**Request for Amendment of IBC Approval**

Appalachian Institutional Biosafety Council

IBC #       *(To be filled out by Research Protections)*

***Instructions****: Complete and send the request form electronically to* *IBC@appstate.edu**.*

***Note:*** *checkboxes can be checked by clicking on the box.*

**Submission Date:**

**Approval Date:**

**Renewal Due Date:**

**Section I: Experiment Description**

1. Project Title:
2. Principal Investigator(s) and responsible faculty member if student is the PI:

Department(s):

PI telephone:

Please provide a general background of your research experience. Include training or relevant experience you have had that supports your planned research.

1. Does the experiment require approval from any of the following committees?

Institutional Animal Care & Use Committee (IACUC) [ ]  Required [ ]  Obtained [ ]  N/A

Human Subjects, Institutional Review Board (IRB) [ ]  Required [ ]  Obtained [ ]  N/A

If obtained for either, what is the protocol number:

1. List the highest level of perceived risk to humans: [ ]  RG1 [ ]  RG2
2. Containment conditions specified in the NIH Guidelines: [ ]  BL1 [ ]  BL2

**Section II: Requested Amendment**

Please check all that apply:

[ ]  New personnel working with biohazardous agents for the experiment(s)?

[ ]  Change in PI contact information?

[ ]  Changes in IACUC or IRB protocol number?

[ ]  Changes in locations where work with biohazardous agents is being conducted?

[ ]  Changes in sequence payload, function, source, or use? List gene name or class:

[ ]  Changes in biohazardous agents or procedures which would not change the biosafety level?

[ ]  Changes in agents used in your lab which could change the biosafety level of the experiment(s)? \*

[ ]  Changes to procedures which could change the biosafety level? \*

[ ]  Are there any changes in vectors or recipients? \*

[ ]  New collaboration—reference relevant protocol numbers:

[ ]  Any additional changes not previously listed?

\* This change would require the approved protocol to be updated with relevant information by the PI and submitted in conjunction with this form. All changes should be highlighted in some way or done with track changes in place so that reviewers can determine which information is new.

1. Please provide a detailed summary for each item checked for your requested amendment.

**Section III: Conflict of Interest**

1. Are there any known or potential conflicts of interest related to this research?

Conflict of interest relates to situations in which financial or other personal considerations may compromise or involve the potential/have the appearance for compromising an employee’s objectivity in meeting University responsibilities including research activities.

Examples of conflicts of interest include but are not limited to: an investigator has equity in a business that conducts research in a related area; an investigator will receive an incentive/bonus based on the number or speed of enrollment or outcome of a study; or an investigator or family member is a consultant, holds an executive position or serves as a board member of the research sponsor or its holdings.

[ ]  No [ ]  Yes

If yes, describe and explain how the potential conflict of interest will be managed.

By submitting this request, the Principal Investigator (and responsible faculty member if PI is a student) accepts responsibility for ensuring that:

1. All members of the research team complete the IBC required CITI training on and are sufficiently trained on the necessary practices and techniques to ensure safety and the procedures for dealing with accidents;
2. Protocols that describe the potential biohazards and the precautions to be taken are available to all members of the research team;
3. All members of the research team are informed of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection); and
4. The study procedures as described in the IBC approved application and the policies in Appalachian’s Policy on the Use of Recombinant DNA in Research and Teaching Laboratories are followed.
5. Annual renewals are sent to IBC@AppState.edu or an IBC Administrator every year;
6. When any amendment is needed, an amendment form is completed and sent to IBC@AppState.edu or an IBC Administrator *before* changes are implemented.

The parties (i.e., the IBC and the Principal Investigator and responsible faculty member if PI is a student) have agreed to conduct this application process by electronic means, and this application is signed electronically by the Principal Investigator and by the responsible faculty member if a student is the PI.

My name and email address together constitute the symbol and/or process I have adopted with the intent to sign this application, and my name and email address, set out below, thus constitute my electronic signature to this application.

PI Name PI Email address

Responsible Faculty Name if PI is a student Responsible Faculty Email address if PI is a student