**Institutional Biosafety and Chemical Safety Committee**



**Modification/Annual Review Form**

**for Recombinant or Synthetic Nucleic Acid Experiments**

**Please submit this form for annual review or to request changes in personnel or project prior to the changes. Send completed MS Word file to IBSCSC@etsu.edu**  **When completing the form using the Mac version of Word, place the cursor in front of the box and tap the space bar. The forms have been revised; please review the instructions prior to completion of the forms.**

**Please indicate all changes by highlighting in yellow the corresponding text and information (hint: use ).**

**East Tennessee State University requires that all recombinant or synthetic nucleic acid work conducted at or supported by this University be registered with and approved by the Institutional Biosafety and Chemical Safety Committee.**

**Please consult the ETSU General Policies for the Use of Recombinant or Synthetic Nucleic Acid Molecules and *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (***[***http://www4.od.nih.gov/oba***](http://www4.od.nih.gov/oba)**) for information needed to complete this form.**

Source of NA (i.e., organism, clone bank, species, etc. and literature citation if appropriate)

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| Biosafety Registration Number that was assigned to this project -- **REQUIRED**: | |
| Principal/Responsible Investigator: | Phone number: |
| E-mail address: | Building & Room #: |
| Department Name and Box #: | Fax #: |
| Location of Experiments (building & room): | Sponsor: |
| Project Title: | |
| Do you have a Materials Transfer Agreement?  Yes  No | |

No changes since last submission

* If containment level requires BSL-2 conditions, provide location and most recent date of certificate.

(See sections 8a & 8b)

* Complete section 13 and 14

Changes in personnel only

* If containment level requires BSL-2 conditions, provide location and most recent date of certificate.

(See sections 8a & 8b)

* Complete sections 13 & 14

Changes in project

* Complete all sections of the Annual Review Form (sections 1-14)

**NON-EXEMPT RECOMBINANT OR SYNTHETIC NUCLEIC ACID REGISTRATION**

1. Please check any of the following that pertain to this experiment. Please note: this category may require additional information to be submitted with the registration, contact the Chair of the Recombinant or Synthetic Nucleic Acid Subcommittee of the ETSU Biosafety and Chemical Safety Committee for further information.

Expression of toxic products

Use of transgenic animals

Use of transgenic plants

Experiment will involve more than 10 liters of culture

2. Check the category (a, b, or c) of Recombinant or Synthetic Nucleic Acid experiments you wish to perform (check all that apply).

a. Experiments that require committee notice at the time of initiation (ETSU General Policies Section 2 and *NIH Guidelines Section III-E*). Please include abrief description of the experimental plan and indicate the relevant section of the *NIH Guidelines*.

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b. Experiments that require approval by this committee before initiation (ETSU General Policies Section 3 and *NIH Guidelines Section III-D*).

* Experiments using an adenovirus or retrovirus vector
* Experiments using human or animal pathogens (Risk Groups 2, 3, or 4 ) as host-vector systems
* Experiments in which DNA from human or animal pathogens is cloned in nonpathogenic prokaryotic or lower eukaryotic host-vector systems
* Experiments involving the use of infectious animal or plant viruses or defective viruses in the presence of helper virus in a tissue culture system
* Experiments involving whole animals or plants

c. Experiments that require specific approval by both NIH and this committee before initiation (ETSU General Policies Sections 4, 5, 6 and *NIH Guidelines Section III-A, B,* C). Please note: this category requires additional information to be submitted with the registration, contact the Chair of the Recombinant or Synthetic Nucleic Acid Subcommittee of the ETSU Biosafety and Chemical Safety Committee for further information.

* Deliberate cloning of genes for highly toxic products
* Deliberate release of recombinant organisms to the environment
* Transfer of drug-resistance if such transfer might compromise use of drug therapeutically
* Transfer of Recombinant or Synthetic Nucleic Acid to humans including gene therapy

For work in all three categories above, please describe the following areas in detail:

3. Source of DNA(s) or Synthetic Nucleic Acids (i.e., organism, clone bank, species, etc., and literature citation   
if appropriate).

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4. Nature if Inserted Sequence (genomic cDNA, PCP products etc.)

