# Instructions

Complete the form in full electronically (incomplete forms *will not be accepted*), print and submit with required signatures to **biosafety@unt.edu**

|  |  |
| --- | --- |
|  | IBC No \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Ms, Mr, or Dr.)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (IBC use only) |

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# Submission Information

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Submission Type | New  Renewal | | ***RMS Use***  ***Only*** | | ***IBC File #*** | | ***Approval Dates*** | |
| ***BSO*** | ***IBC*** |
| Agent Hazard Type(s)  Select all that apply | A biological product or agent[[1]](#footnote-1)  An infectious substance[[2]](#footnote-2)  Recombinant DNA  rDNA  rRNA  Transgenic Plant | | | | | Select agents[[3]](#footnote-3)  Exotic plants and insect pathogens  Human gene therapy trials (HGT)  Animals[[4]](#footnote-4)  Carcinogens, Controlled Substances  Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| NIH Review***[[5]](#footnote-5)*** Requires review by NIH? | Yes | No | |

# Project Information

|  |  |  |  |
| --- | --- | --- | --- |
| Project Title |  | | |
| Start Date | Click here to enter a date. | End Date | Click here to enter a date. |

## Project Sponsors

Identify the source(s) of all external and/or internal funding and attach a complete copy of the funding proposal.

| Project Sponsor | Funding Type | |
| --- | --- | --- |
|  | Internal | External |
|  | Internal | External |
|  | Internal | External |

## Purpose of Study

Briefly state the purpose and procedures of your study in the appropriate language for the UNT IBC’s community members; include the hypotheses or research question(s) you intend to answer.

[Briefly state purpose for study, including hypotheses/research questions/procedures]

## Principal Investigator(s) Information

**NOTE:** Must be the same Principal Investigator(s) named in any proposal for external or internal funding.

|  |  |  |
| --- | --- | --- |
| Principal Investigator |  |  |
| First Name | Last Name | Email |
|  |  |  |
| UNT Department | UNT Building and Room # | Office Phone Number |
|  |  |  |
| Co-Principal Investigator 1 | If necessary |  |
| First Name | Last Name | Email |
|  |  |  |
| UNT Department | UNT Building and Room # | Office Phone Number |
|  |  |  |
| Co-Principal Investigator 2 | If necessary |  |
| First Name | Last Name | Email |
|  |  |  |
| UNT Department | UNT Building and Room # | Office Phone Number |
|  |  |  |

## Project Personnel

List all personnel who will be working with biohazard and/or recombinant DNA covered under this registration, their expertise, and training.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name | | Job Title | | Degree Level | SMP Training***[[6]](#footnote-6)*** | BSL-2 Training |
|  | |  | | Select | Select | Select |
|  | |  | | Select | Select | Select |
|  | |  | | Select | Select | Select |
|  | |  | | Select | Select | Select |
|  | |  | | Select | Select | Select |
| Other Training | (specify) | |  | | | |

## Location of Study

Identify all locations where the study will be conducted.

|  |  |  |
| --- | --- | --- |
| Building | Room Number(s) | Notes |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Biohazard Agents (Non-recombinant DNA)

### Animal Studies

Work involves anesthetics, analgesics, or tranquilizers?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, provide chemical names. |

*[Enter list of anesthetics, analgesics and/or tranquilizers to be used.]*

Work involves use of infection agents?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, safety level*[[7]](#footnote-7)*?  1  2  3  4 |

Are infectious agents hazardous to human health?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, briefly describe route of transmission. |

*[Briefly describe route of transmission for infectious agents hazardous to human health.]*

### Carcinogens

Work involves carcinogens?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, provide chemical names. |

*[Enter list of carcinogens to be used.]*

Are animals exposed to carcinogens?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, safety level?  1  2  3  4 |

Are you registered to use controlled substances?

|  |  |  |
| --- | --- | --- |
| Yes | No |  |

### Select Agents

Work involves use of select agents?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, provide chemical and/or biological names, and safety level.  Safety Level:  1  2  3  4 |

*[Enter list of select agents to be used.]*

Have the CDC\FDA approved this research project yet?

|  |  |  |
| --- | --- | --- |
| Yes | No |  |

### Additional Information Regarding use of Infectious Agents, Select Agents and Carcinogens

*[Enter additional information relating to infectious agents, select agents and carcinogens in project]*

