UNT Health FORT WORTH

Institutional Biosafety Committee

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

Principal Investigator

Phone

_____

Email

_____@unthsc.edu

Institution and Department:

_____

Funding Agency/Sponsor:

_____

Department:

_____

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 for 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).

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**
Use of Viral vectors	☐	☐	
Use of siRNA, miRNA, shRNA	☐	☐	
Use of Plasmids	☐	☐	
Use of Bacterial Artificial Chromosomes	☐	☐	
Use of Infectious Agents (bacteria, virus, fungi, parasites, prions)	☐	☐	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 human fluids and tissues (unfixed)	☐	☐	
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 with the agent	Phone	Email	Biosafety Training completion date	BBP training completion date

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?

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?

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 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 Section VII.	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

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	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

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-primate blood, body fluids, or tissue (e.g. human cell culture) as a minimum of BL-2.

7. Hazardous chemicals

A. 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.

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

b. Are you synthesizing any of the proposed chemicals in your lab? **Yes ☐ No ☐**

If yes: Please provide summary of your synthesis process.

_____

Location of synthesis

_____

Are you using any toxins in the proposed research?

Yes ☐ No ☐

Do you have any toxins in your possession?

Yes ☐ No ☐

If yes complete the following questions.

c. Please list all toxins use in the proposed work or in storage.
Example on how to fill up the column is given in red using cisplatin.

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

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

b. **Respiratory protection:** *N95 respirator is generally recommended for laboratory workers who will be engaged in research with infectious agents that have potential for the 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.

UNTHSC procedures for chemical or biological spill or contamination of the lab will be followed

Specify spill clean-up procedures

PI shall inform all laboratory personnel of the content and location of the Emergency Plan. *In the event of personnel exposure If immediate medical assistance is needed, call 911, During Business Hours – go to the closest Concentra or CareNow facility. If an exposure occurs after hours that requires immediate medical attention, personnel will visit any emergency medical center of their choice. Incident report form is filled out and submitted to Safety Office.*

Specify exposure procedures

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a. Emergency contact person

Name	Office phone	Cell phone

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?).*

III. **Health surveillance:**

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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.*

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 briefly decontamination procedures and frequency

c. What disinfectants will be used?

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 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

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?

_____ _____ _____

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

b. Are using any plants in this research project?

Yes ☐ No ☐

b. Are using any animals in this research project?

Yes ☐ No ☐

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

ABSL 1 ☐ ABSL2 ☐ ABSL3 ☐

d. Are using any vectors in this research project?

Yes ☐ No ☐

e. If yes, what is the source of the vector? Provide a map of the vector for IBC review.

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

Is a helper virus required?

Yes ☐ No ☐

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

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h. Target Recipient:

Animals **Yes** ☐ **No** ☐

Cultured Cells **Yes** ☐ **No** ☐

Describe:

Humans? **Yes** ☐ **No** ☐

Plants? **Yes** ☐ **No** ☐

Other? (please describe)

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:

Does your research	Yes/No	If yes for which agent
1) Increase transmissibility of a pathogen within or between host species	☐ Yes ☐ No	
2) Enhance transmissibility of the pathogen in humans	☐ Yes ☐ No	
3) Increase the virulence of a pathogen or convey a virulence to a non-pathogen	☐ Yes ☐ No	
4) Enhance the virulence of the pathogen in humans	☐ Yes ☐ No	
5) Increase the toxicity of a known toxin or produce a novel toxin	☐ Yes ☐ No	
6) Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin	☐ Yes ☐ No	
7) Alter the host range or tropism of a pathogen or toxin	☐ Yes ☐ No	

8) Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods	☐ Yes ☐ No	
9) Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions	☐ Yes ☐ No	
10) Altera human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin	☐ Yes ☐ No	
11) Enhance the immune evasion of the pathogen in humans such as be modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection	☐ Yes ☐ No	
12) Enhance the susceptibility of a host population to a pathogen or toxin	☐ Yes ☐ No	
13) Generate, use, reconstitute, or transfer an eradicated or extinct PPP (Pathogen with Pandemic Potential) or a previously identified PEPP (Pathogen with Enhance Pandemic Potential)	☐ Yes ☐ No	

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

NIH Guidelines Sections:

