**University of Colorado Colorado Springs**

**IBC BIOSAFETY APPLICATION FORM**

**Instructions for Completing the IBC Biosafety Application and Authorization Review Process**

The Institutional Biosafety Committee (IBC), exercises oversight for all University of Colorado Colorado Springs (UCCS) research, classroom, and field activities involving biological agents or materials[[1]](#footnote-1), to ensure that employees, students, the public and the environment are protected from biohazards associated with UCCS operations.

Complete this form to receive IBC review and authorization for **3 years** for research involving: any biological agents, infected animals or tissues (including field work), recombinant or synthetic nucleic acid (rsNA) molecules, Select Agents & Toxins, and work with human blood, bodily fluids, tissues or cells in culture. Most of the biological research described in this application requires IBC authorization **prior** to initiation.

Note that “any biological agents” even includes 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

Registrations for biological research must be reviewed and approved by the IBC every three (3) years or immediately if there are significant changes**. The Application must be completed electronically.** Hand written, incomplete or illegible forms will be returned. The Addendum form can be used for less significant updates, such as those involving changes in personnel. The IBC meets as needed but at least annually. You can contact Wendy Haggren, Dept. of Chemistry and Biochemistry, 719-255-4156 (whaggren@uccs.edu) or Cynthia Norton, Env. Health and Safety, 719-255-3212 (cnorton@uccs.edu) for meeting

If you have any questions, please contact: Wendy Haggren, Dept. of Chemistry and Biochemistry, 719-255-4156 (whaggren@uccs.edu) or Cynthia Norton, Env. Health and Safety, 719-255-3212 (cnorton@uccs.edu). Please visit the EH&S web site to view and download all of the available support documents for the Campus Biological Safety Program: <http://www.uccs.edu/pusafety/environmental/biosafety.html>.

**Your IBC Biosafety Application will only be reviewed if a completed electronic copy is sent to** **whagrren@uccs.edu****. If an electronic signature is not provided, then a hard copy of only page 2 with your signature must be sent to the: Wendy Haggren, Dept. of Chemistry and Biochemistry.**

**If your research changes during your 3 year approval period, you must submit an IBC Biosafety Application Addendum Form,** [**http://www.uccs.edu/osp/forms.html**](http://www.uccs.edu/osp/forms.html)**. These changes may include: lab personnel changes – names added or deleted; changes or additions of biological agents or materials, select agents, toxins, rDNA, recombinant insert, vector, target recipient of vector-rDNA combination, or dual use research.**

**Biosafety Application#  (Office Use Only)**

**Renewal for Application #** (Office Use Only)

**Title of Application** (PI to Complete)

**Administrative Information**

Principal Investigator:  Office Rm. #

Email Address: Phone

Department: Building: Lab Rm(s). #

**Required Training and Research Review – This application or addendum cannot be approved until all required trainings have been completed for the PI and lab personnel listed in this application. All Training modules and Quizzes are located on the EH&S site at** <http://www.uccs.edu/pusafety/environmental/biosafety.html>

**Please check all sections which apply to this application (everyone must complete items 1-7):**

1. [ ] Section I – Scope of Work Narrative
2. [ ] Section II – Type of Experiments
3. [ ] Section III – Personnel
4. [ ] Section IV – Location of Research Experiment
5. [ ] Section V – Physical Containment Equipment – Biosafety Cabinets
6. [ ] Section VI – Safety Evaluation
7. [ ] Section VII – Biohazard Control Plan
8. [ ] Attachment II – Section A – Recombinant or Synthetic nucleic acid molecules
9. [ ] Attachment II – Section B – Biohazardous Agents & Toxins
10. [ ] Attachment II – Section C – Plants
11. [ ] Attachment II - Worksheet 1 – Recombinant DNA Experiments Questionnaire
12. [ ] Attachment II - Worksheet 2 – Animal Experiment Questionnaire

**Section I - Scope of Work Narrative:**

*Describe in lay terms the goal/purpose of experiments, methods and equipment used in the experimental procedures. Include safety/containment procedures, as well as decontamination and disinfection processes applied during the conduct of research. Narrative must address the potential sources of risk to personnel (e.g., aerosol generation, needle sticks, etc.) and/or the environment (e.g. pollen or interbreeding with wild species) and how these risks will be managed. Indicate if over 10 liters of culture shall be generated or if agents shall be concentrated.* ***Explain any boxes checked in Section VI.***

Narrative:

**Section II – Type of Experiments**

*(Check all applicable boxes and complete attachments as directed).*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| A1 | Use of recombinant or synthetic nucleic acid molecules (e.g., Use of GFP inserts):  | [ ]  Yes  | [ ]  No  | If yes to A1),A2) or A3), complete Attachment II-A, and Worksheet 1 (and 2 for transgenic animals)  |
| A2 | Use of transgenic animals | [ ]  Yes  | [ ]  No  |  |
| A3 | Development and production of novel transgenic animals | [ ]  Yes  | [ ]  No  |  |
|  | Proposed biosafety level of Experiment | [ ] BL1  | [ ]  BL2  |  |
| B | Use of human blood or blood products like serum, plasma or cell preparation or other bodily fluids (i.e. urine) which are not known or anticipated to be infected? | [ ]  Yes  | [ ]  No  | Please note that while we do not anticipate these materials to be infected, we treat all body fluids, etc. as if they were infected. If yes, the IBC may request additional information based upon the scope of work.  |
|  | Proposed biosafety level of Experiment | [ ] BL1  | [ ]  BL2  |  |
|  | Provide IRB Number approval if obtaining specimens from research subjects |  |
| C. | Use of biohazardous agents and Toxins (except those listed in item B above | [ ]  Yes  | [ ]  No  | If yes, complete Attachment II-B.  |
|  | Proposed biosafety level of Experiment | [ ] BL1  | [ ]  BL2  |  |
| D. | Use of CDC/USDA Select Agents/Toxins: (<http://www.selectagents.gov/>) | [ ]  Yes  | [ ]  No  | If yes, complete Attachment II-B. Use of these materials will also make you subject to a Dual Use of Research Evaluation |
| E. | Use of laboratory animal subjects with Biological Agents/Cells/Materials:  | [ ]  Yes  | [ ]  No  | If yes, complete Worksheet 2.  |
|  | Provide IACUC # |  |
|  | Proposed Animal Biosafety Level of Experiment | [ ]  ABSL1  | [ ]  ABSL2  |  |
|  | Proposed location of experiments:  |  |
| F. | Gene Therapy/Vaccine Experiment/Use of Human Research Participant:  | [ ]  Yes  | [ ]  No  | If yes, complete Attachment II-A  |
|  | Provide IRB Number and date of approval  |  |
| G. | Use of infected or potentially infected cell lines , tissue or bodily fluids (except those listed in B above), primary cells:  | [ ]  Yes  | [ ]  No  | If yes, complete Attachment II-B. |
|  | Provide IRB Number approval if obtaining specimens from research subjects |  |
| H.. | Use of animal cell lines, infected or potentially infected tissue or bodily fluids | [ ]  Yes  | [ ]  No  | If yes, complete Attachment II-B. |
| I. | Use of transgenic and/or pathogenic plants | [ ]  Yes  | [ ]  No  | If yes, complete Attachment II-C |
| J. | Use of radioactive materials:  | [ ]  Yes  | [ ]  No  |  |
|  | If yes, list approved isotopes |  |
| K. | Use of transgenic Drosophila melanogaster, Caenorhabditis elegans or Yeast: | [ ]  Yes  | [ ]  No  |  |
| L. | Ship biological materials – may include infectious agents, rDNA, transgenic animals or plants, human blood, blood products, tissue or fluid, animal carcass, tissue or fluid | [ ]  Yes  | [ ]  No  | If yes, complete the Shipping Biological Materials training module. |

**Section III – Personnel (attach a separate paper if there are additional personnel)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **NAME** |  **POSITION (Faculty, PostDoc, Graduate or Undergraduate Student)** | **DEPARTMENT** | **E-MAIL** | **PHONE** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**TRAINING DOCUMENTATION FOR PERSONNEL**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **NAME** |  **LAB SAFETY** | **BIOSAFETY** | **BBP** | **BIOSAFETY CABINET** | **rDNA** | **SHIPPING** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**Section IV - Location of Research Experiment**

Approval of the proposed experiment is given only for the locations listed below.

