IBC REGISTRATION APPLICATION FORM

|  |  |
| --- | --- |
| IBC Number (Assigned by RI Office): |  |

# 1: PRINCIPAL INVESTIGATOR INFORMATION

## 1.1. Principal Investigator Information

Principal Investigator: Click here to enter text.

Position/Title: Click here to enter text.

Department/College: Click here to enter text.

Office/Cell Phone #: Click to enter text.

Email Address: Email address

Protocol Title: (for this proposal) Click here to enter text.

Will this project be funded by a grant, contract, or any pending grants or contracts?  Yes  No

If marked yes, describe the project narrative submitted as part of your grant proposal in the field below or include as a separate attachment. (Do not include other application section, i.e. budget, etc.)

Click here to enter text.

Internal Funding (provide funding source/grant #): Click here to enter text.

External Funding (provide funding source/grant #):Click here to enter text.

Grant Title: (if different from IBC protocol) Click here to enter text.

Grant Principal Investigator: (if different from protocol)asdfasd

Select the type of IBC Submittal:

New (Project is new to FAU, and no prior IBC Registration at FAU for this Grant.

Renewal of IBC Registration (Previous FAU IBC Registration has expired): Enter current IBC#

## 1.2. Biological Materials Checklist

1.2.1. Check all that apply to proposed work:

Aerosol generating procedures

Animal blood, tissue, or bodily fluid.

Biohazardous agents and/or toxins.

Cell lines or primary cell lines.

Gene therapy/vaccine experiment/human subjects.

Human blood, tissue, or bodily fluid.

Import/Export to/from US

Infected or potentially infected cell lines.

Microorganisms.

Recombinant or synthetic nucleic acid molecules.

Sharps (scalpels, hypodermic needles, lancets, cannulas, surgical scissors, fistulas, auto injector,

connection needle, etc.)

Shipping of biological materials.

Transgenic and/or pathogenic plants.

Transgenic animals.

U.S. Select Agent. <https://www.selectagents.gov/SelectAgentsandToxinsList.html>

## 1.3. Biosafety Level

1.3.1. Indicate the [biosafety level](https://www.cdc.gov/training/QuickLearns/biosafety/) of the proposed work.

BSL 1  BSL 2  BSL 3 BSL 1 & BSL 2 BSL1, BSL2, BSL3

## 1.4. Subject Population Checklist

1.4.1. Will this project involve human, animal or plant pathogens, or biological toxins?

Human Subjects

Animals

Plant Pathogens

Biological Toxins

Other

If ‘OTHER’ please describe: Click here to enter text.

1.4.2. Please list the infectious agents or biological toxins to be used and indicate appropriate categories in the table below:

### Table 1.4.2a

To add additional agents, click on the **+** at the end of each box.

| NAME OF INFECTIOUS AGENT OR BIOLOGICAL TOXIN | HUMAN HAZARD? (YES/NO) | ANIMAL HAZARD?  (YES/NO) | INSECT HAZARD? (YES/NO) | LOCATION OF ORIGIN |
| --- | --- | --- | --- | --- |
| Click here to enter text. | Yes  No | Yes  No | Yes  No | Click here to enter text. |
| Click here to enter text. | Yes  No | Yes  No | Yes  No | Click here to enter text. |
| Click here to enter text. | Yes  No | Yes  No | Yes  No | Click here to enter text. |
| Click here to enter text. | Yes  No | Yes  No | Yes  No | Click here to enter text. |
| Click here to enter text. | Yes  No | Yes  No | Yes  No | Click here to enter text. |
| Click here to enter text. | Yes  No | Yes  No | Yes  No | Click here to enter text. |

1.4.3. If this project will involve infectious agents or biological toxins that affect humans, describe **in detail** the symptoms, severity of disease, target organs, vulnerable populations and route(s) of transmission (cutaneous absorption/adsorption through direct contact with skin, mucosal membranes, aerosol, ingestion, etc.(consult the agent safety data sheet for full detail and address here)

Click here to enter text.

## 1.5. Research Location(s)

Please list the research activities, building, room number, and the biosafety level for that space and research activity.

