##



FOR OFFICE USE ONLY

IBC Permit Number:

Date Received:

Date Approved:

**Institutional Biosafety Committee (IBC) Protocol Application rDNA/sDNA 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@unthsc.edu

Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institution and Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Funding Agency/Sponsor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the Person completing the application: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email of person completing permit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@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 specifics on the project you are requesting approval for (Do not include the Specific Aim page of a grant).

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1. **Starting date of activity involving hazardous materials**
2. **List all the hazardous materials use in the proposed project**

|  |  |  |  |
| --- | --- | --- | --- |
| Hazardous Material  | Yes  | No  | Protocol numbers \* IACUC, \*\* IRB, \*\*\* DEA Registration \*\*\*\*RSO consultation date /comments  |
| Use of Recombinant DNA |  |  |  |
| Use of Viral vectors |  |  |  |
| Use of siRNA, miRNA, shRNA |  |  | If rDNA, viral vector and SiRNA are marked as Yes, they should complete the rDNA form and rDNA checklist |
| Use of Plasmids |  |  |  |
| Use of Bacterial Artificial Chromosomes |  |  |  |
| Use of Infectious Agents |  |  |  |
| Use of unfixed Animal tissues or fluids  |  |  |  |
| Animal and or Tumor cell lines |  |  |  |
| Use  |  |  |  |
| Human cell lines  |  |  |  |
| Use of human fluids and tissues (unfixed)  |  |  |  |
| Use of human subjects |  |  |  |
| Use of Toxic Chemicals, Potentially Toxic Medications, Carcinogens |  |  |  |
| Use of Toxins |  |  |  |
| Use of select agents |  |  |  |
| Use of Animal Subjects\* |  |  |  |
| Has a protocol or protocols been submitted and approved for the animal subject issues indicated above ? |  |  |  |
| Use of Human subjects \*\* |  |  |  |
| Has a protocol or protocols been submitted or approved by the IRB? |  |  |  |
| Use of Controlled substance\*\*\* |  |  |  |
| Use of Radioactive materials\*\*\*\* |  |  |  |
| Other  |  |  |  |

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Name /Department | Role/Status | Years of experience with the agent | Phone |  Email | Biosafety Training completiondate | BBP training completion date |
|  |  |  |  |  |  |  |  |
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1. 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 blood borne pathogens?  |
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1. **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 Biosafety Level 2 and above hazardous materials will be used and stored posted withBIOHAZARD warning sign? | Has the laboratories indicated as using or storing Biosafety Level 2 (and higher) hazardous materialsbeen audited by the Biosafety Office? |
|  |  |  |  |  |
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1. **rDNA/sDNA/Viral vectors**
2. 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.
3. Agent’s NIH Risk Group (NIH Guidelines, Section II) \*\*Note: Human pathogenic materials must be registered with IBC

RG1 \_\_\_\_\_\_\_\_\_\_\_\_. RG2\_\_\_\_\_\_\_\_\_\_\_\_

1. Will the experiment involve use or production of more than 10L of culture of viable organisms containing rDNA?

Yes \_\_\_\_\_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_\_\_\_\_

1. Will the experiment involve use or production of more than 10L of culture of viable organisms containing rDNA?

Yes \_\_\_\_\_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_\_\_\_\_

1. Physical containment as specified in NIH Guidelines Section II and Appendix G. Please note: the CDC classifies work with human and non-primate blood, body fluids, or tissue (e.g. human cell culture) as a minimum of BL-2.

BSL1\_\_\_\_\_. BSL2\_\_\_\_\_\_\_\_\_\_\_. BSL3\_\_\_\_\_\_\_\_\_\_.

1. Are using any plants in this research project?

Yes \_\_\_\_\_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_\_\_\_\_

1. Are using any animals in this research project?

Yes \_\_\_\_\_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_\_\_\_\_

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

ABSL1\_\_\_\_\_. ABSL2\_\_\_\_\_\_\_\_\_\_\_. ABSL3\_\_\_\_\_\_\_\_\_\_.

