Stephen F. Austin State University

Application for Review of Proposed Research by the Institutional Biosafety Committee (IBC)

Refer to SFA policy 8.9 - Recombinant DNA and/or Infectious Biohazards in Teaching and Research http://www.sfasu.edu/policies/8.9-recombinant-dna-and-or-infectious-biohazards-in-teaching-and-research.pdf, and the SFA Biosafety Manual http://www.sfasu.edu/safety/442.asp for specific policies and procedures related to biological safety.

SECTION A: *Principal Investigator and personnel information (please type or print)*		
***P.I. Name*:**	***Title*:**	***Dept*:**
***Phone No*:**	***Alternate Phone No.*:**	**Student Name:**
Building and Lab Room No(s):	***E-mail:***	

SECTION B: ***Information about the Research***

This protocol is a(n): ☐**New Protocol** ☐**Renewal Protocol** **This** ☐ **Amendment Protocol**

project will use: ☐**Biohazardous Material** ☐**Biological Toxin** ☐**Recombinant DNA**

*****Notice: Biohazardous agents above Biosafety Level 2 are currently prohibited at SFA facilities.***

Proposed Start date: **Anticipated completion date:**

General Synopsis of the Project:

List types of biological agents/toxins, quantities, duration of use, and/or the rDNA technology to be applied:

Please include any additional information that may assist the IBC in the review of this protocol (e.g. description of experimental design, procedures for sample collection, handling etc.)

SECTION C: ***To determine if your project is Exempt or Non Exempt, complete the six questions below:***

1. Does the construct contain viral DNA that represents more than ½ of any eukaryotic viral genome or is the viral construct from DNA or Risk Group 2 virus or restriced agents?

Yes ☐ No ☐

Notice: Biohazardous agents above Biosafety Level 2 are currently prohibited at SFA facilities.

Use the links below to determine relevant Risk Group and/or select agent of your research materials:
https://my.absa.org/tiki-index.php?page=Riskgroups
http://www.selectagents.gov/SelectAgentsandToxinsList.html

2. Does this study involve the deliberate transfer of rDNA; or DNA or RNA that is derived from rDNA into humans, other vertebrates, invertebrates, or plants; or consist of DNA transferred from a prokaryotic or eukaryotic host that is not a closely related strain or species? NIH Guidelines Section III-D-2.
   ☐ Yes ☐ No

3. Does the study involve the use of a microorganism from a Risk Group 2 or select agent as a Host-Vector System, or cloned DNA from a Risk Group 2 into nonpathogenic prokaryotic or lower eukaryotic Host-Vector System or if using RG-2 organisms, does it involve the movement of DNA between organisms from different Appendix sublists?
   ☐ Yes ☐ No

   Use the links below to determine relevant Risk Group, select agent, or natural exchanger sublist of your research materials:
   https://my.absa.org/tiki-index.php?page=Riskgroups
   http://www.selectagents.gov/SelectAgentsandToxinsList.html
   http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html ***(See Appendix A in NIH Guidelines)***

4. Does the research involve the generation of Toxin Molecules lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram body weight (or 100 µg/kg of body weight) (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin)? NIH Guidelines Section III-B-1.
   ☐ Yes ☐ No

   Specific approval has been given for the cloning in *Escherichia coli* K-12 of DNA containing genes coding for the biosynthesis of toxic molecules which are lethal to vertebrates at 100 nanograms to 100 micrograms per kilogram body weight.

5. Does the research involve the generation of more than 10 liters of culture at one time? NIH Guidelines Section III -D-6.
   ☐ Yes ☐ No

6. Does the research involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally and if so, could this acquisition compromise the use of the drug to control the disease agents in humans, animals and/or plants?
   ☐ Yes ☐ No

7. Project Title:

Nature/Source of inserted DNA: Examples: include genus/Species, name of protein pathway or function	**Host(s)** Examples: E.coli K-12	**Methods of gene transfer/vector(s):** Examples:Virus; Plasmid; naked DNA; conjugation; chemical; mechanical; other – specify type & name	**Intended Use of rDNA:** Examples: cloning; transgenic generation; modification of natural gene expression; new protein expression

Principal Investigator Assurance:

- Agree to use at least Biosafety Level (BSL -1) containment practices with all exempt rDNA work.
- Acknowledge that I will notify the IBC of any changes to this research study by promptly amending this form

_____ _____

Signature of Principal Investigator Date

****Notice: Biohazardous agents above Biosafety Level 2 are currently prohibited at SFA facilities.**

NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (NIH GUIDELINES) - April 2016

Section III-F. Exempt Experiments

The following recombinant DNA molecules are exempt from the NIH Guidelines and registration with the Institutional Biosafety Committee is not required:

Section III-F-1. Those that are not in organisms or viruses.

Section III-F-2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

Section III-F-3. Those 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.

Section III-F-4. Those 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).

Section III-F-5. Those 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), *Major Actions*). See Appendices A-I 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*.

Section III-F-6. Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), *Major Actions*), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III-F-6* for other classes of experiments which are exempt from the *NIH Guidelines*.

Institutional Biosafety Committee (IBC)

Campus Mail: Attn: Dr. Odutayo Odunuga, PO Box 13006, SFA Station • Nacogdoches, Texas 75962-3046
Phone (936) 468-6468 • Fax (936) 468-7634 • E-mail odunugaoo@sfasu.edu (Please email fully completed application)

For IBC Use Only	For ORSP Use Only
Protocol #:	PCF #:
IBC Approval Date:	Submission Date:
NIH Guidelines exemption category:	Completion of Biosafety Training: