Institutional Biosafety Committee

**IBC REGISTRATION BIOLOGICAL MATERIALS AMENDMENT FORM**

|  |  |
| --- | --- |
| IBC Number: |  |
| Date of Approval: |  |
| IBC Chair/BSO Signature: |  |

This amendment form is to be used for changes to biological materials used in specific protocols (i.e., changes and/or additions).

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. Office/Cell Phone #: Click here to enter text.
6. Email address: Click here to enter text.
7. Project Title/Number: Click here to enter text.
8. **Proposed Modification:**

Addition/modification in the use of Human Gene Therapy/Transfer (Complete Section 3)

Addition/modification in the use of Recombinant/Synthetic Nucleic Acids (Proceed to Section 4)

Addition/modification in the use of Microorganisms (Proceed to Section 5)

Addition/modification in the use of Biological Toxins/Venoms (Proceed to Section 6)

Addition/modification in the use of Human or Nonhuman Primate Materials (Proceed to Section 7)

Addition/modification in the use of Field Work with Animals (Proceed to Section 8)

Addition/modification in the Storage of Biological Materials (Proceed to Section 9)

Addition/modification in the Room where work will occur (Proceed to Section 10)

Addition/modification of Procedure (Proceed to Section 11)

# 3. Addition/Modification in the use of Human 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** |
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# 4. Addition/Modification in the use of Recombinant/Synthetic Nucleic Acid Molecules

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. What is the source of the nucleic acid sequence?

|  |  |  |
| --- | --- | --- |
| **Name (Gene, siRNA, etc.)** | **Source (Species, strain, cell line, synthetic, etc.)** | **Function of the genetic element** |
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1. Will you be breeding transgenic rodents?

No  Yes (Specify below)

What genes have been modified/added?

Click or tap here to enter text.

Are toxins being expressed?

No  Yes (Specify below)

What toxins?

Click or tap here to enter text.

1. Nature of the modified DNA

Describe the functional and structural elements of the recombinant DNA, including the regulatory and/or coding regions, percentage of the entire genome, promoter, synthetic antisense sequence, etc. Will this element be expressed? What is your risk assessment for the sequence (tumor suppressor, oncogene, etc.)?

Click or tap here to enter text.

1. Vectors

List the cloning and delivery vector(s) used, including selectable marker(s), reporter gene(s), oncogenes, promoters, 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.). Reference any literature from commercially available vectors.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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** |
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1. Recipient organism

Specify the type of organism, species, strain, cell line receiving the nucleic acid

Click or tap here to enter text.

Will you express a toxin or oncogene?

No  Yes (Specify below)

Click or tap here to enter text.

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. CRISPR/Cas9 is a very powerful genome editing technology that is currently being used in many research projects. This system is revolutionizing the life sciences by making genome modification easier and faster than ever before. Researchers interested in using CRISPR or other genome editing technologies should complete the following information to aid in a comprehensive risk assessment. Please discuss the desired effect of gene editing on the animal or cell line.
   * + 1. Are you using gene editing, genome modification or similar technology (CRISPR, TALENs, zinc fingers, etc.)?

No (If no, please skip to Section H)  Yes (If yes, please describe below)

Click or tap here to enter text.

* + - 1. Which organism(s) is(are) being modified? Targeting of human cells presents additional risks to laboratory workers due to the potential for accidental ingestion, inhalation, injection or other routes of administration.

Click or tap here to enter text.

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

No  Yes (If yes, please list the cell lines/types in section 7 or 8 as appropriate)

* + - 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? Remember that highly homologous genes in nonhuman species may target human genes as well.

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: You must 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.

If the gRNA and Cas9 are on the same vector, explain why they cannot be delivered on different vectors:

Click or tap here to enter text.

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

No  Yes

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. How does route of exposure affect outcome?

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. Will the gene editing technology be used to target embryos/germ cell lines? If so, the biosafety protocol must include an approved or submitted IACUC number.

No  Yes

1. Will the gene editing technology be used for human gene therapy/transfer research? If so, the biosafety protocol must include an approved or submitted IRB number and Section 3, above, must be completed.

No  Yes

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** |
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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  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/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  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 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. |

# 5. Addition/Modification in the use of Microorganisms

1. Identify and describe microorganisms to be employed by this protocol.

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

Click or tap here to enter text.

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, you will need to complete Section 4, above)

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. Describe additional procedures that will be performed with any of the microorganisms not already included on your protocol.

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  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.

# 6. Addition/Modification in the use of Biological Toxins/Venoms

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Toxin** | **Source** | **LD50** | **Maximum Quantities Stored in the Lab** |
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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.

# 7. Addition/Modification of the Use of Human or Nonhuman Primate Materials

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?** |
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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.

1. Is there a written exposure response plan?

No  Yes

# 8. Addition/Modification of the Use of 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** |
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1. What are the potential exposure issues? (e.g., spill, splash, neddlestick)

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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. Is there a written exposure response plan?

No  Yes

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/)

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

|  |  |  |
| --- | --- | --- |
| **Name** | **Training Completed (List)** | **Date of Training Completion** |
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# 9. Addition/Modification of the Storage of Biological Materials

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. |
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| 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. |

# 10. Addition/Modification of the Room(s) where work will occur\*

Is this an addition of space to be utilized for work on this project?  No  Yes

Is this a deletion of space to be utilized for work on this project?  No  Yes

Please provide the location of the work to take place:

|  |  |  |  |
| --- | --- | --- | --- |
| **Campus** | **Building** | **Room #s** | **Deletion?** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | No  Yes |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | No  Yes |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | No  Yes |

\*Please note that lab rooms being added to protocols will require inspection to ensure suitability of the space

# 11. Addition/Modification of Procedure

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.

# 12. Acknowledgment and Authorization

**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 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.



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P.I. (Signature) Date

Click here to enter text.

P.I. (Printed Name, Credentials)