Application Number:_____

APPLICATION FOR INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW AND APPROVAL

South Dakota School of Mines and Technology

(Protocol Submission Form)

This form must be submitted for ALL research or teaching activities involving recombinant DNA (rDNA), infectious agents, toxins, prions, and/or human tissue and fluids.

Submit to: Jerilyn Roberts, Jerilyn.roberts@sdsmt.edu

SECTION I

DEPT./CENTER:		
P.I.:	SDSM&T ID#:	EMAIL:
RANK (CIRCLE ONE): FACULTY / POST-DOC / RESEARCH STAFF	CITIZENSHIP:	
CO P.I.:	SDSM&T ID#:	EMAIL:
RANK (CIRCLE ONE): FACULTY / POST-DOC / RESEARCH STAFF	CITIZENSHIP:	
CAMPUS ADDRESS:		OFFICE PHONE:
LAB PHONE:	HOME PHONE:	

SECTION II

PROJECT TITLE:		
GRANT TITLE:		
FUNDING SOURCE:	APPLICATION DEADLINE:	
PROPOSED START/RENEWAL DATE:	LOCATION: (BUILDING AND ROOM #)	
PROJECT TYPE (CIRCLE ONE): RESEARCH / TEACHING	PROJECT OR COURSE #:	NEW OR RENEWAL?
LIST GRANT NUMBERS AND AGENCIES:		
PROJECT START DATE:	PROJECT END DATE:	

Application Number:_____

If this application requires BL-2 or higher containment circle "yes" or "no":	
YES / NO	The facilities used in these activities have been previously inspected by the IBC and meet appropriate biological laboratory safety standards.
Circle "yes" or "no" for the following agents or materials used and follow instructions:	
YES / NO	Recombinant DNA. Fill out sections even if exempt. Complete sections A, B, C, & D as required.
YES / NO	Infectious agents, toxins, or prions (pathogenic to humans, animals or plants). Fill out section E.
YES / NO	Human tissues or fluids. Fill out section E.
YES / NO	Use and/or possession of select agents according to the Patriot Act (http://epic.org/privacy/terrorism/hr3162.html). Contact the Jerilyn.roberts@sdsmt.edu.
COMPLETION AND SIGNING OF THIS FORM ARE THE RESPONSIBILITY OF THE PRINCIPAL INVESTIGATOR OR FACULTY MEMBER IN CHARGE.	
In signing this form, I agree to abide by all university and federal guidelines and regulations regarding recombinant DNA, infectious agent and/or human tissues and fluids work.	
Principal Investigator is responsible for all liabilities related to use of his/her materials.	
_____ **Principal Investigator Signature**	_____ **Date**

List of Acronyms
IBC – Institutional Biosafety Committee
ORDA-Office of Recombinant DNA Activities
NIH – National Institutes of Health
RAC – Recombinant-DNA Advisory Committee

SECTION A

Application Number:_____

Experiments that require RAC or ORDA review; NIH and IBC approval. Circle "yes" or "no":		
YES / NO	Deliberate formation of rDNAs containing genes for biosynthesis of toxic molecules.	
YES / NO	Deliberate release into the environment of any organism containing rDNA.	
YES / NO	Deliberate transfer of drug resistance trait to microorganisms such that drug control might be compromised.	
YES / NO	Deliberate transfer of rDNA into human subjects.	
SECTION B		
Experiments that require IBC approval before initiation. Circle "yes" or "no":		
YES / NO	Use of other than a Risk Group 1 agent as host-vector system (see Appendix B of NIH Guidelines, 2002).	
YES / NO	Will you use a Class 2, 3, or 4 viral vector? If so, will:	
	YES / NO	Greater than 2/3s of the genome be used?
	YES / NO	Helper virus be used?
	YES / NO	Your experiment enhance pathogenicity (e.g. insertion of oncogene, extend host range)?
YES / NO	Will whole animals or plants be used as hosts?	
YES / NO	Will experiments involve more than 10 liters of culture?	
YES / NO	Will a deliberate attempt be made to obtain expression of a foreign gene?	
	If so, what protein / RNA will be produced:	
YES / NO	Will a toxin be used?	
YES / NO	Will prions be used?	
ALL "YES" ANSWERS ABOVE MUST BE EXPLAINED IN THE NEXT SECTION.		
SECTION C		
Host organism:		
List the vector(s) name and type (e.g., -gt11, retroviral pLNL), and append a DNA map of any novel vectors listing components with their sizes:		
Source organism of DNA to be cloned (e.g., human T-Cell cDNA library, HIV gag gene):		
If the DNA is microbial, circle the appropriate class as given in Appendix B [Current federal guidelines: http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm : 1 2 3 4 5 N/A		
Function of products (protein or RNA) of the cloned DNA:		
For oncogenic viruses, circle appropriate level (Appendix B [and all federal guidelines and Biosafety Manual]): Low Risk Moderate Risk N/A		
Circle containment level specified by the current Federal Guidelines (http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm) and the Biosafety Manual: Exempt BL1 BL2 BL3 BL4		
***All human tissue / body fluid samples require BL2.**		
SECTION D		
Include a succinct description of your project on a separate page and explain WHAT, WHY, and HOW rDNA will be used in your project. This CANNOT be replaced with a grant proposal or reprint.		
SECTION E		
Description of proposed research involving infectious agents, toxins, or prions.		
Describe the purpose of this research project and the experimental procedures to be employed. Explain why and how infectious agent(s), toxins, or prions will be used and the biosafety practices that will be incorporated to		

