Contents

[Section 1: Scope & Purpose 2](#_Toc180656278)

[Section 2: IBC Contacts 3](#_Toc180656279)

[Section 3: General Information 4](#_Toc180656280)

[Section 4: Hazard Declaration Overview 5](#_Toc180656281)

[Section 5: Project Description (Detailed Abstract) 6](#_Toc180656282)

[Section 6: Project Specifics 7](#_Toc180656283)

[Section 7: Safety Measures 9](#_Toc180656284)

[Section 8: PI Project Responsibility Acknowledgement 10](#_Toc180656285)

# Section 1: Scope & Purpose

The Florida Tech Institutional Biosafety Committee (IBC) oversees all campus activities involving biohazardous or potentially biohazardous materials. All institutions receiving Federal Funding, especially from NIH, require the committee to ensure compliance with other agencies, (e.g., OSHA, Florida Department of Health (DOH), CDC, NRC, and the EPA). The IBC will follow the procedures outlined in the [NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)and the Centers for Disease Control [*Biosafety in Microbiological and Biomedical Laboratories*](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf)*.* The IBC comprises a combination of faculty, staff, and external individuals.

Any use of the following materials, including use in non-funded research and classroom activities, must be registered with the IBC before the start of the project. (Although many activities will be exempt from further oversight, they must still be registered.)

* Any material derived from human or non-human primates (includes blood, tissues, body fluids, and established or primary cell lines)
* Mammalian tissues and cell lines
* Work involving recombinant or synthetic nucleic acid molecules
* Plant pathogens
* Transgenic plants or animals
* Biotoxins and select agents (see the CDC Biosafety brochure for a list of select agents)
* Microbial organisms or viruses that can cause disease in humans or animals (this would include any animal that might harbor these)

SPECIAL NOTES

Some IBC protocols may also require the review/approval of other committees. Examples are below:

**Vertebrate Animal Research**

Requires approval through the Florida Tech  [Institutional Animal Care and Use Committee (IACUC)](https://www.fit.edu/research/faculty--researchers/compliance/animal-care-and-use/).

**Human Subject Research**

Requires approval through the Florida Tech [Institutional Review Board (IRB)](https://www.fit.edu/research/faculty--researchers/compliance/human-subjects-regulation/).

# Section 2: IBC Contacts

This registration form should be sent to directly to the below individuals in one correspondence. Additionally, any of the below individuals may be contacted for any concerns or questions:

**Kenia Nunes, MSc. Ph.D.**

Associate Professor of Biology

Department of Biomedical Engineering and Science (BES)

Chair: Institutional Biosafety Committee

[knunes@fit.edu](mailto:knunes@fit.edu)

**Jianhui Li, Ph.D**

Assistant Professor

Department of Biomedical Engineering and Science (BES)

Voting Member: Institutional Biosafety Committee

[li@fit.edu](mailto:li@fit.edu)

**Timothy Crombie, Ph.D.**

Assistant Professor

Department of Biomedical Engineering and Science (BES)

Voting Member: Institutional Biosafety Committee

[tcrombie@fit.edu](mailto:tcrombie@fit.edu)

**Samuel Monzem, Ph.D**

Manager of Animal Program and Facilities

Sponsored Research

Voting Member: Institutional Biosafety Committee

[smonzem@fit.edu](mailto:smonzem@fit.edu)

**Charles “Sonny” Cherrito, RBP (ABSA)**

Assistant Director & Biosafety Officer

Environmental, Health & Safety Office

Voting Member: Institutional Biosafety Committee

[ccherrito@fit.edu](mailto:ccherrito@fit.edu)

**Institutional Biosafety Committee (IBC)**

[ibc@fit.edu](mailto:ibc@fit.edu)

**Environmental Health & Safety Office (EHS)**

[ehs@fit.edu](mailto:ehs@fit.edu)

# Section 3: General Information

|  |  |
| --- | --- |
| Application Date |  |
| Project Title |  |

|  |  |
| --- | --- |
| Principal Investigator |  |
| Phone |  |
| Email |  |
| Department |  |
| Office Location |  |
| Laboratory Location |  |

|  |  |
| --- | --- |
| Alternate Contact |  |
| Phone |  |
| Email |  |

|  |  |
| --- | --- |
| Collaborating Entity |  |
| Phone |  |
| Email |  |
| Entity Address |  |

List **ALL** individuals conducting research on your proposed project, along with their degrees and areas of experience:

|  |
| --- |
|  |

# Section 4: Hazard Declaration Overview

**CHECK ALL THAT APPLY TO YOUR PROJECT:**

|  |  |
| --- | --- |
| Yes | No |
| Prohibited | | [Select Pathogenic Agents](http://www.selectagents.gov/SelectAgentsandToxinsList.html) |
| Prohibited | | [Select Toxins](http://www.selectagents.gov/SelectAgentsandToxinsList.html) |
|  |  | Other Biological Toxins |
|  |  | Etiological Agents |
|  |  | Bloodborne Pathogens |
|  |  | Hazardous Chemicals |
|  |  | Hazardous / Chemotherapeutic Drugs |
|  |  | Investigational Drugs |
|  |  | Human Cells / Tissue |
|  |  | Stem Cells |
|  |  | Non-Human Primate Cells / Tissues |
|  |  | Non-Human Primate Research |
|  |  | Animal Research |
|  |  | Transgenic / Knockout Animal Models |
|  |  | Plant Research |
|  |  | Radioactive Isotopes |
|  |  | Human Research (Clinical Trials) |

|  |  |  |
| --- | --- | --- |
| Yes | No | **Recombinant DNA / Synthetic DNA / Human Gene Therapy** |
|  |  | Does your project involve **Recombinant DNA** or **Synthetic DNA**? |
|  |  | Does your project involve **Human Gene Therapy**? |
| Yes | No | If yes, is your project exempt from the NIH Guidelines, [***Section III-F***](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)*?*  **If your answer is YES, you must thoroughly explain why below.** |
|  |  |
|  | | |

# Section 5: Project Description (Detailed Abstract)

Provide a description **(IN LAYMAN’S TERMS)** of your project as it pertains specifically to recombinant/synthetic DNA (rDNA), etiological agents (biological or toxin hazards) or gene therapy. Additionally, please denote any viruses or bacteria that may be involved (lentiviruses, retroviruses, adenoviruses, adeno-associated viruses, etc.) making certain to describe their role in the project.

**Project Description**

|  |
| --- |
|  |

# Section 6: Project Specifics

For ANY items denoted as “YES”, there must be an explanation denoted.

1. List all the laboratories/facilities where research is to be conducted (specify building, room number, and category (BSL1 or 2) for each):

|  |
| --- |
|  |

1. The source(s) of the DNA.

|  |
| --- |
|  |

1. Nature of the inserted DNA sequences.

|  |
| --- |
|  |

1. The host and vectors to be used.

|  |
| --- |
|  |

1. Does this project include whole animals? If so, what species?

|  |
| --- |
|  |

1. Will a deliberate attempt be made to obtain expression of a foreign gene in the cloning vehicle? If so, what protein(s)?

|  |
| --- |
|  |

1. Will work be conducted at a collaborating entity outside Florida Tech? If so, what specific portions of the project will be conducted off-site at the collaborating entities site?

|  |
| --- |
|  |

1. Will you be using rDNA techniques using a viral host vector system?

|  |
| --- |
|  |

1. Will you be working with or constructing transgenic plants that require registration?

|  |
| --- |
|  |

1. Will you be working with any transgenic vertebrate animals?

|  |
| --- |
|  |

1. Will you be using human and/or animal pathogens?

|  |
| --- |
|  |

1. Will you be using plant pathogens?

|  |
| --- |
|  |

1. Will you be using biotoxins?

|  |
| --- |
|  |

1. Will you be using human materials (including primary or established human cell lines)?

|  |
| --- |
|  |

1. Will you be using non-human primate materials (including primary or established cell lines)?

|  |
| --- |
|  |

1. Will you be using insects and/or arthropods (if so, are they under permit)?

|  |
| --- |
|  |

# Section 7: Safety Measures

1. Describe all methods used to decontaminate lab biohazardous waste (cultures, stocks, used culture dishes/flasks, gloves, disposable loops, serological pipets, pipet tips, etc.):

|  |
| --- |
|  |

1. Describe all methods used to decontaminate biological spills:

|  |
| --- |
|  |

1. Will this project generate biological waste mixed with hazardous chemicals or radiological material?

|  |
| --- |
|  |

1. Indicate what containment conditions you propose to use for laboratory work:

|  |
| --- |
|  |

1. If conducting vertebrate animal research, indicate the containment conditions:

|  |
| --- |
|  |

1. List all sharps being used for this project:

|  |
| --- |
|  |

# Section 8: PI Project Responsibility Acknowledgement

As a condition of research approval and continuation, the PI acknowledges the responsibility for the conduct of this research in accordance with ***Section IV-B-7 of the NIH Guidelines***.

The signed portion acts as a registration with the Florida Tech’s IBC. This page is to be signed and submitted (email, hard copy, etc.) to the IBC with this form. The PI must ensure that the information contained in this registration is accurate and complete. The PI accepts the responsibility for the safe conduct of work with this. The PI will inform all personnel, who may be at risk of potential exposure regarding the work being conducted. The PI will assure that all personnel will receive adequate training to perform all activities safely and proficiently.

Where applicable, the PI agrees to comply with the NIH requirements pertaining to the shipment and transfer of recombinant DNA materials. It is the PI’s responsibility to notify the IBC of any changes in their protocol that involve the hazards mentioned in this application (change in vehicle, dosing route, adverse events, etc.).

The IBC may choose to inspect the facilities in which the material is handled, stored, prepared, transported, administered, or disposed—it is the PI’s responsibility to arrange for the IBC or its members to gain access to the facilities.

The PI shall comply with the reporting requirements for all incidents (adverse events, illnesses, injury, death, misconduct, protocol addendums, etc.) to the NIH as outlined in the *NIH Guidelines*. The PI understands the entities that are to receive the report include, at a minimum, the NIH and the IBC; and other appropriate authorities that are associated with this research.

Principal Investigator (PI) Date