VA PITTSBURGH HEALTHCARE SYSTEM

Institutional Biosafety Committee (IBC)

PART II AMENDMENT REQUEST FORM

# Instructions:

1. This form must be completed when requesting IBC approval for changes to safety related study procedures, as well as research staff changes, on an approved Institutional Review Board (IRB), Central IRB (CIRB), IRB-exempt or Research Scientific Evaluation Committee (RSEC) study.

2. Please do not submit an amendment while a prior amendment is pending review.

3. All amendments involving a change in biological, chemical, physical, or radiation hazards must be reviewed and approved by the fully convened IBC prior to initiation.

Principal Investigator:

MIRB Number:

Protocol Title:

# I certify that none of the requested changes, including personnel, will begin until I have received approval from the appropriate subcommittees.

**I attest that the Scopes of Practice submitted are appropriate to the duties performed.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (please sign) Date

# PLEASE ANSWER All OF THE FOLLOWING QUESTIONS:

1. Is the purpose of the amendment to add\* or delete personnel working with biohazards?

 [ ]  YES (submit a revised research Staff Form)

 [ ]  NO

* Please list all study personnel being removed:

* Please list all study personnel being added:

* Please describe the exact duties/procedures the new staff person will perform on this study (in lay language)
* Please describe their training and experience to perform the procedures describe

2. Is the purpose of the amendment to make changes to the duties of current personnel\* working with biohazards on this project?

 [ ]  YES (complete Section A below).

 [ ]  NO

* Please describe the exact duties/procedures the person will perform on this study (in lay language).

* Please describe their training and experience to perform the procedures described.

**\* Submit a new or revised Scope of Practice for personnel regarding ALL duties to be performed.**

3. Is the purpose of this amendment to change the location of where research is performed?

 [ ]  YES

 [ ]  NO

* Please list new location (building and room number)

(Please revise and highlight changes on Part II: Safety Form)

4. Will this amendment involve a change in safety elements?

 [ ]  YES (complete section A below)

 [ ]  NO

# A. PLEASE ANSWER THE FOLLOWING QUESTIONS TO REQUEST CHANGES TO YOUR APPROVED PART II: SAFETY FORM: (FOR REVIEW BY THE IBC)

1. Is the purpose of the amendment to add the use of human cell or tissue samples that will be processed by researchers?

 [ ]  YES (Please highlight changes on Part II, Section A or Section B, as applicable)

 [ ]  NO

* Please describe the human tissue/specimen/cell lines to be added:

2. Will this amendment involve a change in the type of pathogen (bacteria, virus, fungus, parasites or rickettsiae) or microbial toxin (endotoxin/LPS) used?

 [ ]  YES (Please highlight changes on Part II: Safety Form)

 [ ]  NO

* Please describe the hazardous microorganism, agent or toxin and indicate the biosafety level:

* Does this represent a change in the biosafety level for biohazards already listed on this protocol?

 [ ]  YES

 [ ]  NO

3. Does this amendment involve a change in shipping Biological Hazards/Infectious Substances?

 [ ]  YES (Please highlight changes on Part II, Section A4 or Section B4h)

 [ ]  NO

* Please describe the changes:

4. Is the purpose of the amendment to add new recombinant or synthetic nucleic acid molecules (e.g., siRNA) to the existing protocol?

 [ ]  YES (Please answer all questions on Part II, Section C for any NEW materials)

 [ ]  NO

* Please describe the recombinant or synthetic nucleic acid molecules to be added and indicate the biosafety level of the material:

* Does this represent a change in the biosafety level for recombinant or synthetic nucleic acid materials already listed on the protocol?

 [ ]  YES

 [ ]  NO

5. Are new chemicals being added to the protocol?

 [ ]  YES (Please highlight changes on Part II: Safety Form, Section E and submit a revised chemical matrix that highlights the new chemicals)

 [ ]  NO

* Please list the chemicals to be added:

6. Does this amendment involve use or alterations in the use of Ionizing Radiation?

 [ ]  YES (Complete Part II, Section H and submit Part V for Radiation Safety Committee review)

 [ ]  NO

7. Does this amendment involve use or alterations in the use of Non-Ionizing Radiation?

 [ ]  YES (Complete Part II, Section H)

 [ ]  NO

8. Will there be any additional/unusual Physical Hazards as a result of the proposed amendments? Examples of physical hazards include extreme cold (-80 freezers and liquid nitrogen), electricity, and noise.

 [ ]  YES (Complete Part II, Section I)

 [ ]  NO

* Please list the physical hazards to be added: