSURANCES

PRINCIPAL INVESTIGATOR

I understand Texas A&M International University's rule 15.99.01.L1 Use of Human Participants in Research and **by initialing** below, I certify:

I have read The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles it contains.

I accept responsibility for the scientific and ethical conduct of this research study.

I will obtain prior approval from the Institutional Review Board (IRB) before amending or altering the research protocol or implementing changes in the approved information sheet.

I will immediately report to the IRB any serious adverse events and/or unanticipated effects on participants which may occur as a result of this study.

I will retain the consent forms and other research documents in a locked/secure manner for a minimum of three years. Students must turn over all documents to the primary faculty advisor upon completion of the study in most cases.

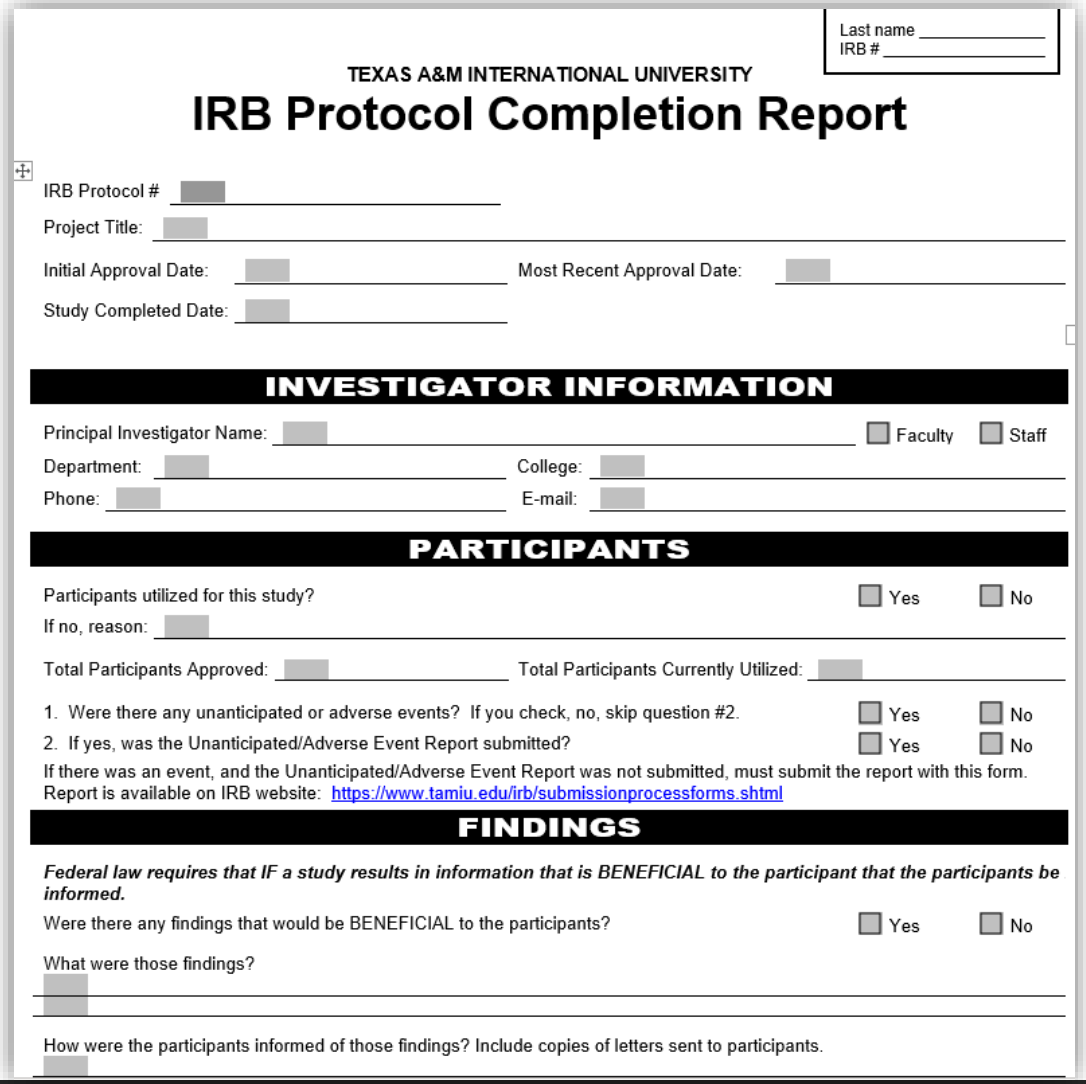
I will complete, on request by the IRB, the Continuation/Final Review forms.

I do not have a personal/financial conflict of interest.

Continuing Review Form

No additional paperwork is required unless status check email includes a **Completion Report Form**, which is required for expedited and full review protocols only

No additional paperwork is required unless status check email includes a **Completion Report Form**, which is required for expedited and full review protocols only



Last name _____
IRB # _____

TEXAS A&M INTERNATIONAL UNIVERSITY

IRB Protocol Completion Report

IRB Protocol # _____

Project Title: _____

Initial Approval Date: _____ Most Recent Approval Date: _____

Study Completed Date: _____

INVESTIGATOR INFORMATION

Principal Investigator Name: _____ ☐ Faculty ☐ Staff

Department: _____ College: _____

Phone: _____ E-mail: _____

PARTICIPANTS

Participants utilized for this study? ☐ Yes ☐ No

If no, reason: _____

Total Participants Approved: _____ Total Participants Currently Utilized: _____

1. Were there any unanticipated or adverse events? If you check, no, skip question #2. ☐ Yes ☐ No
2. If yes, was the Unanticipated/Adverse Event Report submitted? ☐ Yes ☐ No

If there was an event, and the Unanticipated/Adverse Event Report was not submitted, must submit the report with this form.
Report is available on IRB website: https://www.tamiu.edu/irb/submissionprocessforms.shtml

FINDINGS

Federal law requires that IF a study results in information that is BENEFICIAL to the participant that the participants be informed.

Were there any findings that would be BENEFICIAL to the participants? ☐ Yes ☐ No

What were those findings?

How were the participants informed of those findings? Include copies of letters sent to participants.

Download Form

Completion Report Form

If you are a student, ask your faculty mentor if your data collection methods are appropriate for your study.

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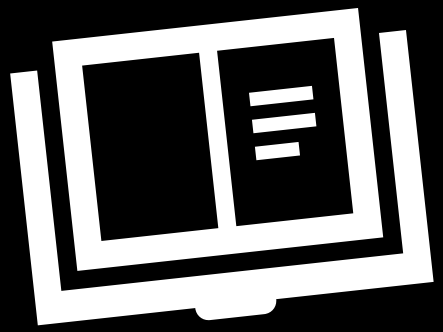

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