

UCDHSC BIOSAFETY APPLICATION FORM

Instructions for Completing the Application Form and Authorization Review Process

The Biosafety Office, in conjunction with the Institutional Biosafety Committee, exercises oversight for all UCDHSC activities involving biological (infectious) agents or materials*, to include all educational and research laboratories, to ensure that employees, students, the public and the environment are protected from biohazards associated with UCDHSC operations.

IBC review and authorization[†] is mandatory for research involving: any biological (infectious) agents, recombinant DNA, Select Agents & Toxins, and work with human blood, bodily fluids or tissues.

Note that use of any infectious viral vector that infects vertebrate cells requires IBC authorization prior to the initiation of any non-exempt recombinant DNA work. Examples of viral vectors that DO REQUIRE agent approval include:

- typical adenovirus vectors
- vaccinia-based vectors

IBC **registration**[‡] is required for viral vectors that contain less than 2/3rds of the wild-type viral genome or that do not infect vertebrate cells. Examples of such vectors include:

- most defective retrovirus vectors (usually MLV-based)
- adeno-associated virus vectors (AAV vectors)
- baculovirus vectors

Complete this form and any appropriate appendices for your research. Incomplete or illegible forms will be returned.

Registration and authorizations for laboratory research with non-exempt rDNA must be updated every three (3) years. Annual reports must be submitted for Human Gene Transfer protocols.

If you have any questions, please contact the UCDHSC Biosafety Officer at 303-724-0235 or send an email to therese.stinnett@uchsc.edu

Please complete and return this form and one copy of the grant abstract (summary) page to: Biosafety Officer, Health and Safety Division, Mailstop F484.

* Biological Agents and Materials are defined as: human blood, bodily fluids, tissues, organs, pathological specimens; human and animal cell culture materials, tumor cell lines or hybridomas; bacteria, viruses (to include oncogenic viruses), parasites, other microorganisms; Select agents and biological toxins; all recombinant DNA or RNA materials.

[†] Authorization, prior to the initiation of research, is required for research involving non-exempt rDNA, Select Agents & Toxins, and all Risk Group 3 infectious agents.

[‡] Registration is for those research projects which only require notification of the IBC and Biosafety Office, per the University policies and NIH Guidelines.

UCDHSC BIOSAFETY APPLICATION FORM

Registration No.

Form Reviewed by:		This space is for Health and Safety Division Use ONLY	
		Date	
Biosafety Officer		_____	
<input type="checkbox"/> Exempt/Registered	<input type="checkbox"/> Form Routed to IBC	_____	
Reviewer 1	_____	_____	
Reviewer 2	_____	_____	
Full Committee Review		_____	
<input type="checkbox"/> Approved	<input type="checkbox"/> Deferred	<input type="checkbox"/> Disapproved	_____
		Biosafety Level	1 2 3

Section I. Administrative Information

CAMPUS /SITE WHERE LABORATORY ACTIVITIES/RESEARCH WILL BE CONDUCTED:

9th & CO Fitzsimons Off-Site _____
Address

Building _____ Laboratory Room # _____

PRINCIPAL INVESTIGATOR: _____ Mailstop _____

SCHOOL/DEPT/DIVISION/INSTITUTE: _____ Phone _____

FAX: _____ Email: _____

CO-INVESTIGATORS: _____ Mailstop _____

LAB/RESEARCH PERSONNEL _____

PROJECT OR GRANT TITLE _____

GRANT/FUNDING SOURCE (i.e., NIH, NIAID, U.S. Army): _____

PERIOD OF FUNDING REQUEST: From: _____ To: _____

I acknowledge all requirements and restrictions of the most current NIH guidelines for the Biosafety Level approved by the IBC. I accept responsibility for the safe conduct of the experiments conducted at this Biosafety Level. I understand that it is my responsibility to assure that all personnel working in my laboratory with any of these hazards are fully informed about their specific dangers, proper actions for safe use, steps to take in case of accidents, and are provided with all necessary safety equipment and instructions in its use.

Date

Signature of Principal Investigator

PLEASE FILL OUT THE REST OF THIS FORM BY ANSWERING ALL SECTIONS APPLICABLE TO THE PROJECT. Attach additional pages if necessary.

Section II. Research Description

A. Goals in Non-Scientific (i.e. "lay") Language (<250 words)

B. Use of Biological Agents or Materials

1. Human Blood, Body Fluids, Tissues, or Organs

a. Will you collect or work with human blood, body fluids tissues, or organs? Yes No

If yes, complete the following section - please check or list **all** that apply. Also, consult with the UCDHSC [COMIRB](#) regarding human use application requirements.

b. Specimens collected or manipulated:

Blood Serum Feces Urine Semen Spinal fluid

Tissues/Organs Other _____

c. Types of manipulation

Centrifugation Pipetting Dissection Blending/mixing Sonication

Frozen Sections Flow Cytometry Fixed/preserved Other _____

d. Will the specimens be labeled with radioisotopes? Yes No

If yes, Isotope: _____ Authorization Number: _____

e. Will you ship any human blood, body fluids tissues, or organs as part of a clinical trial? Yes No

2. Tissue Culture/Cell Culture

a. Will you work with cell or tissue cultures? Yes No

If yes, specify cell lines or strains and indicate if human or animal origin & Indicate if immortalized or primary cultures

Are you planning on immortalizing cell lines? Yes No

Will you use viral transformation? Yes No

List virus transformation agent to be used: _____

Will you transform cell lines with oncogenes in culture? Yes No

b. Will you use any of the following materials in cell culture?

Cytotoxic/chemotherapy Agents Select Agent Toxins _____

Other chemical compounds (list) _____

Radioisotopes Isotope: _____ Authorization Number: _____

3. Biological (Infectious) Agents

a. Will you conduct experiments involving [Select Agents or Toxins](#) as listed in 42 CFR 73 or 9 CFR 121?
All work with and possession of Select Agents or Toxins is federally regulated.

If **yes**, you must also submit a completed UCDHSC Biosafety Authorization Form [Appendix A](#) to the Institutional Biosafety Committee, c/o Biosafety Officer, Mailstop F484

b. Does your research involve the use of any of the following biological agents or DNA or RNA from one of these agents?

Bacteria Yes No
Fungi Yes No
Rickettsia Yes No

Parasites Yes No
Viruses Yes No
Prions Yes No

c. Is the organism infectious or potentially infectious to humans or animals? Yes No
Is this organism already available in your laboratory or on campus? Yes No

If **NO**, you may need to apply for the appropriate permits,[§] for the importation or transport of these agents. Contact the Biosafety Office for additional assistance.

d. Will the organism be labeled with radioisotopes? Yes No

e. If yes, is there a vaccine available to research staff? Yes No

f. Is the organism to be used in animals? Yes No

If yes, IACUC Protocol Number & Approval Date _____

UCDHSC Vivarium Facility _____

g. Will you conduct experiments involving infectious agents** or nucleic acids which may be capable of encoding an agent that can infect human cells? Yes No

h. Will you conduct experiments which would involve the deliberate transfer of drug resistance trait to microorganisms that are unknown to acquire the trait naturally? Yes No

(If acquisition of drug resistance could compromise use of the drug to control disease agents in humans, veterinary medicine or agriculture, it is subject to review and approval at the NIH. Contact the Biosafety Officer for additional information).

i. If **yes**, to any of the above, complete the following section **for each organism** to be used in the lab. Use additional pages as necessary.

1) List agent(s) by Species, strain (& isolates)

_____ Risk Group _____

2) Location(s) where organism will be used/handled? _____

3) Is a Biological Safety Cabinet (tissue culture hood) available? Yes No

Biosafety Cabinet Information

Manufacturer Model Class Type Serial Number Date of Certification

[§] To transport or import human pathogens, contact the [CDC Permit Program](#) For animal pathogens and animal products, contact the [USDA-APHIS Permit Program](#).

** Includes all viruses, bacteria, fungi, rickettsia or parasites. Refer to [NIH Guidelines, Appendix B](#), the [CDC BMBL Agent Summary](#) Statements, or discuss with the Biosafety Office.

- 3) Is antibiotic resistance expressed? Yes No
 Other markers _____
- 4) Largest volume†† of organisms used/produced is _____ LITERS
- 5) Is a toxin produced? Yes No
- 6) Do you work with this toxin? Yes No
- 7) Is the organism inactivated prior to other lab manipulations? Yes No
 Specify methods of inactivation
 Heat Chemical Radiation Other _____
- 8) Do you concentrate the organism? Yes No
 Specify methods of concentration:
 Centrifugation Precipitation Filtration Other _____

j. Briefly describe your Standard Operating Procedures to protect personnel from exposure to infectious agent during *in vitro* studies.

4. Recombinant DNA (rDNA)

All work with rDNA is governed under the [NIH Guidelines](#). Recombinant materials are defined as either:
 (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or
 (ii) molecules that result from the replication of those described in (i) above.

Will you conduct research involve recombinant DNA? Yes No

If yes, complete the checklists below, to determine if you will be conducting experiments which are exempt or non-exempt under the NIH Guidelines. If your experiments are **non-exempt**, you must also complete all of the applicable items in this section and provide supporting documentation as necessary.

a. Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval before Initiation.

1. Major Actions (see [Section III A of the NIH Guidelines](#)).

1a. Deliberate transfer of drug resistance trait to microorganisms that are unknown to acquire the trait naturally, if such acquisition could compromise use of the drug to control disease agents in humans, veterinary medicine or agriculture.

b. Experiments that Require NIH/ORDA and Institutional Biosafety Committee Approval before Initiation.

1. Experiments Involving the Cloning of Toxin Molecules with LD₅₀ of Less than 100 Nanograms per Kilogram Body Weight. (see [Section III B of the NIH Guidelines](#))

c. Experiments that Require Institutional Biosafety Committee and COMIRB Approvals and NIH/ORDA Registration before Initiation

1. Experiments Involving the Deliberate Transfer of Recombinant DNA or DNA or RNA derived from Recombinant DNA into One or More Human Subjects (Human Gene Transfer). You must also complete and submit 3 copies of the UCDHSC-specific answers to the questions of the Appendix M (*Points to Consider*), 3 copies of the Clinical Protocol and 3 copies of the Investigator's Brochure.

†† Large-scale (greater than 10 liters of culture) research or production involving viable organisms containing recombinant DNA molecules is governed under [NIH Guidelines, Appendix K](#).

d. Experiments that Require Institutional Biosafety Committee Authorization before Initiation

- 1. Experiments Using Risk Group 2, Risk Group 3, Risk Group 4^{##} or Restricted Agents as Host-Vector Systems.
- 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.
- 3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems.
- 4. Experiments Involving Whole Animals.
- 5. Experiments Involving More than 10 Liters of Culture.

e. Experiments that Require Institutional Biosafety Committee Registration Simultaneous with Initiation (see [Section III, F](#) of the NIH Guidelines, Exempt Experiments)

- 1. Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus.
- 2. Experiments Involving Transgenic Rodents
- 3. Experiments Involving *E. coli* K-12 or *Saccharomyces spp.* host-vector systems.^{§§}

5. Recombinant Insert (Transgene):

a. Source(s) of DNA/RNA sequences (include genus, species, gene name and abbreviation):

b. If the recombinant contains viral DNA, does the insert represent more than 2/3 of the viral genome?
 Yes No

c. What is the biological activity of the gene product or sequence inserted?

c. Will a deliberate attempt be made to obtain expression of *the foreign gene* encoded in the recombinant DNA?
 Yes No

6. Vector:

a. Host strain for propagation of the recombinant (give genus, species and parent strain):

b. Is a helper virus required? No Yes, specify: _____

c. Is a vector (specific phage, plasmid or virus) required? no yes

d. Identify specific vector: _____

e. If viral vector, what % of the viral genome remains? _____% n/a

7. Target Recipient of vector-recombinant DNA combination (indicate species or cell lines used):

Animals: _____

Tissue culture: _____

Gene therapy, specify target host(s)- (human, animal species): _____

DNA Vaccine, specify target recipient(s): _____

^{##} Many, but not all microorganisms are listed in their respective Risk Groups in [Appendix B](#), NIH Guidelines. Additional Agent Summary information may be found in the [CDC BMBL](#).

^{§§} Most experiments involving *E. coli* K-12 host vector system and *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host vector systems are exempt from the NIH Guidelines, [Appendix C](#).

8. Dual Use Research^{***}

Check any categories below that apply to your project:

- Renders a useful vaccine ineffective
- Adds antibiotic resistance affecting response to a clinically useful drug
- Enhances pathogen virulence
- Increases pathogen transmissibility
- Widens a pathogen's host range
- Lets a pathogen evade diagnostic or detection modalities
- Weaponization (e.g., environmental stabilization of pathogens)

- Check here if none of the above apply

C. Chemical Usage

Will you use any of the following materials in your laboratory?

- | | |
|-------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Bacterial Toxins: including Select Agents Toxins (e.g. tetrodotoxin, botulinum, etc.) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Heavy metal-containing chemicals: (e.g. Ag, As, Ba, Cd, Cr, Hg, Pb, Se, Tl, Ur) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Cytotoxic/antineoplastic drugs (cyclophosphamide, streptozotocin, mitomycin C, etc) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Teratogens (e.g. thalidomide, lead, formamide, urethane, etc) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Carcinogens (e.g. benzene, benzidine, phorbol myristate acetate, etc) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Mutagens (e.g. ethidium bromide, propidium iodide, Hoechst dye, etc) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Neurotoxins/Acetylcholinesterase Inhibitors (e.g. acrylamide, etc) | <input type="checkbox"/> Yes <input type="checkbox"/> No |

NOTE: The Principal Investigator is responsible for obtaining **Material Safety Data Sheets**, keeping them on file; ensuring that lab staff working with hazardous chemicals are familiar with their properties and disposal requirements; and take appropriate steps to protect themselves during use. The PI is responsible for compliance of all laboratory personnel with the Hazardous Chemical Waste Generator training requirements and disposing of these chemicals through the Health and Safety Division (HSD).

D. Risk Assessment and Containment

Does this project constitute any other potential risk or hazards to human health or the environment which is not stated above? Yes No

If yes, explain. Use additional pages as necessary. _____

^{***} [Dual Use research](#), as defined by the federal government, is under the oversight of the NIH, Office of Biotechnology Activities (OBA), [National Science Advisory Board for Biosecurity](#) (NSABB).