

Institutional Biosafety Committee

**IBC REGISTRATION APPLICATION FORM**

|  |  |
| --- | --- |
| IBC Number (Assigned by RI Office): |  |
| Date of Approval:  |  |
| Biosafety Level:  |  |
| IBC Chair Signature:  |  |

Investigators utilizing biohazardous materials are required to register their work with the FAU IBC. Biohazardous materials include: Microorganisms (bacteria, viruses, parasites, fungi, prions and rickettsia) infectious to humans, animals or plants; Biologically active agents (toxins or venoms); Human and nonhuman primate materials (blood, tissue, etc.); Animal materials other than human and nonhuman primates; and Recombinant and synthetic nucleic acid. Not all work will require review by the full IBC.

**Instructions: All Applicants Complete Sections 1-7, and Sections 17-24. Complete all other sections as applicable to your research as outlined in Section 5.**

# **Sections 1-4. Project Information**

1. **PI Information:**
2. Name: Click here to enter text.
3. Position/Title: Click here to enter text.
4. Department/College: Click here to enter text.
5. Department Chair: Click here to enter text.
6. Office/Cell Phone #: Click here to enter text.
7. Email address: Click here to enter text.
8. Project Title: Click here to enter text.
9. **Funding Information:**

Will this project be funded by a grant or contract?

 [ ]  No [ ]  Yes (If yes, provide information below)

|  |  |  |  |
| --- | --- | --- | --- |
| **Funding Source** | **Grant #** | **Title** | **PI** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. **Type of Project:**

[ ]  New [ ]  3-Year Renewal (Enter current IBC project #: Click here to enter text. )

1. **Study Personnel, Training and Medical Monitoring**
2. Personnel

Please indicate the key personnel working on the project. Provide information on their role in the project.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Title** | **Role** | **Email** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. Required Training\*

The following modules are required for all laboratory personnel on an IBC protocol. Protocol will not receive approval until all training is completed:

Through IBC— (<https://about.citiprogram.org/en/course/initial-biosafety-training/>)

 Initial Biosafety Training, CITI

Through EHS— (<http://www.fau.edu/ehs/training/>)( <http://www.fau.edu/ehs/training/cmbjtv2.pdf>)

Please indicate the training modules that have been completed by study personnel:

|  |  |  |
| --- | --- | --- |
| **Name** | **Training Completed (List)** | **Date of Training Completion** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**\*Please note that additional training may be required, depending upon the research type. These additional training modules are listed within the specific sections below**

1. Are personnel enrolled in the EH&S Medical Monitoring Program

[ ]  No [ ]  Yes

# **Sections 5-7. Project Uses (check all that apply and complete the corresponding sections in the form**

[ ]  Human Research (Gene Therapy/Gene Transfer; Please fill out Section 8)

[ ]  Recombinant/Synthetic Nucleic Acids (Including Transgenic Rodent Breeding; Please fill out Section 9)

[ ]  Microorganisms (Please fill out Section 10)

[ ]  Biological Toxins/Venoms (Please fill out Section 11)

[ ]  Human/Nonhuman Primate Materials (Please fill out Section 12)

[ ]  Field Work with Animals (Please fill out Section 13)

[ ]  Storage of Biological Materials (Please fill out Section 14)

1. **Location**

Please provide the location of the work to take place:

|  |  |  |
| --- | --- | --- |
| **Campus** | **Building** | **Room #s** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. **Project description**
2. Non-technical (Lay) Abstract

Please describe in lay terms (language that a 12th grader can understand) the background and goals of the project

 Click or tap here to enter text.

1. Scientific Research Description

Please outline ALL experimental procedures, practices and manipulations to be performed with hazards (Do not copy/paste from a grant proposal; Identify potential risks (needle sticks, splashes, aerosols, etc.) to personnel and/or environment that are associated with experimental procedures and how these risks will be mitigated). Do not put in extensive information about animal usage—focus on direct work with the hazards. If animals are involved in the project, indicate how hazards are administered and what potential risks there are with the animals that receive hazards.