1. Are using any vectors in this research project?

Yes \_\_\_\_\_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_\_\_\_\_

1. If yes, what is the source of the vector? Provide a map of the vector for IBC review.
2. What is the Host strain(s) for propagation? (genus, species and parent strain)

Is a helper virus required? Yes \_\_\_\_\_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_\_\_\_\_

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

Animals Yes \_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_

Cultured Cells Yes \_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_

Describe:

Humans? Yes \_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_

Plants? Yes \_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_

Other? Yes \_\_\_\_\_\_\_\_. No\_\_\_\_\_\_\_\_

1. **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:

|  |  |  |  |
| --- | --- | --- | --- |
| **Categories** | **Yes** | **No**  | **Comments** |
| Renders a useful useful vaccine ineffective |  |  |  |
| Adds antibiotic resistance affecting response to a clinically useful drug  |  |  |  |
| Enhances pathogen virulence |  |  |  |
| Lets a pathogen evade diagnostic or detection modalities |  |  |  |
| Weaponization (e.g., environmental stabilization of pathogens)  |  |  |  |

1. **Infectious agents/ human cell lines/ animal cell lines/ human unfixed tissue**
2. Name of Organism (note specific strain) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Source of the organism: ­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Biosafety level: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. Risk Group:­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. Principal Risk:
7. Will sharps be used?

Please describe what sharps will be used and how they will be disposed of.

1. Infectious Dose \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Ordinary Route of Entry \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Does the organism exhibit antibiotic resistance ? Yes \_\_\_\_\_\_\_\_\_ No
4. Describe antibiotic resistance \_\_\_\_\_\_\_
5. Does the organism produce a toxin? \_\_\_\_\_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_
6. If yes, will work be done with the toxin? Yes \_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_
7. Will the organism be inactivated prior to the other laboratory manipulations?
8. Yes \_\_\_\_\_\_\_\_\_ No \_\_\_\_\_\_ Specify methods(s)

Heat \_\_\_\_\_\_\_\_\_

Chemical \_\_\_\_\_\_

Radiation \_\_\_\_\_\_

Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Amount, number of organisms used per week, and total volume \_

# Procedures and controls

Describe the **procedures** involving the use of the pathogen/biohazard agent

1. **Personal Protective Equipment (PPE):** Describe the personal protective equipment to be used in the laboratory while performing experiments.
2. **Containment:** Identify additional safety equipment or procedures such as fume hoods, biological safety cabinets, autoclaves, etc.
3. **Emergency Procedures:** Please describe procedures to be followed in the event of
	1. A chemical or biological spill or contamination of the lab
	2. Personnel exposure (PI is responsible for informing all laboratory personnel of the content and location of the Emergency Plan). (PI is responsible for informing all laboratory personnel of the content and location of the Emergency Plan). Include procedures for seeking medical treatment. *(In the event of personnel exposure during business hours the PI will be informed and the personnel will visit the occupational health clinic at the UNTHSC health pavilion, 855 Montgomery Street Fort Worth TX. 76107. If the exposure occurs after business hours or on a weekend, personnel will inform the PI and go to Texas Health Harris Methodist emergency room at 1301 Pennsylvania Ave., Fort Worth, TX 76104.)*
4. Emergency contact person

|  |  |  |
| --- | --- | --- |
| **Name** | **Office phone**  | **Cell phone**  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **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?).*
2. **Health surveillance:**
3. **Immunizations:** *Immunization is generally recommended for laboratory workers who will be engaged in research with infectious organisms for which an effective vaccine is available. If your research involves infectious agents, please describe the available vaccines (if any) and the method of obtaining the vaccine for laboratory personnel.*
4. **Respirator for protection:** *N95 Respirator Fit Testing – N95 respirator is generally recommended for laboratory workers who will be engaged in research with infectious agents potential for the spread of disease through the airborne route. Please provide information about the N95 fit testing.*
5. **Decontamination and Waste Disposal:**
6. Describe procedures for inactivation of pathogens, biohazards, or unused stocks. (autoclave, chemical treatment, incineration, etc.)
7. Describe briefly decontamination procedures and frequency
8. What disinfectants will be used?
9. Is an autoclave available?
10. Is a sharp disposal container available?
11. **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.
12. **Unattended Operations:** Please describe portions of the experiment, if applicable, that may run unattended and steps taken to prevent accidental exposures.

# Animal Use

Are laboratory animals in this research project? Yes \_\_\_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_\_\_

If yes, please provide the following information

* Animal Project Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Are the animals infected with the agent? Yes \_\_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_
* What is the route of inoculation for this experimental ?

iv \_\_\_\_\_\_\_ ip \_\_\_\_\_\_\_\_\_ aerosol \_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Will infected animals show signs of clinical disease? Yes \_\_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_

Will the agent(s) be shed by the infected animals? Yes \_\_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_

Indicate route(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are special precautions required for housing the infected animals?

Yes \_\_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_

If yes, please explain \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are special precautions required for handling animal cages? Yes \_\_\_ No \_\_\_

If yes, please explain \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

How are animal carcasses to be disposed? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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PI ( Name) PI ( Signature) Date