Please Check <u>all</u> that apply in the boxes below: *Recombinant or synthetic nucleic acid molecules (rsNA) apply to all *Guideline* sections. Synthetic sequences are considered the same as RNA, DNA, recombinant RNA/DNA and use RG of host/gene in sequence.	**<u>NIH Guidelines reference</u>**:

a.	☐	**Transfer of Drug Resistance trait to microorganisms** i.e., a drug used to treat disease caused by the biological agent under study if compromises ability to control disease agent -Requires NIH/OBA, RAC approval	III-A-1-a
b.	☐	**Cloning of toxin molecules with an LD_{50} < 100 ng/kg body weight** -Requires NIH/OBA approval	III-B
c.	☐	**Deliberate transfer of rsNA or DNA or RNA derived from rsNA into humans** - Requires NIH/OBA, RAC approval	III-C
d.	☐	**Use of Risk Group 2, 3, 4 or restricted agent as Host-Vector Systems**	III-D-1
e.	☐	**Administration of rDNA material into animals** (transformed/transduced cells, vectors, siRNA, microorganisms)	III-D-1, III-D-4
f.	☐	**Experiments involving transgenic/knockout animals requiring ABSL-2 containment or higher**	III-D-1, III-D-4b
g.	☐	**Cloning genes from a Risk Group 2, 3, 4 or restricted agent into a nonpathogenic prokaryotic or lower eukaryotic Host-Vector System** except toxins with an LD_{50} < 100 ng/kg BW -Requires NIH/OBA approval	III-D-2
h.	☐	**Use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in a tissue culture system**	III-D3, or III-E1
i.	☐	***De novo* generation of transgenic/knockout animals requiring ABSL-1 containment**	III-D-4-a
j.	☐	***De novo* generation of transgenic/knockout animals requiring ABSL-2 containment or higher**	III-D-4-b
k.	☐	**Experiments involving whole plants including algae, creating transgenic plants**	III-D-5 or III-E2
l.	☐	**Propagating modified organisms with culture volumes exceeding 10 liters**	III-D-6
m.	☐	**Experiments involving influenza virus** (H2N2, HPAI H5N1, 1918 H1N1)	III-D-7
n.	☐	**Use of cells/cell lines containing <2/3 eukaryotic viral genome** (cells must lack helper virus if using defective virus if propagated and maintained in culture)	III-E-1
o.	☐	**Use of RG-1 Host-Vector systems & genes not covered elsewhere, may be conducted using BSL-1 containment**	**III-E**
p.	☐	**De novo generation of transgenic/knockout Rodents requiring ABSL-1 containment**	III-E-3
q.	☐	**Synthetic nucleic acid molecules that**: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of < 100 ng/ kg body weight.	III-F-1
r.	☐	**Use of rsNA that is not in organisms or viruses and not modified to penetrate cell membranes, consists of DNA segments from one nonchromosomal or viral DNA source**	III-F-2 or III-F-3
s.	☐	**Consist entirely of nucleic acids from a prokaryotic host including indigenous plasmids or viruses when propagated in that host**	III-F-4
t.	☐	**Consist entirely of nucleic acids from a eukaryotic host propagated in that host**	III-F-5
u.	☐	**Consist entirely of DNA molecules segments from different species exchange DNA by a known physiological process** (App A for qualified natural exchangers exempt species sublist)	III-F-6 Appendix A
v.	☐	**Genomic DNA that has acquired a transposable element if it does not contain any rsNA**	III-F-7
x.	☐	**Use of cells/cell lines containing <1/2 eukaryotic viral genome of RG-1 or RG-2 viruses** (propagated and maintained in culture)	III-F-8 Appendix C-I
x.	☐	***E. coli* K-12 Host-Vector Systems for cloning/expression** except if *E. coli* host contains: (i) conjugation proficient plasmids or generalized transducing phages, (ii) lambda/lambdaoid/Ff bacteriophages or non-conjugative plasmids used as vectors (iii) >10L cultures, (iv) cloning of DNA from RG-3, RG-4, restricted organisms, biotoxins	III-F-8 Appendix C-II
y.	☐	***S. cerevisiae, S. uvarum,* or *Kluyveromyces* Host-Vector Systems for cloning/expression** (except (i) >10L cultures, (ii) cloning of DNA from RG-3, RG-4 or restricted organisms or biotoxins)	III-F-8 Appendix C-III III-F-8 Appendix C-IV

z.	☐	***B. subtilis or B. licheniformis* Host-Vector Systems (asporogenic strains) for cloning/expression** (except (i) >10L cultures, (ii) cloning of DNA from RG-3, RG-4 or restricted organisms or biotoxins)	III-F-8 Appendix C-V
aa.	☐	**The purchase or transfer of transgenic rodents requiring ABSL-1 containment**	III-F-8 Appendix C-VII
ab.	☐	**Transgenic rodent colony maintenance, breeding, crossing strains to create a new strain requiring ABSL-1 containment** except if either parent strain or progeny requires ABSL-2 and neither parent strain contains genetic modifications of (i) incorporation of >1/2 exogenous eukaryotic virus genome; or (ii) incorporation of transgene under control of gammaretroviral LTR, and progeny is not expected to contain >1/2 exogenous eukaryotic virus genome	III-F-8 Appendix C-VIII

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