ORC USE ONLY

HSRP #:

Date Received:

Adverse Event Report for Human Subjects Research Protocol for Exempt, Expedited, or Full Board Review

TEXAS A&M UNIVERSITY CORPUS CHRISTI
RESEARCH COMMERCIALIZATION OUTREACH

Instructions and Researcher Certifications

Complete this form to report any anticipated or unanticipated adverse event(s) under a Human Subjects Research Protocol (HSRP) or Amendment.

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

1. Have read and understood the responsibilities set forth in TAMUCC Rule 15.99.01.C1.01;

2. Have reported the adverse event(s) immediately after its occurrence(s) to the Institutional Review Board (IRB) or the Office of Research Compliance (ORC), any sponsor, and/or other third-party, as appropriate; and

3. Have read and reviewed this Adverse Event Report; certify the accuracy of its contents; have signed the Adverse Event Report electronically.

After completing the foregoing, submit the Adverse Event Report with supporting documentation via email to the IRB Mailbox:
irb@tamucc.edu

For questions, email:

research.compliance@tamucc.edu

HSRP Overview

HSRP #:

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:

Funding

Indicate whether the research is supported by funding. Yes No

If **"yes,"** provide the following information.

Maestro #:

Sponsor:

Adverse Event(s)

Date of Event:

Describe the adverse event(s), causes (if known), actions taken to manage it, and preventive procedure(s) implemented.
Include related correspondences and other pertinent information as attachments.

Researcher Signatures

By signing this Adverse Event Report, the Researcher(s) certifies that he/she has read and understood the requirements and responsibilities set forth in the section entitled "Instructions and Researcher 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: