**Registration of Exempt Recombinant DNA Experiments**

**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 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?
	1. Animal Care & Use Committee (IACUC) [ ]  Required [ ]  Obtained [ ]  N/A
	2. Human Subjects, Institutional Review Board (IRB) [ ]  Required [ ]  Obtained [ ]  N/A

If obtained, what is the protocol number**?**

1. Provide a brief description of the research.
2. Please provide detailed description of research methodology.

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

1. Please read the following Section descriptions from the [NIH Guidelines](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm) and select the category that best fits the experiment you are conducting.

Select all that apply:

[ ]  Use of recombinant nucleic acids that involve only the *in vitro* and does **NOT** involve the cloning and propagation of recombinant DNA in cells OR viruses. Including PCR, synthetic double stranded RNA **III-F-1**

[ ]  Use of molecules that are not in organisms, cells or viruses that have not been modified or manipulated to render them capable of penetrating cellular membranes. **III-F-2**

[ ] Exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. **III-F-3**

[ ] Involves DNA from a prokaryotic host when propagated only in that host or a closely related strain of the same species, or when transferred to another host by well-established physiological means. **III-F-4**

[ ] Involves DNA from a eukaryotic host (excluding viruses) when propagated only in that host (or a closely related strain of the same species). **III-F-5**

[ ]  Use of recombinant DNA entirely segments from different species that exchange the DNA by a known physiological process (see appendix A of NIH Guidelines) **III-F-6**

[ ]  Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. **III-F-7**

[ ]  Use of recombinant DNA determined by the NIH director to not be a significant risk to health or the environment. (see appendix C of *NIH Guidlines*) **III-F-8**

[ ]  *E. coli* K-12 host-vector system **III-F-8**

[ ]  *Saccharomyces* host-vector system **III-F-8**

[ ]  *Kluyveromyces* host-vector system **III-F-8**

[ ]  *B. subtilis or licheniformis* host-vector system **III-F-8**

[ ]  Extrachromosomal elements of gram positive organisms **III-F-8**

[ ] Transfer, purchase or breeding of transgenic rodents **III-F-8**

2. Explain why the experiment meets the category.

|  |
| --- |
| **Exempt Experiments: Category III-F-1.**Those synthetic nucleic acids that:  (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.  If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section. Explain why:       |
| **Exempt Experiments: Category III-F-2.**  Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. Explain why:       |
| **Exempt Experiments: Category III-F-3**.  Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.Explain why:      **Exempt Experiments: Category III-F-4.**  Experiments that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means. Explain why:       |
| **Exempt Experiments: Category III-F-5.**  Experiments that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species) Explain why:       |
| **Exempt Experiments: Category III-F-6.**  Experiments that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent.  A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see [Section IV-C-1-b-(1)-(c)](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261599), *Major Actions*).  See [Appendices A-I](http://oba.od.nih.gov/oba/rac/Guidelines/APPENDIX_A.htm#_blank) through A-VI, *Exemptions Under Section III-F-5--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*. Explain why:       |
| **Exempt Experiments: Category III-F-7.** Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. Explain why:       |
| **Exempt Experiments: Category III-F-8.**  Experiments that the NIH Director has determined do not present a significant risk to health or the environment and are therefore exempt. These can be found in Appenix C sections II-VIII. Recombinant DNA in tissue culture, *E. coli* K-12 host-vector system, *Saccharomyces* host-vector system, *B. subtilis or licheniformis* host-vector system, Extrachromosomal elements of gram positive organisms, Transfer or purchase of transgenic rodents. Explain why:       |

**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 personnel 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)

Personnel Table

|  |  |  |  |
| --- | --- | --- | --- |
| **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. | **Completion of Required Training** (Y/N) |
|  |  |  |  |
|  |  |  |  |

1. Describe additional training personnel have received 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 IV: 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. renewals are sent to IBC@AppState.edu or an IBC Administrator every three years;
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