## Dual-Use Research

Check all 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

Increase pathogen transmissibility

Widens a pathogen’s host range

Lets a pathogen evade diagnostic or detection modalities

Weaponization (e.g., environmental stabilization of pathogens)

Check if none of the above applies

## Biological/rDNA Transport

Will any biological or rDNA materials be transported outside of the lab area (i.e., out of the building where the lab is located), or shipped off-site?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, describe briefly and attach documentation or permit. |

*[Enter brief description of transport requirements]*

## Human Materials

Brief description of use, including potential risk assessment and precautions to be taken:

*[Enter brief description of use of human materials]*

### Human Cadavers

Briefly describe procedures for handling and removal of human cadaver materials.

*[Enter brief description of handling and removal of human materials]*

## Safety Measures

Check the biological/rDNA safety level is recommended by NIH/BMBL/USDA guidelines for the propagation and handling:

|  |  |  |  |
| --- | --- | --- | --- |
| BSL1 (BL1-P) | BSL2 (BL2-P) | BSL3 (BL3-P) | BSL4 (BL4-P) |

## Requirements for BSL-2 levels (blood-borne pathogens risk)

Have you submitted an on-site manual to RMS?

|  |  |  |
| --- | --- | --- |
| Yes | No | *If no, expected submission date* |

Submission of Exposure Control Plans to RMS?

|  |  |  |
| --- | --- | --- |
| Yes | No | *If no, expected submission date* |

The protective clothing and equipment used when handling this agent:

|  |  |  |  |
| --- | --- | --- | --- |
| Gloves  Lab Coat | Face shield  Goggles | Cover gown  Respirator | Fume Hood  Biosafety Cabinet |
| [Other; enter description] | | | |

Method for disposable of biohazardous waste:

|  |  |
| --- | --- |
| Place in double bag for disposal.  Place in double bag for incineration.  Autoclaved then placed in regular trash. | Chemical disinfection then placed in regular trash.  Chemical disinfection of liquid then poured down sanitary sewer. |

Disinfectant(s) used for surface decontamination and spills:

|  |  |  |
| --- | --- | --- |
| Bleach | 70% alcohol | Phenolic |
| [Other; enter description] | | |

# Bio-Hazardous Agents[[8]](#footnote-8)

## Agent Classification

| Agent***[[9]](#footnote-9)*** | Classification***[[10]](#footnote-10)*** | Risk Group***[[11]](#footnote-11)*** | Human Susceptible | Immunization Required | Duration |
| --- | --- | --- | --- | --- | --- |
|  | Select | Select | Select | Select |  |
|  | Select | Select | Select | Select |  |
|  | Select | Select | Select | Select |  |
|  | Select | Select | Select | Select |  |
|  | Select | Select | Select | Select |  |

#### Laboratory Transmission Routes

If “**Human Susceptibility**” was “**Yes**” for any agents for use in research, provide a description of laboratory transmission route for each below.

1. *[Enter laboratory transmission routes for agents identified as human susceptible]*
2. *[Enter laboratory transmission routes for agents identified as human susceptible]*
3. *[Enter laboratory transmission routes for agents identified as human susceptible]*
4. *[Enter laboratory transmission routes for agents identified as human susceptible]*

### Risk Planning

Below provide a brief description of use, including potential risk assessment outcomes and precautions to be taken. Attach a MSDS sheet and additional risk assessment information if available.

*[Enter brief description of project use of agents]*

#### Describe pathogenicity, including disease incidence and severity

*[Enter pathogenicity]*

#### Stability of agent(s)

*[Enter stability for all agent(s)]*

#### Infectious dose(s)

*[Enter infectious dose(s) per agent]*

#### Concentration[[12]](#footnote-12) and volume that will be handled

*[Enter concentration and volume per agent]*

#### Where is the geographic location of the infectious material, host, or nature of source?

*[Enter geographic location of each agent]*

#### Does animal data of pathogenicity, infectivity and route of transmission in animals exist?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, describe briefly and attach documentation or references. |

1. *[Enter brief description of pathogenicity, infectivity and route of transmission]*

#### Is there effective prophylaxis or therapeutic intervention available?

*[Enter description of prophylaxis or therapeutic interventions]*

#### What systems will be used to propagate the agent(s) listed above?

*[Enter description of systems to propogate agent(s)]*

# rDNA Project Specifications

## rDNA Project Information

### NIH Section III review classification and category designation[[13]](#footnote-13), [[14]](#footnote-14), [[15]](#footnote-15), [[16]](#footnote-16)

### ***Select NIH Review Category***

#### Which NIH review classification and category applies to this work?

Check the appropriate box for your review category and indicate the subcategory that applies to this work.

|  |  |
| --- | --- |
| Review Category | Subcategory |
| III-A: Requires IBC, RAC & NIH approval before initiation  Subcategory: | |
| III-B: Requires NIH/OBA and IBC approval before initiation  Subcategory: | |
| III-C: Requires IBC and IRB approvals and RAC review before participant enrollment  Subcategory: | |
| III-D: Requires IBC approval before initiation  Subcategory: | |
| III-E: Requires IBC notice simultaneous with initiation  Subcategory: | |
| III-F: Requires Exempt, IBC registration is not required but recommended to assure that work is properly classified  Subcategory: | |

#### Recombinant Molecule(s)[[17]](#footnote-17)

*[Enter recombinant molecules]*

#### Source of DNA/RNA (species)

*[Enter source of recombinant species]*

#### Types of vector(s)[[18]](#footnote-18)

*[Enter vector types]*

#### Types of promoter(s)[[19]](#footnote-19)

*[Enter promoter types]*

#### Size of the insert/total genome

*[Enter insert/total genome size]*

#### Nature of inserted sequences

*[Enter nature of inserted sequences]*

#### Protein(s) produced

*[Enter protein(s) produced]*

#### Does the inserted gene encode a known toxin?

|  |  |  |
| --- | --- | --- |
| Yes | No | If “Yes”, body weight: *[LD50 < 100 ng/Kg of body weight]* |

#### Does the inserted gene encode a known oncogene?

|  |  |
| --- | --- |
| Yes | No |

#### Does viral DNA integrate into the host genome?

|  |  |  |
| --- | --- | --- |
| Yes | No | *If “Yes”, what % of the viral genome remains? [##%]* |

#### Modification has the potential to increase the replication capacity of the virus?

|  |  |
| --- | --- |
| Yes | No |

#### The inserted gene has the potential for altering the cell cycle?

|  |  |
| --- | --- |
| Yes | No |

#### Use of infectious DNA/RNA?

|  |  |
| --- | --- |
| Yes | No |

#### Use of defective DNA/RNA with helper virus?

|  |  |
| --- | --- |
| Yes | No |

#### The probability of generating replication-competent viruses?

|  |  |  |
| --- | --- | --- |
| High | Low | N/A |

#### Target recipient of vector-recombinant DNA combination[[20]](#footnote-20)

*[Indicate species or cell lines used]*

#### Transgenic animal research

|  |  |  |
| --- | --- | --- |
| Yes | No | *If “Yes”, what species? [Indicate species]* |

#### Tissue culture

|  |  |  |
| --- | --- | --- |
| Yes | No | *If “Yes”, what tissue culture types? [Indicate tissue culture types]* |

#### Plants

|  |  |  |
| --- | --- | --- |
| Yes | No | *If “Yes”, what plants? [Indicate plants]* |

#### Gene therapy

|  |  |  |
| --- | --- | --- |
| Yes | No | *If “Yes”, specify target hosts? [Indicate human, animal]* |

#### DNA Vaccine

|  |  |  |
| --- | --- | --- |
| Yes | No | *If “Yes”, specify target hosts? [Indicate human, animal]* |

#### Radioisotope use in conjunction with recombinant DNA use

|  |  |  |
| --- | --- | --- |
| Yes | No | *If “Yes”, provide an explanation of this use in your summary of techniques to be used* |

#### Transgene Mapping

*Attach a map to the completed form of the transgene or vector with transgene to this registration form before submitting.*

# Signature and Provisional Approval

## Principal Investigator(s)

|  |  |  |  |
| --- | --- | --- | --- |
| I certify that the above statements accurately describe my proposed use of these materials. I have read and understand the UNT Biosafety Policy and the Biosafety Handbook and will comply with all applicable requirements. | | | |
| ***Print Name*** |  | | |
| ***Principal Investigator*** |  | *Date* |  |
| I certify that the above statements accurately describe my proposed use of these materials. I have read and understand the UNT Biosafety Policy and the Biosafety Handbook and will comply with all applicable requirements. | | | |
| ***Print Name*** |  | | |
| ***Co-Principal Investigator 1*** |  | *Date* |  |
| I certify that the above statements accurately describe my proposed use of these materials. I have read and understand the UNT Biosafety Policy and the Biosafety Handbook and will comply with all applicable requirements. | | | |
| ***Print Name*** |  | | |
| ***Co-Principal Investigator 2*** |  | *Date* |  |

## Provisional Approval

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ❑ | Work on this project **MAY BEGIN** as of the date below, but the project will not be finally approved until it has been reviewed and approved by the IBC. | | | |
| ❑ | Work on this project **MAY NOT BEGIN** until the project has been reviewed and given final approval by the IBC. | | | |
| ***Biosafety Officer***  ***or IBC Chair*** | |  | *Date* |  |

## Final IBC Approval

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ❑ | This project has been reviewed by the IBC and is **APPROVED**. | | | |
| ❑ | This project has been reviewed by the IBC and is **NOT APPROVED**. (IBC Chair must provide supplemental information regarding steps needed to achieve approval or explanation for unconditional termination of project) | | | |
| ***IBC Chair*** | |  | *Date* |  |

1. Any virus, therapeutic serum, toxin, antitoxin, blood, blood component or derivative, allergenic product, or analogous product, or arphenamine, or derivative of arphenamine [↑](#footnote-ref-1)
2. Etiological agents, affecting animals or humans [↑](#footnote-ref-2)
3. Select agents or high consequence livestock pathogens and toxins [↑](#footnote-ref-3)
4. Including their blood, tissues and cell lines, wild-trapped animals, sheep, macaques, and transgenic/knockout animals [↑](#footnote-ref-4)
5. See *NIH Section III review classification and category designation* later in form [↑](#footnote-ref-5)
6. Standard microbiological practices [↑](#footnote-ref-6)
7. **Safety Level 1**: Agents pose low risk to personnel and the environment.

   **Safety Level 2**: Agents pose moderate risk to personnel and the environment. Effective treatment and preventive measures are available in the event that an infection occurs.

   **Safety Level 3**: Agents cause serious disease (human, animal or plant) or can result in serious

   economic consequences.

   **Safety Level 4**: Agents produce very serious disease (human, animal or plant) that is untreatable. [↑](#footnote-ref-7)
8. Any microorganism, virus, infectious substance, or toxin that is biological in nature and capable of producing deleterious effects upon humans, animals, plants, or the environment [↑](#footnote-ref-8)
9. Name of plant or microorganism; attach a copy of MSDS sheet if available [↑](#footnote-ref-9)
10. HGT – Human Gene Therapy; Sel. Ag. – Select agent; P/I Path. – Plant/Insect Pathogen; transgenic plant; others [↑](#footnote-ref-10)
11. Consult the NIH “Classification of Human Etiological Agents on the Basis of Hazard” on the NIH Office of Biotechnology Activities website (<http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_B.htm>) [↑](#footnote-ref-11)
12. Number of infectious organisms per unit volume [↑](#footnote-ref-12)
13. Check the appropriate box for your review category and indicate the subcategory that applies to project. For detailed consult: http://oba.od.nih.gov/oba/rac/Guidelines/NIH\_Guidelines.htm" [↑](#footnote-ref-13)
14. Sections III A, B, C, III-A is for Major Actions, III-C category is for human gene therapy trials only [↑](#footnote-ref-14)
15. Section III-F (Exempt experiments) [↑](#footnote-ref-15)
16. Sections III-E: Requires IBC notice simulations with initiation [↑](#footnote-ref-16)
17. e.g. E.coli Dh5-α rather than E.coli or IPTG-inducible lac promoter rather than inducible promoter [↑](#footnote-ref-17)
18. Describe the class of vector, source organism or derivative, etc [↑](#footnote-ref-18)
19. Include source and activity [↑](#footnote-ref-19)
20. Indicate species or cell lines used [↑](#footnote-ref-20)