Click or tap here to enter text.

# Section 8. Human Research (Gene Therapy/Transfer):

You will need to provide the following documents: Protocol; Investigator’s Brochure; Informed Consent; Lab Manual (SOPs)

1. Briefly describe the protocol design (number of study subjects, location of treatment administration, number of rounds of therapy and length of follow-up):

Click or tap here to enter text.

1. Please describe the agent being used for therapy:

Click or tap here to enter text.

1. Is this a first-in-human use? [ ]  No [ ]  Yes

If no, please summarize the safety profile of the agent in humans, thus far:

Click or tap here to enter text.

1. Please provide a brief summary of the biosafety concerns related to the use of this agent (pathogenicity, spill/splash/aerosol/needlestick hazards, potential for transmission (horizontal or vertical), genome integration, adventitious infection and environmental implications):

 Click or tap here to enter text.

1. Describe the potential staff exposure risks:

Click or tap here to enter text.

1. Provide the controls employed to mitigate these risks:

Click or tap here to enter text.

1. **Required Training: NIH Recombinant DNA Guidelines** (<https://about.citiprogram.org/en/course/nih-recombinant-dna-guidelines/>)

Please indicate the personnel on the project that have completed this training:

|  |  |  |
| --- | --- | --- |
| **Name** | **Training Completed (List)** | **Date of Training Completion** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

# Section 9. Recombinant/Synthetic Nucleic Acids Use

Refer to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (<https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html>).

1. **Required Training: NIH Recombinant DNA Guidelines Training** (<https://about.citiprogram.org/en/course/nih-recombinant-dna-guidelines/>).

Please indicate the personnel on the project that have completed this training:

|  |  |  |
| --- | --- | --- |
| **Name** | **Training Completed (List)** | **Date of Training Completion** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. Are you simply breeding transgenic rodents?

[ ]  No [ ]  Yes (Describe the transgenic rodents below; you can then proceed to section J)

Click or tap here to enter text.

1. What is the source of the nucleic acid sequence (the specific gene(s) that is(are) being cloned, expressed, etc.)?

|  |  |  |
| --- | --- | --- |
| **Name (Gene, siRNA, etc.)** | **Source (Species, strain, cell line, synthetic, etc.)** | **Function of the genetic element** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. Nature of the nucleic acid sequence being studied

Describe the basic functional elements of the recombinant DNA (e.g., is there a specific promoter to direct expression in certain cell types). Will this element be expressed? What is your risk assessment for the sequence (e.g., is it potentially harmful--tumor suppressor, oncogene, immunomodulator, etc.)?

 Click or tap here to enter text.

1. Vectors

List the cloning and delivery vector(s) used (plasmids, viruses, phages, etc.), including selectable marker(s), reporter gene(s), packaging cell line, assay system for detection, quantification, and/or host range of packaged viral vector. Detail the risk attenuation phenotype (e.g. replication defective, helper virus, potential for reversion, etc.). If this is a commercially available vector, please list the vendor and specific catalog number.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name****(Include the genus species if derived from plasmid/virus)** | **Type****(plasmid, phage, virus, etc.)** | **Source****(vendor/supplier)** | **Generation****(1st, 2nd, etc.)** | **Risk Attenuation Phenotype** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. Recipient organism

Specify the type of organism (virus, bacteria, animal, etc.), species, strain, cell line receiving the nucleic acid

 Click or tap here to enter text.

If the recipient organism is an animal, then an IACUC protocol is required. Is there one in place?

[ ]  No (If no, please submit a protocol to the FAU IACUC) [ ]  Yes

1. Will the vector host range be altered?

[ ]  No [ ]  Yes (Describe below)

 Click or tap here to enter text.

1. Will the project use infectious DNA/RNA viruses, defective DNA/RNA viruses, or phages in the presence of helper virus in a tissue culture system?