**If applicable, complete the location of animal experiments in Section I-D, page 1 and Worksheet 2.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Room used for:**(e.g.: general lab, Tissue culture, microscopy, etc.) | **BUILDING** | **ROOM** | **BIOSAFETY LEVEL** **(BL-1, BL-2)** | **SHARED ROOM**  |
|  |  |  |  | [ ] Yes |
|  |  |  |  | [ ] Yes |
|  |  |  |  | [ ] Yes |

**BIOLOGICAL MATERIALS STORAGE**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **BUILDING** | **ROOM** | **-70 FREEZER** | **REFRIGERATOR** | **INCUBATOR** | **OTHER** |
|  |  | [ ] Yes | [ ] Yes | [ ] Yes |  |
|  |  | [ ] Yes | [ ] Yes | [ ] Yes |  |

**Section V – Physical Containment Equipment - Biosafety Cabinets**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **BUILDING** | **ROOM** | **BIOSAFETY CABINET** **MANUFACTURER (e.g., Baker)** | **TYPE (e.g., Class II, Type A)** | **BSC # (listed on green sticker)** | **DATE OF CERTIFICATION** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Section VI – Safety Evaluation**

(Include any safety evaluation information in your scope of work narrative on page 5).

**I. Experimental Risks**

**A**. **Use of** **Sharps (parenteral inoculation hazard)** [ ]  Yes [ ]  No

 **If yes, check all used in experimental procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]   | **Needles & syringes** | [ ]   | **Pasteur pipettes** |
| [ ]   | **Razors** | [ ]   | **Drills** |
| [ ]   | **Scalpels** | [ ]   | **Glass** |
| [ ]   | **blades** | [ ]   | **Other**       |
| [ ]   | **Microtome probes** |  |  |

**Sharps Mitigation**- **check all used**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]   | sharps container  | [ ]   | engineered sharps (e.g. self-sheathing needle)  |
| [ ]   | broken glass container  | [ ]   | Other |

1. **Aerosol Generating Procedures (Inhalation Hazard)** [ ]  Yes [ ]  No

 **If yes, check all performed experimental procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]   | **Centrifugation** | [ ]   | **Mixing** |
| [ ]   | **Blending** | [ ]   | **Grinding** |
| [ ]   | **Sonicating** | [ ]   | **Pipetting** |
| [ ]   | **Flow cytometry analysis/sorting** | [ ]   | **Other**       |

**Aerosol Engineering Controls**-**check all applicable used to minimize the hazards**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]   | **Class II Biosafety Cabinet** | [ ]   | **Chemical Fume Hood** |
| [ ]   | **Sealed Vial** | [ ]   | **Sealed Rotor** |
| [ ]   | **Centrifuge Cone** | [ ]   | **HEPA Filtered Cage** |
| [ ]   | **Local Exhaust-snorkel** | [ ]   | **Other**       |

1. **Disinfectants used to clean the work area.**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]   | **chlorine (e.g.,10% bleach, 1-5-1 preparation of clydox)**  | [ ]  | **iodophors (e.g., 0.47% wescodyne** |
| [ ]   |  **alcohols (e.g. )70% ethanol, 70% isopropanol** | [ ]  | **phenolics (e.g.,amphyl)**  |
| [ ]   | **quaternary ammonia compounds** | [ ]  | **Other**  |

1. **Mitigation of Other Risks**

. **A. Include a description of radioactive material or hazardous chemical use in the narrative.**

**B. Biological Waste Management- Check here the used and describe the disposal of biological waste in the Scope of Work narrative**

[ ]  Sharps Container [ ]  Red Bag [ ]  Broken Glass Box [ ]  other 

[ ]  Autoclave Location: Building , Room 

1. **Personal Protective Equipment (PPE):**

 **Check all used and include use of PPE in the narrative**

[ ]  **safety eyewear:**[ ]  safety glasses [ ]  goggles [ ]  face shield [ ]  surgical mask

[ ]  **respirator:**[ ]  N95 [ ]  PAPR [ ]  other 

[ ]  **gloves:**[ ]  latex [ ]  nitrile [ ]  other 

[ ]  **lab coat:**[ ]  reusable, laundered [ ]  tyvek suit [ ]  disposable

[ ]  **other: types of PPE used:** [ ] shoe covers [ ]  head cover/bonnet [ ]  ear plugs

**D. Check safety equipment items available in the laboratory:**

[ ]  deluge shower [ ]  eyewash [ ]  hand washing sink  [ ]  overhead uv light [ ]  first aid kit

[ ]  fire extinguisher [ ]  spill kit [ ]  other 

**Section VII: Biohazard Control Plan**

**Please visit the EH&S Campus Biological Safety Program web site:** [**http:/www.uccs.edu/pusafety/environmental/biosafety.htm**l](http://www.uccs.edu/pusafety/environmental/biosafety.html) **to view a “sample” Biohazard Control Plan.**

**Instructions:** *Principal investigator is required to develop a plan to assure adequate protection of employees, students, the community, and the environment. The plan should take into account the nature of the research and the degree of risk. General information regarding biological safety can be obtained from the University of Colorado Colorado Springs* [*Department of Environmental Health and Safety*](http://www.colorado.edu/ehs/protocol/biosafety.html) *(*[[*http:/www.uccs.edu/pusafety/environmental/biosafety.html*](http://www.colorado.edu/ehs/protocol/biosafety.html)](http://www.uccs.edu/pusafety/environmental/biosafety.html)*)or from the following reference sources:* [*Biosafety in Microbiological and Biomedical Laboratories*](http://www.cdc.gov/biosafety/publications/bmbl5/index.htm) *(*[*http://www.cdc.gov/biosafety/publications/bmbl5/index.htm*](http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)*), Centers for Disease Control and National Institutes of Health, HHS publication no. (CDC) 93-8395, 5th ed., February 2007; "*[*Guidelines for Research Involving Recombinant DNA Molecules*](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)[*http://oba.od.nih.gov/rdna/nih\_guidelines\_oba.html*](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)*)," Federal Register 51: 16958-16985 (1986) and current revisions.*

|  |  |
| --- | --- |
| **1. Exposure determination:****Note: For research involving human blood, body fluids, and reagents derived from blood or body fluids, investigators are required to treat all materials as if known to be infectious for HIV, hepatitis B or hepatitis C virus and/or other blood-borne pathogens.****Personnel should be previously listed in the application document. It is required that all lab personnel receive information about the risks associated with any research involving infectious agents. This is especially important for lab personnel who may be immune-compromised.****The general types of experimental procedures that will be performed (e.g. cell culture, protein purification, drawing blood, etc). These should have already been detailed in the scope of work** |  |
| **2. Control methods:** |  |
| **a. *Describe facility in which work is to be performed.***  |  |
| **b. *Describe who will have access to the facility and how access will be controlled (If relevant, describe signs, doors, type of lock, separation from corridors and other work areas, etc.)*** |  |
| **c. *How and when will facility be cleaned and decontaminated? Will Facilities Management custodial personnel have routine access, and if so, how will they be protected from hazardous materials?***  |  |
| **d. *Describe safety devices that will be used. These may include some or all of the following: biosafety cabinets, hand washing facilities, mechanical pipetting devices, puncture resistant sharps containers, splash guards, self-sheathing needles.***  |  |
| **e. *What types of personal protective equipment will be used (gloves, masks, lab coats, etc). How will the equipment be decontaminated, laundered, or disposed of?*** |  |
| **3. Vaccination*: Will it be necessary to vaccinate workers against infectious agents? If so, describe plans for vaccinations. Human fecal material may contain the hepatitis A virus, so lab personnel who handle this material have the right to be vaccinated against HAV at no cost to them. Human cells, blood or bodily fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; unfixed tissue or organs may contain hepatitis B virus (HBV), so lab personnel who handle this material have the right to be vaccinated against HBV at no cost to them. HAV and HBV vaccinations can be arranged through EHS 719-255-3212 (Please note there is a cost to the department for these vaccinations).*** |  |
| **4. Accidents: *What procedures will be followed in case of an accident? (Note that incidents involving worker exposure to infectious material are covered under Worker's Compensation for initial medical care. Refer to*** [***https://www.cu.edu/content/workerscompensation***](https://www.cu.edu/content/workerscompensation) ***for approved locations for Worker’s Compensation treatment. Workers have the right to confidential medical evaluation, follow-up, and counseling). The IBC and EH&S must be notified immediately of incident, even if there is a “perceived” exposure. A Risk Management “Employee Injury Report Form” must be completed for all injuries,*** [***https://urm.cu.edu/docs/forms/incident\_report\_form.asp***](https://urm.cu.edu/docs/forms/incident_report_form.asp) ***and a “Needle Stick or Bodily Fluid Exposure Report Form” for these types of injuries/exposures,*** [***https://urm.cu.edu/docs/forms/needlestick\_incident\_report\_form.asp***](https://urm.cu.edu/docs/forms/needlestick_incident_report_form.asp) |  |
| 1. **Waste disposal: *Describe provisions for disposal of hazardous materials. If all or part of hazardous material is to be decontaminated on site, specify procedures to be used. All biohazardous waste will be processed according to EH&S “***[***Biowaste Management Policy***](file:///C%3A%5CUsers%5Ccnorton%5CDocuments%5CIBC%20-%20Biosafety%5CBoulder%20forms%5CBiowaste%20Management%20Policy)***” (http://www.uccs.edu/Documents/pusafety/EHS/UCCS.Biowaste.pdf).***
 |  |
| 1. **Labeling: *Describe tags, labels, or bags that will be used to identify hazardous materials. If hazardous material is to be decontaminated on site, specify how material will be labeled to indicate that it is no longer infectious.***
 |  |
| 1. **Training: *Describe how workers will be trained to handle all hazardous materials (biological, chemical and radioactive). For training in biological lab safety, blood-borne pathogens, biological safety cabinets, animal biosafety, and shipping biological materials, please visit*** [***http://www.uccs.edu/pusafety/environmental/biosafety.html***](http://www.uccs.edu/pusafety/environmental/biosafety.html) ***or contact EH&S at 255-3212 or Cindy Norton at (******cnorton@uccs.edu******)***
 |  |

**THE UNIVERSITY OF COLORADO COLORADO SPRINGS**

**INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) APPLICATION**

**PRINCIPAL INVESTIGATOR'S STATEMENT OF AGREEMENT**

**FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES**

 **AND BIOLOGICAL AGENTS**

I certify that the information contained in the IBC application is accurate to best of my knowledge.

I agree to comply with all University and IBC requirements with regard to the use, handling, storage and disposal of biological agents and recombinant or synthetic nucleic acid molecules.

I agree to follow the current *National Institutes of Health (NIH) Guidelines for the Use of Recombinant or Synthetic Nucelic Acid Molecules (March 2013)* and the recommendations from the CDC/NIH handbook, *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition.*

I ensure that all research personnel listed on this application have or will complete all biosafety training modules and 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. Prior to the initiation of experimental work all vaccinations or medical surveillance requirements recommended by the IBC and EH&S will be met.

Personal protective equipment, necessary for experimental procedures, will be provided to all laboratory workers. All biosafety cabinets shall be maintained properly and certified ***annually*.**

**I will notify the UCCS Biosafety Officer (719-255-3212) in the event of the following:**

1. Accident resulting in inoculation, ingestion, and inhalation of biological agents or recombinant or synthetic nucleic acid molecules or any incident causing serious exposure of personnel or danger of environmental contamination. **It is an NIH requirement for any institution that receives NIH funding to report any accident involving the use of recombinant or synthetic nucleic acid molecules within 24 hours.**

2. Malfunction of biological and physical containment safety equipment (biosafety cabinet), or facility failure, which may compromise building engineering controls and the safety of the workers in the lab.

3. All experimental work has been completed.

I will not proceed with the experiment until I have received an official notice of approval from the IBC unless otherwise specified. I acknowledge that IBC approval granted by this application is non-transferable to any other UCCS researcher.

Principal Investigator signature:  Date: 

Principal Investigator Printed Name: 

1. 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; infected animals or tissues (including field work); bacteria, viruses (to include oncogenic viruses), parasites, other microorganisms; Select agents and biological toxins; all recombinant or synthetic DNA or RNA materials. [↑](#footnote-ref-1)