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5. Specific Host(s)

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6. Specific Vector(s) (e.g. source of vector, supplier and type)

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7. List the Risk Group for your source or vector (*Defined in Appendix B of the NIH Guideline)*

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8. List the Containment Level (*Defined in Appendix G of the N IH Guidelines*): Biosafety Level (BL)

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| BL- |

If BL-2, give a) the location and b) the date of certification.

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9. Will the studies include deliberate attempts to obtain expression of a foreign gene (a gene originally exogenous to the host-vector system used)?

Yes  No

If yes, what protein will be produced?

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10. Does this research protocol require either ETSU IRB or ETSU Animal Care Committee approval? If yes, which?

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**\* If IACUC approval is required, please complete Appendix A for administration to animals. \***

11. List the names of all personnel participating in this study and have them initial by their names to indicate that they have read and understand the nature of these experiments and that they can safely and properly handle the material described (add more rows if necessary).

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| **NAME** | **TITLE** |
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12. Please describe progress of ongoing studies and list any proposed changes. Please limit to one page.

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13. **Principal Investigator Affirmation:**

I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-7 of the *NIH Guidelines*. I accept responsibility for the safe conduct of work with this material and have received appropriate training on the hazards and the level of containment required to perform this research safely. I will report to the Biosafety and Chemical Safety Committee any accident or incident that results in a potentially toxic exposure to personnel or any incident releasing Recombinant or Synthetic Nucleic Acid or other potentially hazardous materials into the environment.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Principal Investigator (signature) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Chairperson, Biosafety and Chemical Safety Committee (signature) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

14. **Project Personnel AFFIRMATION:** (All personnel listed in Section 11 must complete individually)

I accept responsibility for the safe conduct of work with this material and have received the appropriate training on the hazards and the level of containment required to perform this research safely. I will report to the Principal Investigator and the Biosafety and Chemical Safety Committee any accident or incident that results in a potentially toxic exposure to personnel or any incident releasing recombinant DNA or other potentially hazardous materials into the environment.

Project Personnel Names (please type):

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Add as many lines as necessary to allow for signatures for all personnel you listed.)

**Appendix A: Animal Safety Protocol**

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| **Animal Safety Protocol For**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ In Mice And Rats**  **\_\_\_\_\_ type of \_\_\_\_\_\_\_ TOXIN** | | | https://www.osha.gov/dsg/hazcom/pictograms/image7.jpg |
| **Investigator Name:**  **IACUC #:**  **Emergency Phone #:**  **Date:** | | **IBSCSC Approval**  **Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| Investigator Responsibility-  **Notification of Animal Resources:** | Research staff will inform animal care staff ahead of time that **\_\_\_\_\_\_\_\_\_\_\_\_\_** will be used, and arrangements will be made for housing of animals. Fresh cages will be used for the animals at the time of administration. | | |
| All Responsible-**Basic Precautions:** | ***NOTE THAT \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ will be administered continuously for up to \_\_\_\_\_\_ days/weeks/months so precautions will need to be followed for the duration of study when handling animal cages.***   * Animal bedding is not to be changed for at least \_\_\_\_ days after the administration of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. * Disposable gown and a 2nd pair of nitrile gloves in addition to the usual protective clothing worn. * Safety glasses with side shields at a minimum will be worn. * Additional PPE should be removed before leaving the animal room. | | |
| Investigator’s Responsibility-**Posting**  **Requirements:** | * This ASP will be posted on the door of the cubicle in which the animals will be housed. * Cages will be labeled with a green card denoting **“\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”** along with date of the initial administration and stated that “\_\_\_\_\_\_\_\_\_\_ will be administered continuously for \_\_\_\_\_ days/weeks/months | | |
| Investigator’s Responsibility-  **Administration:** | Follow dosage and precautions in the PI’s approved IBC protocol. | | |
| DLAR Responsibility-**Cage Change:** | The **first cage change** after the initial drug administration is to be done by the animal care technicians **no sooner than** **\_\_\_\_\_\_ days after administration.**  The bedding is considered contaminated for the duration of the study.  ***All cage manipulations/changes that occur during the study must be done using the requirements listed above in the Basic Precautions following the below procedures.***   * Transfer the animals to clean cages. * Replace the tops on the soiled cages and transport to dirty cage wash. * Cages are dumped using a HEPA filtered dumping station that draws air away from the user. * Soiled cages are processed in rack washer | | |