[ ]  No [ ]  Yes (Provide details on the pathogenicity, host range, or generation system)

 Click or tap here to enter text.

1. Gene Editing
	* + 1. Are you using gene editing, genome modification or similar technology (CRISPR, TALENs, zinc fingers,

 etc.)

[ ]  No (If no, please skip to Section I below) [ ]  Yes (If yes, please describe below and continue with the questions in this section)

Click or tap here to enter text.

* + - 1. Which organism(s) is(are) being modified?

 Click or tap here to enter text.

* + - 1. Is the work in cell culture?

[ ]  No [ ]  Yes (If yes, please list the cells/cell lines here; if human cells/cell lines are used, please also fill out Section 12)

Click or tap here to enter text.

* + - 1. Is the work in embryos or germ cell lines?

[ ]  No [ ]  Yes (If yes, please list the organism(s))

Click or tap here to enter text.

* + - 1. Is the work in the whole organism?

[ ]  No [ ]  Yes (If yes, please list the organism(s))

Click or tap here to enter text.

* + - 1. What gene(s) is(are) being modified?

 Click or tap here to enter text.

* + - 1. What is the function of the gene(s) being modified?

 Click or tap here to enter text.

* + - 1. What will be the function of the gene(s) following modification?

Click or tap here to enter text.

* + - 1. How is the gene editing technology being delivered?

Click or tap here to enter text.

* + - 1. CRISPR information: If you are using CRISPR technologies, please discuss the desired effect of gene editing on the animal or cell line. You must also address the potential effects due to accidental worker exposure. If unknown, state that. Points to consider are:
1. Are the guide RNA (gRNA) and nuclease (Cas 9) on the same plasmid, vector or delivery vehicle?

[ ]  No [ ]  Yes If yes, can this plasmid, vector or delivery vehicle transfect or infect a human cell and can the gRNA or CRISPR nuclease be expressed in human cells? Explain below:

Click or tap here to enter text.

1. Is the gRNA sequence specific for animals, humans, or could it affect both?

[ ]  Animals [ ]  Humans [ ]  Both

1. What is known about off-target effects by your gRNA? You **ARE REQUIRED** to perform a Genome Target Scan (GT-Scan)—necessary to determine if there is homology to human DNA and for assessing the risk of potential exposure in the event of an unanticipated incident. An off-target database is available at: <http://www.rgenome.net/cas-offinder/>.

 Click or tap here to enter text.

1. Can the mutation potentially drive through a population?

[ ]  No [ ]  Yes

1. What should be done in the event of an accidental exposure (e.g., needle stick) to the gene editing system?

Click or tap here to enter text.

1. What safety precautions should be in place for the work?

 Click or tap here to enter text.

1. NIH Guidelines Category

Please indicate below to which category your research belongs:

|  |  |  |
| --- | --- | --- |
| **CATEGORY** | **OVERSIGHT BY** | **INCLUDES/SUBCATEGORIES** |
|  [ ]  III-A | NIH Director, RAC & IBC | Studies that involve the deliberate transfer of a drug resistance to microorganisms (not known to acquire that 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 | 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 | RAC, IRB & IBC | Transfer of recombinant or synthetic DNA/RNA (r/sNA), or DNA or RNA derived from recombinant DNA, into one or more human subjects. |
| [ ]  III-D | 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/kg body weight, check section III-B above.  [ ]  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 [ ]  NoExperiment 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/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 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 [ ]  NoRecombinant 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 ng/kg body weight, see section III-B above). [ ]  D-6: Experiments involving cultures of 10L increments or greater. |
| [ ]  III-E | 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? [ ]  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 | FAU Policy requires Biosfaety Approval Form Submittal | Exempt by NIH Guidelines (Please attach information from NIH Guidelines that verifies the exempt status). |
| [ ]  N/A | FAU Policy requires Biosafety Approval Form Submittal | Does not apply to NIH Guidelines, but involves work with biohazardous materials.  |

# Section 10. Microorganisms

1. Identify and describe microorganisms to be employed by this protocol (**This section does not need to be filled out for those using recombinant viral vectors—that information should be included in Section 9**).

