**Experiments Requiring Notification with Initiation**

**Appalachian Institutional Biosafety Council**

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

***Instructions:*** *Complete and send the request form electronically to* [*IBC@appstate.edu*](mailto:irb@appstate.edu)*.*

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

**Today’s 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 what 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. Provide a brief timeline for the research.
2. Provide a brief description of the research and research methodology.

**Section II: Experiment(s) Classification and Materials**

Please read the following Section descriptions from the [NIH Guidelines](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm) (scroll down about a page to get to the Table of Contents) and briefly explain why the experiment meets the category.

**Section III-E**.    **Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation.**  Experiments not included in NIH Guidelines Sections [III-A](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261560), [III-B](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261562), [III-C](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261564), [III-D](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261566), [III-F](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261577), and their subsections are considered in [Section III-E](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261573).  All such experiments may be conducted at BL1 containment.  For experiments in this category, a registration document shall be dated and signed by the investigator and filed with the local Institutional Biosafety Committee at the time the experiment is initiated.  The Institutional Biosafety Committee reviews and approves all such proposals, but Institutional Biosafety Committee review and approval prior to initiation of the experiment is not required.  For example, experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes fall under [Section III-E](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261573) and may be conducted at BL1 containment.   
Explain why:      

1. List any appropriate microbiological practices to be used for the research.
2. Describe all applicable laboratory techniques to be used for the research.
3. Do these experiments involve more than 10 liters of culture at one time?  No  Yes
4. If experiments involve a deliberate attempt to obtain an expression of a foreign gene, identify what proteins will be produced:
5. Will recombinant DNA, recombinant RNA, virus particles or other micro-organisms containing recombinant DNA or RNA, or cells containing recombinant DNA or RNA be introduced into whole plants or animals?  No  Yes
6. Recipient organisms or cells to be used (e.g. *E.coli*, mouse, tobacco, mouse primary liver cells):

|  |  |  |
| --- | --- | --- |
| Organism | Line or Strain | Use |
|  |  |  |
|  |  |  |

1. List organisms, viruses and cells to be used and their sources :

|  |  |  |  |
| --- | --- | --- | --- |
| Organism, Virus, Cells Name | Line or Strain | Use | Source |
|  |  |  |  |
|  |  |  |  |

1. Nature of the inserted sequences (payload) and original source of the DNA:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Payload Name | Function | Source | Use | Recipient |
|  |  |  |  |  |
|  |  |  |  |  |

1. Do these experiments involve release of genetically modified organisms to the environment?

No  Yes

1. If the proposed experiments are to be carried out off-campus, are the recombinant DNA assurances from the off campus site attached to this form?

No  Yes

**Section III: Research Personnel and Location of Research**

Required Training for All Personnel Listed by Category

|  |  |
| --- | --- |
| **Category** | **Required Training** |
| Exempt, no transgenic plants or animals | * Training for Investigators/NIH Recombinant DNA Guidelines CITI course |
| Exempt, with transgenic plants or animals | * Training for Investigators/NIH Recombinant DNA Guidelines CITI course * AsULearn Transgenic Quiz completion |

*\*All Biosafety Level 2 lab ancillary students (students who use the lab but are not on the protocol) must complete the ASULearn Institutional Biosafety training quiz titled* ***“Biosafety Training Quiz”****. Personnel should be able to enroll themselves, but if they have an issue, please contact IBC@appstate.edu\**

Enter each team member (including PI) in the table below. Add additional rows as necessary by right clicking on a row.

**(Note:** Personnel changes can be submitted via email with the information below)

|  |  |  |
| --- | --- | --- |
| **Name** | **Role** (e.g., PI, co-I, Research Assistant, Research Cord., Faculty Advisor, etc.) | **Receive IBC Correspondence** (Y/N)?  If yes, provide preferred email address. |
|  |  |  |
|  |  |  |

1. Describe how personnel have been trained in the handling of agents to be used (e.g., hands on training in the lab, lab meeting etc.).
2. List the building and room number in which the recombinant DNA experiments will be conducted:

**Section II: Source of Funding and Conflict of Interest**

1. **Project Support**:

Grant: Agency        Pending  Funded, Proposal #:

Proposal Grant #:       Sponsored Program #:

Departmental support:

Teaching course number(s), year(s), semester(s) offered:

Other: Specify:

If funds awarded/pending, provide sponsor name, Sponsored Programs number:

2. 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, please 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 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](mailto: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](mailto: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