Form 01: Registration for the Use of Biological Materials

Please return to: Environmental Health and Safety (EHS)
135 College St., Suite 100
Tel. 737-2121 Fax 785-7588

OEHS Use Only
BSL: _____❑BBP ❑State ❑Select ❑USDA
BioReg #: _____
_____
Reg. Expiration Date: _____

Please print or type:
Principal Investigator: _____ NETID#: _____

Office Bldg./Rm. number: _____ Tel #: _____(office) _____(lab)

Lab Supervisor (if other than PI): _____ Tel #: _____(office) _____(lab)

List all laboratory rooms used (Bldg./Rm.): _____

Department: _____

I am aware of the CDC-NIH Biosafety containment levels and precautions applicable to the work described here. I understand that I am responsible for the safety of others in my laboratory, and those who handle the waste generated by my laboratory. A new FORM 01 must be completed every three years. I understand that I must review my current registration for accurate information *annually* and *when there are changes* during the year regarding the use of biological materials. Changes include: addition or deletion of biological materials, addition or deletion of employees or changes in room locations.

I further attest that all research personnel under my supervision on this project, have attended all appropriate Safety Training sessions and that they are familiar with the hazards and symptoms of exposure relevant to the biological materials used within the laboratory. All laboratory personnel have been briefed on emergency procedures, good laboratory work practices, and the safe operation of laboratory equipment prior to the initiation of experimental work.

P.I. Signature _____ Date _____

Type of laboratory (Check all that apply) ☐Teaching ☐Research ☐Clinical ☐Environmental
Are Biological agents used? ☐Yes ☐No Are Plants used? ☐Yes ☐No

The sections on the following pages refer to the laboratory's use of biological materials (e.g.; microorganisms, cell lines, human materials, animals, toxins). Please complete only those sections that are relevant to the work of the laboratory.

I. RECOMBINANT DNA EXPERIMENTS:

1. Does your laboratory perform any Recombinant DNA experiments? ☐ Yes ☐ No

2. If yes, have you registered your Recombinant DNA experiments? ☐ Yes ☐ No

3. If yes, provide your Yale Registration #: _____

4. If no, are your Recombinant DNA experiments exempt from NIH guidelines? ☐ Yes ☐ No *(see checklists below)*

Checklist To Determine Whether Tissue Culture Experiments Are Exempt From The Recombinant DNA Guidelines

Many tissue experiments with recombinant DNA molecules are exempt from the NIH Guidelines. If the answer to <u>all 5</u> of the following questions are no, then the tissue culture experiments are exempt according to Appendix C-I.

Yes No

☐ ☐ Do any recombinant DNA molecules contain one-half or more of any eukaryotic viral genome?

☐ ☐ Do any experiments involve Risk Groups 3, 4 or restricted organisms or nucleic acids from Risk Groups 3, 4 or restricted organisms?

☐ ☐ Do any experiments involve introduction of genes coding for molecules toxic for vertebrates?

☐ ☐ Do any experiments involve infectious viruses?

☐ ☐ Do any experiments involve defective viruses in presence of helper viruses?

Checklist To Determine Whether Experiments With E.coli K12 And Yeast Are Exempt From The Recombinant DNA Guideline

Most experiments involving *E. coli* K-12 host vector systems and *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host vector systems are exempt from the NIH Guidelines. If the answer to <u>all 3</u> of the following questions are no, then the experiments are exempt according to Appendix C-II (for *E. coli* K-12) or Appendix C-III (for *Saccharomyces cerevisiae* and *Saccharomyces uvarum*).

Yes No

☐ ☐ Do any experiments involve Risk Groups 3, 4 or restricted organisms or nucleic acids from Risk Groups 3, 4 or restricted organisms?

☐ ☐ Do any experiments involve introduction of genes coding for molecules toxic for vertebrates?

☐ ☐ Will there be any large-scale experiments (more than 10 liters of culture)?

Checklist To Find Relevant Section Of The Recombinant DNA Guidelines

Section III-D: Experiments that require IBC approval before initiation.
Section III-E: Experiments that require IBC notice simultaneous with initiation.

Yes No

☐ ☐ Is any human or animal pathogen (defined as a Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents) used as either the host organism or as a vector? Section III-D-1

☐ ☐ Is any DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems? Section III-D-2

☐ ☐ Do recombinant DNA or RNA experiments involve the use of infectious animal or plant viruses in tissue culture systems? Section III-D-3

☐ ☐ Do recombinant DNA or RNA experiments involve the use of defective animal or plant viruses in the presence of helper virus in tissue culture systems? Section III-D-3

☐ ☐ Do recombinant DNA experiments involve whole animals (Section III-D-4) or plants (Section III-D-5)?

☐ ☐ Do experiments involving more than 10 liters of culture? Section III-D-6

☐ ☐ Do experiments Involving Influenza Viruses? Section III-D-7.

☐ ☐ Section III-E: Catchall section for experiments that are not exempt but are not covered in other sections.

☐ ☐ Do Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus? Section III-E-1.

☐ ☐ Do Experiments Involving Whole Plants? Section III-E-2

☐ ☐ Do Experiments Involving Transgenic Rodents? Section III-E-3.

Note: Transgenic or knockout rodent experiments that require BSL1 containment may be initiated simultaneously with IBC notification. The purchase of transgenic rodents for BSL1 experiments is exempt from the NIH Guidelines.

Section III-A: Experiments that require IBC, RAC Review and NIH Director approval before initiation.
Section III-B: Experiments that require NIH/OBA and IBC approval before initiation.
Section III-C: Experiments that require IRB and IBC approval and RAC Review before research participant enrollment.

Yes No

☐ ☐ III-A-1: Transfer of drug resistance trait to organism that does not acquire it normally (if it could compromise the use of the drug to control disease agents in humans, animal or agriculture).

☐ ☐ III-B-1: Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms per Kilogram Body Weight

☐ ☐ III-C-1: Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants (Human gene transfer experiments).

I. RECOMBINANT DNA EXPERIMENTS continued:

5. If Recombinant DNA Experiments are non-exempt, complete the *Registration of Recombinant DNA Experiments* form.

6. If Recombinant DNA Experiment exempt, please describe, below, specific host(s), vector(s), DNA(s) and what proteins will be produced?

Host Cells:

Vector(s):

Inserted DNA:

Protein produced (if applicable):

II. MICROORGANISMS

Agent (list Genus and Species)	Strain (if known)	Human Pathogen	Opportunistic Human Pathogen	Animal Pathogen	Plant Pathogen	Non-pathogenic	Risk Group Biosafety Level 1, 2, 3, 4	All Bldg./rms. where used/stored
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		
		☐	☐	☐	☐	☐		

III. HUMAN MATERIALS

Does your laboratory examine any specimens for the purpose of providing information to physicians? Yes ☐ No ☐

If yes, what type of organisms do you normally look for?_____

What are the test results used for? research ☐ diagnostic purposes ☐ treating patients ☐

Blood, Body Fluids, Organs, Tissues Containment at Biosafety Level ☐1 ☐2 ☐3 ☐4 (Check one)

Human Material	Type/Source (applicable)	All Bldg./rms. where used/stored
☐**Blood**		
☐**Body Fluids**		
☐**Organs**		
☐**Tissues**		

For additional materials, please use separate sheet.

Tissue Culture Containment at Biosafety Level ☐1 ☐2 ☐3 ☐4 (Check one)

Primary Cell Lines/Continuous Cell Lines *(please indicate)*	Source	Bldg./Rm. where used/stored

For additional materials, please use separate sheet.

Transplantable tumors Containment at Biosafety Level ☐1 ☐2 ☐3 ☐4 (Check one)

Tumor/Description	Institutional source	Animal or Tissue culture	Containment test date	Bldg./Rm. where used/stored

For additional materials, please use separate sheet.

Hybridoma Containment at Biosafety Level ☐1 ☐2 ☐3 ☐4 (Check one)

Carrier cell line	*In vivo/In vitro*	Specify animals used	Bldg./Rm. where used/stored/housed

: For additional materials, please use separate sheet.

IV. ANIMALS, ARTHROPODS, INSECTS OR PLANTS

Containment at Biosafety Level 1 2 3 4 (circle one)

Animal Arthropods, Insects or Plants	Bldg./rms. housed

Tissue Culture Containment at Biosafety Level ☐1 ☐2 ☐3 ☐4 (Check one)

Cell line	Source	Bldg./Rms. where used/stored

For additional materials, please use separate sheet.