minimize any risks. Specific issues to be addressed include: contamination control, spill response, waste management, use of protective apparel, and inventory control.
List the infectious agent(s), toxins, or prions:
Circle level of research according to the federal guidelines and Biosafety in Microbiological and Biomedical Laboratories (hhttp://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm). BL1 BL2 BL3 BL4
SECTION F
Human Tissues and Fluids Usage
Submit to the IBC a statement of that intent and include an outline (abstract) of the proposed activity, and sufficient information that will clarify to the reader that the guidelines involving human tissue and fluids are understood and that the submitting individual is able and intends to adhere to those guidelines.
FOR BIOSAFETY COMMITTEE USE ONLY
APPROVED **DISAPPROVED** **EXEMPT/BL1**
RESTRICTIONS:
For BL2 Level Research or higher:
☐ The facilities used in this activity have been previously inspected and meet appropriate laboratory safety standards.
☐ The facilities used in this activity require IBC inspection prior to initiation.
Facilities surveyed by:
This application for use of rDNA, infectious agents or human tissues or fluids has been reviewed and approved by the South Dakota School of Mines and Technology Institutional Biosafety Committee.
_____ **Chair / Biosafety Officer for Biosafety Committee Signature** _____ **Date:**

Application Number:_____

Project Description

Project Goal:

Experimental Procedures:

Material Handling Procedures

Standard Microbiological Practices

Special Practices

Personal Protective Equipment

1. .

Recombinant DNA

List of Individuals working on project

Section III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation

Prior to the initiation of an experiment that falls into this category, the Principal Investigator must submit a registration document to the Institutional Biosafety Committee which contains the following information: (i) the source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the *NIH Guidelines.* For experiments in this category, the registration document shall be dated, signed by the Principal Investigator, and filed with the Institutional Biosafety Committee. The Institutional Biosafety Committee shall review and approve all experiments in this category prior to their initiation. Requests to decrease the level of containment specified for experiments in this category will be considered by NIH (see Section N-C-I-b-(2)-(c), *Minor Actions).*

Section III-D-I. Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems (See Section II-A, *Risk Assessment)*

Section III-D-l-a. Experiments involving the introduction of recombinant DNA into Risk Group 2 agents will usually be conducted at Biosafety Level (BL) 2 containment. Experiments with such agents will usually be conducted with whole animals at BL2 or BL2-N (Animals) containment.

Section III-D-l-b. Experiments involving the introduction of recombinant DNA into Risk Group 3 agents will usually be conducted at BL3 containment. Experiments with such agents will usually be conducted with whole animals at BL3 or BL3-N containment.

Section III-D-l-c. Experiments involving the introduction of recombinant DNA into Risk Group 4 agents shall be conducted at BL4 containment. Experiments with such agents shall be conducted with whole animals at BL4 or BL4-N containment.

Section III-D-l-d. Containment conditions for experiments involving the introduction of recombinant DNA into restricted agents shall be set on a case-by-case basis following NIWORDA review. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see Section V-G and V-L, *Footnotes and References of Sections I-IV).* Experiments with such agents shall be conducted with whole animals at BU or BL4-N containment.

Section III-D-2. Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems

Section III-D-2-a. Experiments in which DNA from Risk Group 2 or Risk Group 3 agents (see Section II-A, *Risk Assessment)* is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment. Experiments in which DNA from Risk Group 4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment after demonstration that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant. In the absence of such a demonstration, BU containment shall be used. The Institutional Biosafety Committee may approve the specific lowering of containment for particular experiments to BL 1. Many experiments in this category are exempt from the *NIH Guidelines* (see Section III-F, *Exempt Experiments).* Experiments involving the formation of recombinant DNA for certain genes coding for molecules toxic for vertebrates require NIH/ORDA approval (see Section III-B-l, *Experiments Involving the Cloning of Toxin Molecules with LD_{50} of Less than 100 Nanograms Per Kilogram Body Weight)* or shall be conducted under NIH specified conditions as described in Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates.*