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Microorganism Name****(genus, species, strain name)** | **Source** | **Risk Group** | **Maximum Quantities Produced** | **Human Pathogen** | **Animal Pathogen** | **Plant Pathogen** | **Produce Toxin** | **In Vivo Use** | **Receive rNA material** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]

1. Please describe your experience working with the agent(s) listed above:

Click or tap here to enter text.

1. Occupational Health
	* + 1. Is the agent being used infectious for humans? [ ]  No (proceed to D) [ ]  Yes
			2. Is the infection associated with replication in humans, or is it abortive (no infectious progeny, i.e., viral replicons or defective vectors)?

 [ ]  Abortive (proceed to D) [ ]  Unknown [ ]  Replicative

1. Can the agent cause disease in healthy humans? [ ]  No [ ]  Yes [ ]  Unknown

b. Can the agent cause disease in immunocompromised humans? [ ]  No [ ]  Yes [ ]  Unknown

* + - 1. Is medical surveillance recommended for the agent prior to commencement of work, and/or ongoing during project?

 [ ]  No [ ]  Yes

* + - 1. If yes, what type of surveillance is recommended?

 [ ]  Initial [ ]  Ongoing

* + - 1. Is a vaccine available for the agent?

 [ ]  No (proceed to D) [ ]  Yes, [ ]  FDA approved [ ]  Internationally available

 [ ]  Experimental (IND) List vaccine: Click here to enter text.

* + - 1. Is immunization recommended by the ACIP (Advisory Committee on Immunization Practices; <https://www.cdc.gov/vaccines/acip/index.html>) at the listed biosafety level?

 [ ]  No [ ]  Yes

1. Are any of the agent(s) listed in A above considered to be Select Agents (<https://www.selectagents.gov/SelectAgentsandToxinsList.html>)

[ ]  No [ ]  Yes

1. What is the infectious dose of the agent (if known)?

Click or tap here to enter text.

1. What is the natural route of infection? What are the potential routes of lab transmission?

Click or tap here to enter text.

1. What is the maximum concentration of the agent being produced/used in the lab? Is this a higher concentration then observed in natural infections?

Click or tap here to enter text.

1. Are genetic modifications being made to the agent?

 [ ]  No [ ]  Yes (If yes, please describe below)

 Click or tap here to enter text.

1. Are lab members made aware of the symptoms/signs of infection with the agent?

Click or tap here to enter text.

1. Describe the stability of the agent in the environment.

Click or tap here to enter text.

1. Will the project involve inactivating agent or samples?

 [ ]  No [ ]  Yes (If yes, provide inactivation procedure and verification)

 Click or tap here to enter text.

1. List disinfectant(s) used for surface decontamination, spills and liquids:

Click or tap here to enter text.

1. Is there a written emergency plan for spills/exposures?

 [ ]  No [ ]  Yes If No, the lab is required to develop a policy before the project is approved.

1. Are animals being infected with the organisms?

[ ]  No [ ]  Yes If yes, complete below:

* + - 1. Has an IACUC protocol registration been completed?

[ ]  No (If no, please complete one) [ ]  Yes

* + - 1. Will infected animals present a human health risk after administration of the infectious organism?

[ ]  No [ ]  Yes, provide the following information:

Route of exposure: [ ]  Respiratory [ ]  Milk [ ]  Urine [ ]  Feces

 [ ]  Saliva [ ]  Blood [ ]  Other: Click or tap here to enter text.

* + - 1. Will infected animals be transported by laboratory staff out of or between vivarium?

[ ]  No [ ]  Yes, provide the following information:

Reason for removal: Click or tap here to enter text.

Location of animal manipulation/necropsy: Click or tap here to enter text.

Procedures for transportation of cages to and from vivarium: Click or tap here to enter text.

PPE worn by all personnel present in the lab: Click or tap here to enter text.

PPE worn by those handling animals: Click or tap here to enter text.

# Section 11. Biological Toxins/Venoms

1. Identify the Toxins/Venoms you will be working with

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Toxin** | **Source** | **LD50** | **Maximum Quantities Stored in the Lab** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. Does the toxin fall under the Select Agent Program?

[ ]  No [ ]  Yes

1. Do you agree to comply with Appendix I of the BMBL, which includes maintaining an inventory system, secure storage and proper use of primary and secondary containment (<https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF>)?

Click or tap here to enter text.

 [ ]  No [ ]  Yes If No, please explain below:

 Click or tap here to enter text.

1. Is there a written emergency plan for spills/exposures?

 [ ]  No [ ]  Yes If No, the lab is required to develop a policy before the project is approved.

1. Are animals being treated with the toxins/venoms?

[ ]  No [ ]  Yes If yes, complete below:

1. Has an IACUC protocol registration been completed?

[ ]  No [ ]  Yes.

1. Will treated animals present a human health risk after administration of the toxin/venom?

[ ]  No [ ]  Yes, provide the following information:

Route of exposure: [ ]  Respiratory [ ]  Milk [ ]  Urine [ ]  Feces

 [ ]  Saliva [ ]  Blood [ ]  Other: Click or tap here to enter text.

1. Will infected animals be transported by laboratory staff out of or between vivarium?

[ ]  No [ ]  Yes, provide the following information:

Reason for removal: Click or tap here to enter text.

Location of animal manipulation/necropsy: Click or tap here to enter text.

Procedures for transportation of cages to and from vivarium: Click or tap here to enter text.

PPE worn by all personnel present in the lab: Click or tap here to enter text.

PPE worn by those handling animals: Click or tap here to enter text.

# Section 12. Human or Nonhuman Primate Cells/Tissues/OPIM

1. Identify the Human/Nonhuman Primate materials to be used:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Material (cells, blood, tissue, etc.)** | **Source** | **Technical Name** | **In vivo use** | **Receive rNA construct** | **Receive microorganism** | **Pathogen Screening Performed?** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ] [ ] [ ]

1. What are the potential exposure issues? (e.g., spill, splash, needle stick)

Click or tap here to enter text.

1. How will the risks of exposure be mitigated? (list all types of controls in use—Engineering, SOPs, PPE, Administrative)

 Click or tap here to enter text.

# Section 13. Field Work with Animals

1. List animal species being worked with in the field

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Direct Contact with Animals? (yes or no)** | **Animal Samples Being Obtained** | **Collection Method** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

1. What are the potential exposure issues? (e.g., spill, splash, neddlestick)

Click or tap here to enter text.

1. How will the risks of exposure be mitigated? (list all types of controls in use—Engineering, SOPs, PPE, Administrative)

 Click or tap here to enter text.

1. **Required training: Working Safely with Animals (for laboratory work) and Animal Field Research Safety Overview (**[**http://www.fau.edu/ehs/training/**](http://www.fau.edu/ehs/training/)**)(**[**http://www.fau.edu/ehs/training/cmbjtv2.pdf**](http://www.fau.edu/ehs/training/cmbjtv2.pdf)**)**

Please indicate the personnel on the project that have completed this training:

|  |  |  |
| --- | --- | --- |
| **Name** | **Training Completed (List)** | **Date of Training Completion** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

# Section 14. Storage of Biological Materials (This section is for storage of materials that are not currently being used in laboratory research)

List locations for storage of all biological materials

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Material** | **Building** | **Room** | **Freezer** | **Refrigerator** | **Incubator** | **Other** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | [ ]  No [ ] Yes | [ ]  No [ ] Yes | [ ]  No [ ] Yes | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | [ ]  No [ ] Yes | [ ]  No [ ] Yes | [ ]  No [ ] Yes | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | [ ]  No [ ] Yes | [ ]  No [ ] Yes | [ ]  No [ ] Yes | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | [ ]  No [ ] Yes | [ ]  No [ ] Yes | [ ]  No [ ] Yes | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | [ ]  No [ ] Yes | [ ]  No [ ] Yes | [ ]  No [ ] Yes | Click or tap here to enter text. |

**The next sections request information on equipment/procedures that will be used to mitigate hazards and should be filled out for all projects**

# **Sections 15 – 22. Safety**

**15) Engineering Controls**

 Identify the engineering controls/lab equipment to be used (Biosafety Cabinet, Fume Hood, Centrifuge Rotor Cup Covers, Autoclave, Sonicator, etc.):

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Equipment** | **Manufacturer/Model** | **Location (Building/Room)** | **Last Certification Date** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**16) Personal Protective Equipment (PPE)**

Check the PPE worn when handling agents:

[ ]  Lab Coat/Disposable Gown

[ ]  Coveralls

[ ]  Head Covers

[ ]  Sleeve Covers

[ ]  Shoe Covers

[ ]  Gloves

[ ]  Double Gloves

[ ]  Eye Goggles

[ ]  Face Shield

[ ]  N-95 Respirator: Explain when and why this is worn: Click here to enter text.

[ ]  PAPR: Explain when and why this is worn: Click here to enter text.

[ ]  Other: Click here to enter text.

**17)** **List disinfectant(s) used for surface decontamination, spills and liquid biohazardous waste (Should be EPA registered):**

[ ]  Spor-Klenz

[ ]  Sani-Cloth Wipes

[ ]  Cavicide

[ ]  Accel TB

[ ]  Micro-Chem Plus

[ ]  Wescodyne

[ ]  Bleach

[ ]  Other: Click here to enter text.

1. **Method for disposal of Dry biohazardous waste:**

[ ]  Placed in red bag for disposal by medical waste company

[ ]  Autoclaved, then placed in regular trash

[ ]  Autoclaved, then packaged for incineration

[ ]  Other: Click here to enter text.

1. **Method for disposal of Liquid biohazardous waste:**

[ ]  Chemical disinfection, then poured down sanitary drain

[ ]  Autoclave of bulk liquid, then poured down sanitary drain

[ ]  Effluent treatment system

[ ]  Other: Click here to enter text.

1. **Is there a written exposure response plan for the laboratory?**

[ ]  No (If no, please complete one) [ ]  Yes

1. **Dual Use Research of Concern**

Please examine the attached questionnaire on Dual Use Research and complete the form as it applies to your research. Submit along with this form.

1. **Biosafety Level**

Indicate the biosafety level(s) you deem appropriate for the proposed work (check all that apply; ultimate decision on biosafety level is determined by the IBC):

[ ]  BSL1 [ ]  BSL2 [ ]  BSL2+ [ ]  BSL3

If multiple levels are selected, is there physical separation of lab spaces? [ ]  No [ ]  Yes

1. **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 minimum, include: laboratory coats (or other protective clothing such as disposable gowns, aprons, scrubs, coveralls, etc.), safety goggles or glasses, gloves resistant to the material used and 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 modules.

[ ]  **CONTAINMENT BREACH:** I will immediately report any biological hazard spills/exposures to the FAU Biosafety Officer and Chemical & Hazardous Materials Manager in EH&S 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, including 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.

[ ]  **ACKNOWLEDGMENT AND AUTHORIZATION:** The information provided in this document is accurate to the best of my knowledge. I agree to abide by the provisions set forth in this plan as approved by the FAU IBC. I accept responsibility for providing all lab personnel with a copy of this IBC Registration Form and providing training for all lab personnel involved in the research project described before commencement of work. 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.



\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click or tap here to enter text.

P.I. (Signature) Date

Click here to enter text.

P.I. (Printed Name, Credentials)



\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click or tap here to enter text.

Department Chair (Signature) Date

Click here to enter text.

Department Chair (Printed Name, Credentials)