### Table 1.5.a. Research Activities

To add additional research activities, click on the **+** at the end of each box.

| RESEARCH ACTIVITIES | BUILDING | ROOM | BIOSAFETY LEVEL | SHARED ROOM? (YES/NO) |
| --- | --- | --- | --- | --- |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | BSL 1  BSL 2  BSL 3  BSL 1 & BSL 2  BSL1, BSL2, BSL3 | Yes  No |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | BSL 1  BSL 2  BSL 3  BSL 1 & BSL 2  BSL1, BSL2, BSL3 | Yes  No |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | BSL 1  BSL 2  BSL 3  BSL 1 & BSL 2  BSL1, BSL2, BSL3 | Yes  No |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | BSL 1  BSL 2  BSL 3  BSL 1 & BSL 2  BSL1, BSL2, BSL3 | Yes  No |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | BSL 1  BSL 2  BSL 3  BSL 1 & BSL 2  BSL1, BSL2, BSL3 | Yes  No |

## 1.6. Biological Materials Storage

List locations for storage of biological materials and locations of biological safety equipment (biosafety cabinet, autoclave, etc.). Include most recent certification date for biosafety cabinets.

### Table 1.6.a. Biological Materials Storage

To add additional locations, click on the **+** at the end of the box.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| BUILDING | ROOM | FREEZER | REFRIGERATOR | INCUBATOR | OTHER |
| Click here to enter text. | Click here to enter text. | Yes  No | Yes  No | Yes  No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Yes  No | Yes  No | Yes  No | Click here to enter text. |

**Table 1.6.B. Biological Safety Cabinets**

|  |  |  |  |
| --- | --- | --- | --- |
| BIOLOGICAL SAFETY EQUIPMENT USED | BUILDING /  ROOM | MOST RECENT CERTIFICATION DATE | SERIAL NUMBER |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |  |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |  |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |  |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |  |

## 1.7. Exporting & Importing

1.7.1. Will you be exporting/importing samples (tissues, blood, organs, etc.), plasmids, or research products outside/ inside of the United States of America?

Yes  No

## 1.8. IACUC/IRB Review

1.8.1. Has this project been approved or is it being reviewed by the IACUC or IRB?

YES, there is an associated approved **IACUC** protocol.

* List protocol number. Click or tap here to enter text.
* If approved, attach FAU IACUC approval letter

IACUC approval is pending IBC

YES, there is an associated approved **IRB** protocol.

* List protocol number. Click or tap here to enter text.
* If approved, attach FAU IRB approval letter.

IRB approval is pending IBC

NO, this research does not require IACUC or IRB review/approval.

# 2: NIH REVIEW CATEGORY & SUBCATEGORY

Check all the categories, subcategories and information that apply.

NIH Office of Science Policy Website: <https://osp.od.nih.gov/>

| CATEGORY | OVERSIGHT BY | INCLUDES/SUBCATEGORIES |
| --- | --- | --- |
| [III-A](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc3457032) | NIH Director, RAC & IBC | Studies that involve the deliberate transfer of a drug resistance to microorganisms (not known to acquire the trait naturally) that can compromise the use of the drug to control the microorganism and its disease in humans, veterinary medicine or agriculture |
| [III-B](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc3457034) | NIH/OSP & IBC | This category is limited to cloning of genes that encode for toxin molecules with LD50 less than 100 nanograms/kg body weight (e.g., botulinum, tetanus, diphtheria toxins). |
| [III-C](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc3457037) | RAC, IRB & IBC | Transfer of recombinant or synthetic DNA, or DNA or RNA derived from recombinant DNA, into one or more human subjects. |
| [III-D](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc3457039) | IBC Approval before initiation | D-1: Experiments using Risk Group 2. Risk Group 3, Risk Group 4 or restricted agents as host-vector systems.  D-2: Experiments in which nucleic acids from Risk Group 2, Risk Group 3, Risk Group 4 or restricted agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems. For cloning toxin molecules with LD50 of less than 100 nanograms per kilogram body weight check section III-B above. Section D-2 does not apply.  D-3: Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of a helper virus in tissue culture systems.  Experiment is likely to enhance pathogenicity. Yes  No  Experiment extends the host range. Yes  No  D-4: Experiments involving whole animals in which the animal’s genome has been altered by stable introduction of r/sNA, or r/sNA derived there from, into the germ-line (transgenic animals) and experiments involving viable r r/sNA-modified microorganisms tested on whole animals. For the latter, other than viruses which are only vertically transmitted, the experiments may not be conducted at BL1-N containment. A minimum containment of BL2 or BL2-N is required (see E-3 for BSL-1 transgenic rodent experiments).  Fraction of viral genome being utilized may lead to productive infection.  Yes  No  Recombinant r/sNA: source is greater than 2/3 eukaryotic viral genome.  Yes  No  D-5: Experiments involving the generation of transgenic plants or use of recombinant microorganisms or recombinant insects in plants. (For cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight, see section III-B above. Section D-5 does not apply.)  D-6: Experiments involving cultures of 10L increments or greater. |
| [III-E](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc3457047) | IBC approval simultaneous with initiation | E-1: Experiments involving less than 2/3 of a eukaryotic virus genome. All viruses from a single family being considered identical.  Do cells contain helper viruses for family of viruses being used? (If yes, see III-D3).  Yes  No  E-2: Experiments involving the generation of transgenic plants or use of recombinant microorganisms or recombinant insects in plants. For those not described in III-A, III-B, III-C, III-D or III-F.  E-3: Experiments involving the generation of transgenic rodents for BSL-1 only (see III-D4 for experiments requiring BSL-2, 3 or 4). |
| [III-F](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc3457051) | FAU policy requires Biosafety Approval Form Submittal | Exempt by NIH Guidelines (Please attach information from NIH Guidelines that verifies the exempt status). |

# 3: SPECIFIC AIMS OR PROJECT AND PROTOCOLS USED

## 3.1. Specific Aims

3.1.1. Provide an overall summary of the project and briefly explain in **language understandable to the general public,** the specific aim(s) of the study.

Click here to enter text.

## 3.2. Benefits

3.2.1. Explain in **language understandable to the general public,** how the information gained in this study will benefit human or animal health, the advancement of knowledge, and/or serve the good of society.

Click here to enter text.

## 3.3. Outline of Protocols

3.3.1. Provide a detailed outline of the biohazard control plan for recombinant DNA work and other biohazardous work.

* Briefly describe the general types of experimental procedures that will be performed.
* Address the potential sources of risk to personnel (aerosol generation, needle sticks, etc.) and/or the environment, and how these risks will be managed.
* Describe safety devices that will be used (e.g. biosafety cabinets, hand washing facilities, puncture resistant sharps containers, etc.)
* Include decontamination/disinfection processes.
* Include plans for disposing of materials.

Click here to enter text.

# 4: BIOLOGICAL MATERIALS IN PROJECT

4.1. List the recombinant DNA used in the proposed work.

* Include cloned gene(s), vectors used; give both name and type of each vector.

Click here to enter text.

4.2. List the genes described above that will be expressed:

Click here to enter text.

4.3. List cell lines used in the proposed work:

Click here to enter text.

4.4. Include information if any recombinant or synthetic DNA materials will be used in any vertebrate or invertebrate animal models:

Click here to enter text.

4.5. List the infectious or pathogenic agents used in the proposed work.

* Number and provide a short description of each agent.

Click here to enter text.

4.6. List any materials of human or mammalian origin (blood, tissues, fluids, etc.)

* Indicate whether each material is certified pathogen free.
* Attach documentation that certifies cell lines are pathogen free.
* Provide IRB documentation (i.e., IRB approval, protocol number) in 1.9 if obtaining specimens from human research subjects.

Click here to enter text.

If applicable, explain what the specific product of the gene expressed will be (i.e., tissue culture or animals) and if there is any anticipated toxicity.

Click here to enter text.

# 5: PERSONNEL AND TRAINING

5.1. Please list the PI and other personnel who will be handling biological agents as part of this registration. Attach training certificates and/or proof of completion of training for all personnel.

### Table 5.1.a. Personnel and Training

To add additional personnel, click on the **+** at the end of the box.

|  |  |  |
| --- | --- | --- |
| PERSONNEL AND TRAINING | | |
| **NAME:** | Click here to enter text. | |
| **POSITION/TITLE:** | Click here to enter text. | |
| **PHONE #:** | Click here to enter text. | |
| **EMAIL ADDRESS:** | Click here to enter text. | |
| **CREDENTIALS:** | Click here to enter text. | |
| **SPECIFIC DUTIES ON PROJECT:** | Click here to enter text. | |
| **COMPLETED CITI TRAINING:** | | |
|  |  | Biosafety Modules (For protocols including recombinant DNA) |
|  | Date Completed: |
|  | Bloodborne Pathogens Module (For personnel working with human cell lines, tissue, blood or body fluids are required to take Bloodborne Pathogen training annually). |
|  | Date Completed: |
|  | NIH Guidelines (for protocols including recombinant DNA) |
|  |  | Date Completed: |
|  |  | Dual Use (For protocols including recombinant DNA) |
|  |  | Date Completed: |
|  |  | Other: |
|  |  | Date Completed: |

5.2. Briefly describe the training plan for lab members who lack experience in handling biological materials below. Include who will lead the training as well as the practices and techniques that will be taught.

Click here to enter text.

### Table 5.2.a. Training

To add additional people, click on the **+** at the end of each box.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| NAME | PHONE # | EMAIL ADDRESS | CREDENTIALS | COMPLETED TRAINING | ROLE IN PROJECT |
| Click here to enter text. |  | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. |  | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. |  | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. |  | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

# 6. PROCEDURES FOR LABORATORY SAFETY AND EXPERIMENTAL PROCEDURES

## 6.1. Laboratory Personal Protective Equipment (PPE)

I understand University policy requires that PPE must be worn when working with laboratory hazards (chemical, biological, and radioactive materials).

At the minimum, this must include:

* Laboratory coats (or other protective clothing such as aprons, scrubs, coveralls, etc.)
* Safety goggles or glasses
* Gloves resistant to the material used
* Appropriate footwear (closed at the heel and toe)

Sandals must not be worn when working in the laboratory. Other protective equipment, such as splash goggles, face shields, aprons, thermal or cut-resistant gloves, hearing protection or respirators, must be worn when conditions dictate.

In a class situation, student shall purchase or obtain the necessary and approved PPE designated by the department or instructor responsible for the course. Students must be trained in the proper usage and care of the PPE.

## 6.2. Special Precautions

Please list any special precautions, in addition to the PPE and the regulatory guideline requirements, which may be employed in the laboratory for safety and waste handling. If this question is not applicable, please indicate N/A.

Click here to enter text.

# 7: SENDING OR RECEIVING BIOLOGICAL SAMPLES

This includes genetically modified organisms, body fluids, tissue samples, blood samples, and pathogens.

If you will be sending or receiving biological samples, and need assistance in facilitating that shipment, contact the Biological Safety Officer (BS0) in the Environmental Health and Safety Office (EH&S) at [washgraves@fau.edu](mailto:washgraves@fau.edu).

If you need to establish contractual agreements regarding such shipments via Material Transfer Agreement (MTA), contact the Sponsored Programs office in the Division of Research at [sponsoredprograms@fau.edu](mailto:sponsoredprograms@fau.edu).

Will you be:

RECEIVING samples from outside of FAU?

SENDING samples outside of FAU?

IF YES is selected for either, please provide the following information:

## 7.1.

What outside organization(s) will be sending or receiving samples?

**Click here to enter text.**

## 7.2.

What are the samples that will be sent or received?

Click here to enter text.

# 8: PRINCIPAL INVESTIGATOR AGREEMENT

A checked box indicates agreement by the PI for the statement checked.

**IBC EDUCATION:** I confirm that all individuals working on this protocol have completed the required CITI Initial Biosafety Training and maintain valid (within 3 years) certification.

**PERSONAL PROTECTIVE EQUIPMENT (PPE):** PPE will be worn when working with laboratory hazards (chemical, biological, and radioactive materials) and will at the minimum, include: laboratory coats (or other protective clothing such as aprons, scrubs, coveralls, etc.), safety goggles or glasses, gloves resistant to the material used, appropriate footwear (closed at the heel and toe).

**EH&S EDUCATION**: I confirm that all individuals working on this protocol have completed the required FAU Environmental Health and Safety Laboratory Safety Training.

**CONTAINMENT BREACH**: I will immediately report any biological hazard spills to the FAU Chemical & Hazardous Materials Manager in EHS and document spills in my Annual Report to the IBC.

**AMENDMENTS:** I will submit an amended application and receive IBC approval prior to instituting any changes in the project as described in the approved application or making changes to research personnel.

**TRAINING:** I will keep written and organized documentation of training sessions in my lab, and make this documentation available to the IBC during periodic inspections and/or audits.

**AUTHORIZATION:** I authorize individuals listed on this application to conduct procedures involving biological materials and I accept responsibility for their oversight in the conduct of this proposal.

Please sign electronically by clicking the box below to upload a signature image:

(To sign, create an image file of your signature and click the icon below to upload. If you experience troubles, sign and scan this page only and include as a separate file with your submission.)

 (Click here to enter date)

Responsible Principal Investigator Date