Transplantable tumors Containment at Biosafety Level ☐1 ☐2 ☐3 ☐4 (Check one)

Tumor/Description	Institutional source	Animal or Tissue culture	Containment test date	Bldg./Rms. where used/stored

For additional materials, please use separate sheet.

Hybridoma Containment at Biosafety Level ☐1 ☐2 ☐3 ☐4 (Check one)

Carrier cell line	*In vivo/In vitro*	Specify animals used	Bldg./Rms. where used/stored/housed

For additional materials, please use separate sheet.

Potential Biohazardous Animal Material (e.g. unfixed tissues or other samples from Non-Human Primates, or samples from animals used in biohazard research protocols)

Animal Material	**Animal Species**	**Biohazard**	**Source material obtained from (PI, Institution)**	**All Bldg./rms. where used/stored**
Blood				
Body Fluids				
Organs				
Tissues				
Other (specify)				

For additional materials, please use separate sheet.

V. BIOLOGICAL TOXINS Containment at Biosafety Level ☐1 ☐2 ☐3 ☐4 (Check one)

Type of Toxin	Experimental Concentration	Supplier	Toxin LD50		All Bldg./rms. where used/stored
			Human	Animal	
Abrin					
Aflatoxins					
Amanitin					
Bacterial Toxins (specify toxin):					
Bee Venoms					
*Botulinum Toxins					
Castorbean					
Clostridium perfringens epsilon toxin					
Conotoxins					
Diacetoxyscirpenol					
Insect Toxins					
Lectins					
Mycotoxins					
Ricin					
*Ricin D					
Saxitoxin					
Shigatoxin					
Staphylococcal enterotoxins					
Snake venoms					
Tetrodotoxin					
*Tetrodotoxin citrate, 2 hydroxy					
T-2 toxin					
Other(specify toxin):					

*Botulinum toxins, Ricin D, and Tetrodotoxin citrate, 2 hydroxy… have LD50 values <100ng/kg body weight and are non-exempt. CDC Select Agent Rule (42 CFR Part 72) requires registration of facilities with CDC for their use, storage and transfers.

For additional toxins, please use separate sheet.

Antidote available ☐yes ☐no Source _____ Antidote in your possession ☐yes ☐no

Plan to inactivate toxin

_____

VII. DUAL USE

In reviewing registrations, the Yale IBC considers "dual use" potential, namely the potential for research projects with a beneficial purpose to provide knowledge, products or technologies that could be directly misapplied to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or material. For a full discussion of this topic, consult http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern

Will you be conducting research that directly uses nonattenuated forms of one or more of the following agents? ☐Yes ☐No.

If yes, please check the agent involved:

☐Avian influenza virus (highly pathogenic)
☐Bacillus anthracis
☐Botulinum neurotoxin (in any quantity)
☐Burkholderia mallei
☐Burkholderia pseudomallei
☐Ebola virus
☐Foot-and-mouth disease virus
☐Francisella tularensis
☐Marburg virus
☐Reconstructed 1918 influenza virus
☐Rinderpest virus
☐Toxin-producing strains of Clostridium botulinum
☐Variola major virus
☐Variola minor virus
☐Yersinia pestis

Do any of your experiments fall into any of the followingexperimental categories? ☐Yes ☐No

If yes, please check all that apply:

☐Enhances the harmful consequences of the agent or toxin;

☐ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/ or agricultural justification;

☐ Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;

☐Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;

☐Alters the host range or tropism of the agent or toxin;

☐Enhances the susceptibility of a host population to the agent or toxin; and

☐Generates or reconstitutes an eradicated or extinct listed agent or toxin.

☐Provide other knowledge, products or technologies that could be directly misapplied to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or material.

Comment on aspects of your research, if any, with potential for dual use:

VI. LIST OF LABORATORY PERSONNEL

List all Personnel that work in the laboratory and indicate what they work with by checking box

NAME	NET ID	Recombinant DNA Experiments	Microorganisms	Human Materials	Animals, Arthropods, Insects or Plants	Biological Toxins
		☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐
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