

ORC USE ONLY	
HSRP #:	<input type="text"/>
Date Received:	<input type="text"/>
Amendment #:	<input type="text"/>

Amendment to Human Subjects Research Protocol for Exempt, Expedited, or Full Board Review



Instructions and Researcher Certifications (Failure to follow may result in a delay in processing)

Complete this form if **changes** will be made to the research.

If the research is **not changing**, complete the form entitled "Continuing Review of Human Subjects Research Protocol for Exempt, Expedited, or Full Board Review," instead.

By signing this Amendment to Human Subjects Research Protocol for Exempt, Expedited, or Full Board Review (Amendment), all Principal Investigators (PIs), co-PIs, and personnel (collectively, "Researchers") certify the following:

1. CITI Training "Human Subjects Basic Refresher Course" has been completed and is current for **any research activity** regardless of source of funding or whether unfunded (expires after three years);
2. CITI Training "Responsible Conduct of Research Course" has been completed and is current **only if** the source of funding is the **National Institutes of Health (NIH)** or the **National Science Foundation (NSF)** (expires after three years);
3. Have read and understood the responsibilities set forth in TAMUCC Rule 15.99.01.C1.01;
4. Have read and reviewed this Amendment; any applicable supporting documentation or third-party approval has been obtained from the appropriate authority and has been included as an attachment to the Amendment (e.g., recruitment script, informed consent, parental consent, child assent, public school district approval, facility use permission, grant, Translator Certification, Interpreter Certification, etc); have signed the Amendment electronically;
5. Will immediately report any adverse event to either the Institutional Review Board (IRB) or the Research Compliance and Export Control Officer;
6. Research has stopped until the Amendment is approved;
7. Will submit a Completion Report at the conclusion of research under this Amendment.

After completing the foregoing, submit the Amendment with supporting documentation via email to the IRB Mailbox:

irb@tamucc.edu

For questions, email:

research.compliance@tamucc.edu

HSRP Overview

Maestro # (if funded):

Researcher Information

Principal Investigator

Name:

Address:

Phone:

Email:

Faculty Staff Undergraduate Student Graduate Student Other

Specify Other:

Co-Principal Investigator

Name:

Address:

Phone:

Email:

Faculty Staff Undergraduate Student Graduate Student Other

Specify Other:

Co-Principal Investigator

Name:

Address:

Phone:

Email:

Faculty Staff Undergraduate Student Graduate Student Other

Specify Other:

Co-Principal Investigator

Name:

Address:

Phone:

Email:

Faculty Staff Undergraduate Student Graduate Student Other

Specify Other:

External Funding

Indicate whether the project is funded. Yes No

If "**yes**," indicate whether the source of funding has changed. Yes No

Description of Amendment(s)

Provide a detailed description of the proposed amendment(s)

with justification. Address changes in procedure(s), level of risk to participant(s), and forms to be used, if applicable. (Include revised documents as an attachment. For change in personnel, provide training or experience).

Researcher Signatures

By signing this Amendment, the Researcher(s) certifies that he/she has read and understood the requirements and responsibilities set forth in the section entitled "Instructions and Certifications" in relation to the research. In addition, the Researcher(s) certifies that he/she will abide by any and all applicable federal, state, and/or institutional regulations, including any requirements from the Institutional Review Board (IRB) and/or the Office of Research Compliance (ORC).

Principal Investigator

Name:

Signature:

Date:

Co-Principal Investigator

Name:

Signature:

Date:

Co-Principal Investigator

Name:

Signature:

Date:

Co-Principal Investigator

Name:

Signature:

Date: