

ORC USE ONLY

BU# #:

Date Received:

Amendment #:

Amendment
to
Biohazardous Use Protocol for Research, Testing,
or Teaching
or
Exempt Biohazardous Use Protocol for Research,
Testing, or Teaching



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

Complete this form if major or minor changes will be made to the research, testing, or teaching.

Major changes include (not exhaustive): adding/changing biohazardous materials, change in containment level, adding a new species, or adding/changing a transgene.

Minor changes include (not exhaustive): adding/removing co-PIs, adding/changing/removing cell lines, or adding/changing/removing transgenic animals.

If the research, testing, or teaching is **not changing**, complete the form entitled "Annual Review of Biohazardous Use Protocol for Research, Testing, or Teaching or Exempt Biohazardous Use Protocol for Research, Testing, or Teaching," instead.

By signing this Amendment of Biohazardous Use Protocol for Research, Testing, or Teaching or Exempt Biohazardous Use Protocol for Research, Testing, or Teaching ("Amendment"), all Principal Investigators (PIs), co-PIs, and personnel (collectively, "Researchers") or Instructors, as applicable, certify the following:

1. CITI Training "Initial Biosafety Training - Basic Course" has been completed and is current (expires after three years);
2. Have enrolled in or opted-out of the Occupational Health and Safety Program (OHSP) (annual requirement);
3. Have completed the Risk Assessment form for this Amendment and included it as an attachment; have read and understood the information provided in the BUP sections entitled "Medical Assessment" and "Medical Treatment" about the risks to personnel; as appropriate, have consulted and reviewed information about risks and biosafety practices and procedures as set forth in the CDC *Appendix A: CDC Guidance and Information on Microorganisms*, NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), American Biological Safety Association (ABSA) Risk Group Database, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), CDC Index Search, or other relevant sources;
4. Have read and understood the "Responsibilities of the Principal Investigator" as set forth in TAMUCC Rule 15.99.06.C1;
5. Have read and understood the laboratory's standard operating procedures and/or Biosafety Manual; will implement and maintain required records of activities;
6. 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., biosafety manual, permit, grant, institutional approval, third party permission, etc); have signed the Amendment electronically;
7. Research, testing, or teaching has **stopped** until the Amendment is approved; and
8. Will submit a Completion Report at the conclusion of research, testing, or teaching under this Amendment.

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

IBC@tamucc.edu

BUP #:

Approval Date:

Principal Investigator or Instructor

Name:

Office Address
(Building and Room):

Email:

Phone:

Emergency Phone:

Laboratory location
(Building and Room):

Emergency Contact
Name:

Emergency Contact
Phone:

Co-Principal Investigator or Instructor

Name:

Office Address
(Building and Room):

Email:

Phone:

Laboratory location
(Building and Room):

Co-Principal Investigator or Instructor

Name:

Office Address
(Building and Room):

Email:

Phone:

Laboratory location
(Building and Room):

Amendment(s)

Indicate all that apply.

Personnel

Biohazardous Materials (e.g., biological agents; toxins of biological origin; recombinant or synthetic nucleic acid molecules; human and non-human primate blood, tissue, cells, or cell lines; or any material requiring a CDC or USDA permit)

- Procedure(s)
- Building or Room Location
- Containment Level [i.e., Biological Safety Level (BSL)]
- Funding (Provide Maestro # below; include proposal or award as an attachment).
- Other

Description

Provide a detailed description in layman's terms of the change(s).

Provide how the change(s) meet the objective(s) of the research, testing, or teaching.

Researcher or Instructor Signatures

By signing this Amendment, the Researcher(s) or Instructor(s), as applicable, 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, testing, or teaching. In addition, the Researcher(s) or Instructor(s) certifies that he/she will abide by any and all applicable federal, state, and/or institutional regulations, including any requirements for the Institutional Biosafety Committee (IBC), Environmental, Health and Safety (EHS), and/or the Office of Research Compliance (ORC).

Principal Investigator or Instructor Signature

Name:

Signature:

Date:

Co-Principal Investigator or Instructor Signature

Name:

Signature:

Date:

Co-Principal Investigator or Instructor Signature

Name:

Signature:

Date:

IBC Approval

Name:

Signature:

Date: