Environmental Health and Safety

FOR OFFICE USE ONLY

IBC Permit Number:

Date Received:

Date Approved:

# Institutional Biosafety Committee (IBC) Protocol Application Bio Safety Permit

## INSTRUCTIONS

All pertinent sections must be completed in detail. If a section is left incomplete or no information is provided, your permit will be postponed, and all proposed activities and/or concurrent experiments must be halted until the plan is modified to meet the IBC's expectations.

The form provides text boxes for you to enter information. These boxes will expand as you enter text and do not have a set number of characters. Please provide as much detail as possible.

When you have completed the form, print a copy, then sign and date the signature page. Email a completed copy to ibc@unthsc.edu.

### General Information

**Project Title**

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**Principal Investigator**

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**Phone**

_____

**Email**

_____@unthsc.edu

**Institution and Department:**

_____

**Funding Agency/Sponsor:**

_____

**Name of the Person completing the application:**

_____

**Phone**

_____

**Email**

_____@unthsc.edu

**Purpose of this application**

In accordance with the Hazardous Material/Agent Permit Activation and Renewal Policy, this permit only allows a 3-year period of activity. When additional time is needed, the permit must be revised, re-submitted, reviewed, and re-approved by the IBC for another activity period, which will again be limited to three years.

**Lay Summary / Abstract:** Please provide a lay summary of the nature and purpose of the work. The summary should be aimed at non-specialists in the field and written in a way that they can easily understand (do not include the Specific Aim page of a grant). Please provide information regarding the proposed use of biohazardous materials.

## 1. Starting date of activity involving hazardous materials

_____

## 2. List all the hazardous materials use in the proposed project

| Hazardous Material | Yes | No | Details |
|---|---|---|---|
| Use of Recombinant DNA | ☐ | ☐ | If your project involves use of recombinant/synthetic nucleic acids, complete **Appendix 1** and IBC-rDNA-Review Checklist |
| Use of Viral vectors | ☐ | ☐ | |
| Use of siRNA, miRNA, shRNA | ☐ | ☐ | |
| Use of Plasmids | ☐ | ☐ | |
| Use of Bacterial Artificial Chromosomes | ☐ | ☐ | |
| Use of fixed Animal tissues or fluids | ☐ | ☐ | Provide details in **section 6** |
| Use of unfixed Animal tissues or fluids | ☐ | ☐ | |
| Use of Animal and or Tumor cell lines | ☐ | ☐ | |
| Use of Human cell lines | ☐ | ☐ | |
| Use of unfixed human tissues or fluids | ☐ | ☐ | |
| Use of select agents (exempt quantities) | ☐ | ☐ | |
| Use of Biological toxins | ☐ | ☐ | |
| Use of Hazardous Chemicals | ☐ | ☐ | Provide details in **section 7** |
| Use of Animals | ☐ | ☐ | Add IACUC protocol (s) # Provide details in **section 8 (VII)** |
| Has a protocol or protocols been submitted and approved for the animal subject issues indicated above? | ☐ | ☐ | |
| Use of Human subjects | ☐ | ☐ | Add IRB protocol (s) # |
| Has a protocol or protocols been submitted or approved by the IRB? | ☐ | ☐ | |
| Human research protocol involves phlebotomy | ☐ | ☐ | If YES complete **Appendix 2** |
| Use of Controlled substance | ☐ | ☐ | Add DEA registration information |
| Use of Radioactive materials | ☐ | ☐ | Add RSO consultation date/comments |
| Other (provide details) | | | |

## 3. Personnel - Research Personnel *(Add more rows if needed)*

| Name /Department | Role/Status | Years of experience | Phone | Email | Biosafety Training completion | BBP training completion date |
|---|---|---|---|---|---|---|

| | | with the agent | | | date | |
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**4. Personnel – Functions (Mark Yes or No for each box)** *(Add more rows if needed)*

| Name | Will you be handling biohazardous materials? | Will you be handling chemical hazards? | Will you be handling radioactive materials? | Will you be handling animals? | Will you be handling human materials? |
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**5. Locations**

*List all location where hazardous materials, specified under Summary Tab, will be used and stored*

| Bldg | Room | Biosafety level | Is the location(s) where biohazardous materials will be used and stored posted with BIOHAZARD warning sign? | Has the laboratories indicated as using or storing biohazardous materials been audited by the Biosafety Office? |
|---|---|---|---|---|
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**6. Infectious agents/ human cell lines/ animal cell lines/ human/non-human primate unfixed tissue**

**Are you using Infectious agents/ human cell lines/ animal cell lines/ human/non-human primate unfixed tissue in the proposed research?**

**Yes ☐ No ☐**

**If yes complete the following questions:**

***Example on how to fill up the column is given in red using Ad5 as agent/organism.***

| -Material/Agent? - Recombinant? (Yes/No) If yes, describe in Appendix 1. | Source | Species/Strain | Risk Group* | Lab Biosafety Containment Level** | Administered to Animals? (If yes, specify which animal) | Route of Administration | Animal Biosafety Containment Level |
|---|---|---|---|---|---|---|---|
| Ad5 (yes) | Commercial vendor: Addgene | Human adenovirus C /Type 5 | RG2 | BSL2 | Yes/mice | IV | ABSL2 |
| | | | | | | | |
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**In the space below, please briefly describe how each of these biological materials/agents will be used including their recombinant nature (e.g., transgenes, modifications):**

**For each entry in the above table please complete the following:**

***Example on how to fill up the column is given in red using Ad5 as agent/organism.***

| Material/Agent | Sharps use? (Yes/No) | Infectious Dose (for humans) | Antibiotic Resistance | Toxin Production | Inactivation? Type (e.g., heat, chemical) | Routes of infection (e.g., inhalation) | Largest volume/concentration to be handled |
|---|---|---|---|---|---|---|---|
| Ad5 | Yes | >150 viral units | None | No | No | Inhalation, droplet, needle stick | 1 x $10^6$ IFU/PFU |
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**For each entry containing antibiotic resistance and/or toxin production, please describe below:**

**Agent-specific information, including Risk Group, may be obtained from American Biosafety Association (ABSA) Risk Group database or Public Health Canada Pathogen Safety Sheets*

**CDC classifies work with human and non-human primate blood, body fluids, or tissue (e.g. human cell culture) as a minimum of BL-2.

## 7. Hazardous chemicals

**Are you using any hazardous chemicals in the proposed research?**

**Yes ☐ No ☐**

**If yes complete the following questions.**

a. Please list all hazardous chemicals use in the proposed work.
***Example on how to fill up the column is given in red using Cisplatin as chemical***

| Name of the chemical | CAS# | Associated h azard | Source | Intended use |
|---|---|---|---|---|
| Cisplatin | 15663-27-1 | Acute toxicity, carcinogenicity, mutagenicity. May cause serious eye damage. | Cayman Chemicals | Animal Injections |
| | | | | |
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b. Are you synthesizing any of the proposed chemicals in your lab? **Yes ☐ No ☐**

If yes: Please provide a summary of your synthesis process.

Location of synthesis

## 8. Procedures and controls

Please provide a summary of the proposed research. Describe the **procedures** involving the use of the pathogen/biohazard agent.

For each entry listed in Section 6 please complete the following

a. *Provide a step-by-step description of the study procedure highlighting the steps that may lead to the personnel's exposure to biohazardous materials. Plan control measures. Use a new row for each task/activity.*
***Example on how to fill up the column is given in red using Ad5 as agent/organism.***

| Material/Agent | Procedure | Significant Hazard | Control measures | |
|---|---|---|---|---|
| | | | Containment | PPE |
| Ad5 | *Sample aliquoting* | Infectious aerosol | BSC | gloves, lab coat |
| | | | | |
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b. **Respiratory protection:** *N95 respirator is generally recommended for laboratory workers who will be engaged in research with infectious agents that have the potential for spread of disease through the airborne route. If the N95 respirator has been selected as the control measure, please provide the dates of N95 fit testing.*

I. **Emergency Procedures:** Please describe procedures to be followed in the event of spill or exposure.

Specify procedures to be followed in the event of a spill:

☐ PI shall inform all laboratory personnel of the content and location of the Emergency Plan. *(In the event of personnel exposure during business hours, the PI will be informed, and the personnel will visit the Priority Care Clinic, IREB First floor 3430 Camp Bowie Blvd. Fort Worth TX. 76107. If the exposure occurs after business hours or on a weekend, personnel will inform the PI and go to emergency clinic of your choice.)*

Specify procedures to be followed in the event of a personnel exposure:

a. Emergency contact person

| Name | Office phone | Cell phone |
|---|---|---|
| | | |
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*II.* **Lab Security:** Describe the procedures for site security (*How will lab access be limited? How will lab entries be kept secure? Will anyone have access besides personnel listed in this protocol?).*

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III. **Health surveillance:**

*a.* **Immunizations:** *Immunization is generally recommended for laboratory workers who will be engaged in research with infectious agents for which an effective vaccine is available. If your research involves an infectious agent, please describe vaccines available for this infectious agent and the method of obtaining the vaccine for laboratory personnel.*

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**IV. Decontamination and Waste Disposal:**

a. Describe procedures for inactivation of pathogens, biohazards, or unused stocks. (autoclave, chemical treatment, etc.)

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b. Describe decontamination procedures and frequency

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c. What disinfectants will be used?

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d. Is an autoclave available?
**Yes** ☐ **No** ☐

e. Is a sharp disposal container available?
**Yes** ☐ **No** ☐

V. **Transfer of Biohazard Material:** If pathogens or biohazards will be transferred between laboratories or work locations, please describe the transport procedures, containment, and appropriate safety precautions. (Please refer to UNTHSC SOP for biohazard transport)

VI. **Unattended Operations:** Please describe portions of the experiment, if applicable, that may run unattended and steps taken to prevent accidental exposures.

## VII. Animal Use

Are laboratory animals in this research project? **Yes** ☐ **No** ☐

**If yes, please provide the following information**

Are the animals infected or injected with the agent? **Yes** ☐ **No** ☐

***Example on how to fill up the column is given in red using Ad5 as agent/organism.***

| Material/Agent | Inoculation route(s), e.g. IV, IP, aerosol | Signs of clinical disease, if any | Shedding, if YES indicate route(s) | Use of sharps |
|---|---|---|---|---|
| Ad5 | intratumorally | no | feces | yes |
| | | | | |
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Are special precautions required for housing the infected animals?

**Yes** ☐ **No** ☐

If yes, please explain

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Are special precautions required for handling animal cages? **Yes** ☐ **No** ☐

If yes, please explain

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How are animal carcasses to be disposed?

_____ _____ _____

PI ( Name) PI ( Signature) Date

**APPENDIX 1**

**rDNA/sDNA/Viral vectors**

**a. List original source(s) of DNA/RNA sequences and nature of inserted sequences (include gene names, biological markers, sequences, etc. and describe the function/activity of the DNA or its product). Attach the map of vectors.**

| **Recombinant material** | **Risk Group** *NIH Guidelines, Section II* | **Production of more than 10L of culture Y/N** | **Containment level** Section II and Appendix G |
|---|---|---|---|
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Please provide a summary of the proposed research. Describe the **procedures** involving the use of the Vectors/biohazard agent. Please provide the vector map

b. Will any plants be used in this research project?

**Yes** ☐ **No** ☐

b. Will any animals be used in this research project?

**Yes** ☐ **No** ☐

c. If **Yes,** what will be the recommended physical containment level?

**ABSL 1** ☐ **ABSL2** ☐ **ABSL3** ☐

d. What is the Host strain(s) for propagation? (genus, species and parent strain)

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Is a helper virus required?

**Yes** ☐ **No** ☐

e. For experiments involving a deliberate attempt to obtain expression of a foreign gene, identify what proteins will be produced and their biological activity

f. Target Recipient:
Animals **Yes** ☐ **No** ☐

Cultured Cells **Yes** ☐ **No** ☐

Describe:

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Humans? **Yes** ☐ **No** ☐

Plants? **Yes** ☐ **No** ☐

Other? (please describe)

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**Dual Use Research** (research intended to enhance scientific understanding and public health but could generate results that could be misused to advance biological weapon effectiveness): Indicate whether any of the categories below pertain to your project:

**Renders a useful vaccine ineffective**
**Yes** ☐ **No** ☐

**Adds antibiotic resistance affecting response to a clinically useful drug**
**Yes ☐ No ☐**

**Enhances pathogen virulence**
**Yes ☐ No ☐**

**Allows a pathogen to evade diagnostic or detection modalities**
**Yes ☐ No ☐**

**Weaponization (e.g., environmental stabilization of pathogens)**
**Yes ☐ No ☐**

**If you answer YES to any of the questions, provide details:**

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|---|
| |

PI ( Name) PI ( Signature) Date

**APPENDIX 2**

**Research involving Phlebotomy procedures.**

Will phlebotomy be performed on human subjects at any point in this protocol?
**Yes ☐ No ☐**

If yes, answer section below.

a. Are all personnel performing the phlebotomy procedure approved by the IRB. Please list the approved IRB protocol(s).

| |
|---|
| |

b. Provide the location the phlebotomy will be conducted.

c. Provide specific details of the blood draw procedure pertaining to biosafety review.

d. Provide specific details how the blood will be transported and stored.

**Attestation statement:**

☐ All personnel performing phlebotomy have completed the BBP training and have read and understand all requirements for phlebotomy detailed in the HSC biosafety manual section 16.6

| PI (Name) | PI ( Signature) | Date |
|---|---|---|