**BIOSAFETY REGISTRATION FORM**

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| Biosafety Registration Code: **2022/OR-NSU/IBC/\_\_\_** |

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| --- | --- | --- | --- | --- | --- | --- |
| **Type of Application:** |  | **New** |  | **Resubmission** |  | **Renewal** |

|  |  |
| --- | --- |
| School SRC/ CTRG Review Code: |  |

**1. Title of Research Project:**

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|  |

**2. Principal Investigator:**

|  |  |
| --- | --- |
| **Name:** |  |
| **Faculty Rank:** |  |
| **Department:** |  |
| **Email:** |  |
| **PABX or Mobile number:** |  |

**3. Co-investigators:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Faculty Rank** | **Email** |
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**4. Project Duration:**

*(Note: Biosafety registration is effective for a maximum of three calendar years from the date of commencement*

*of research activity.)*

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| --- | --- |
| Project Start Date: |  |
| Project Completion Date: |  |

**5. Does this project require approvals or permits from any of the following government authorities?** *(Note: If answered “Yes” on any of the following, a copy of all relevant approvals must accompany this application for IBC review.)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Department of Health |  | Yes |  | No |
|  |  |  |  |  |
| Department of Natural Resources |  | Yes |  | No |
|  |  |  |  |  |
| Fisheries Permit  |  | Yes |  | No |
|  |  |  |  |  |
| Environment |  | Yes |  | No |
|  |  |  |  |  |
| Other (provide detail below) |  | Yes |  | No |

**6. Will the proposed research be involved with a Material Transfer Agreement (MTA)?**

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

**7. Is the proposed research funded by either internal or external grant in whole or in part?**

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

*[If “yes” identify the funding organization, grant ID (whether pending or approved).]*

**8. Does this project involve inter-institutional (including international) collaboration?**

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

 *(If “yes,” provide names, titles, roles of co-investigators along with identified institutional affiliations.)*

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| **Name** | **Faculty Rank / Title** | **Affiliated Institution/Location** | **Role/Function** |
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**9. Project Research Type:** *(check one--✔-- or more as applicable)*

|  |  |
| --- | --- |
|  | In vitro experiments |
|  | Whole animals IACUC No: Approval date:  |
|  | Human subjects IRB No: Approval date: |
|  | Human gene transfer |

**10. Overview of the Research Activity**

1. Specific aims of the research project

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1. Abstract/Summary of the research project

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1. Methodology *(Briefly describe the methodologies employed in the proposed research. If applicable, include all recombinant*

 *or synthetic nucleic acid constructs and their combinations, the targets for expression/transformation/transduction/gene*

 *editing (e.g.: CRISPR/Cas9) and if the resultant genetic manipulation is transient, stable, heritable and/or infectious.) If you*

*are using flow cytometry please include a brief procedural description, instrument (type and location), and list the name of the user.*

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**11. Names of microorganisms (viruses, bacteria, etc.), recombinant DNA/Synthetic nucleic acids,**

 **human cell lines, and/or hazardous drugs used**

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**12. Recombinant DNA or Synthetic Nucleic Acids**

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| a. RECOMBINANT INSERT (TRANSGENE) |
| (1) | Specify the source of the DNA/RNA sequences (gene of interest, including genus, species, gene name(s) and specify oncogenes): |
|  |
| (2) | If the recombinant DNA or synthetic nucleic acids contain viral DNA, does the insert represent more than 2/3 of the viral genome?  | [ ]  N/A  | [ ]  No | [ ]  Yes |
| (3) | Will a deliberate attempt be made to obtain expression of the foreign structural or regulatory gene encoded in the recombinant DNA or synthetic nucleic acids?  | [ ]  No  | [ ]  Yes |
|  (4)  | What is the biological activity of the gene product, sequence inserted or sequence knockdown? |
|   |
| b. VECTOR |
| (1) | List the name(s) of the plasmid(s) for propagation of the recombinant DNA or synthetic nucleic acids (include genus, species and parent strain). Provide the genetic map of the plasmid(s). |
| (2) | Is the host strain prokaryotic (for example, use *E. Coli* amplify the plasmid(s))? If yes, complete the following.  | [ ]  No | [ ]  Yes |
|  | (a) | Is it a plasmid, phage, or other? List the strains of *E. Coli*.  |
|  |  |   |
|  | (b) | Is a packaging cell lines or transfected plasmids with helper functions required? Check the box if applicable[ ]  Use of two or three plasmids lentivirus expression system (BSL2)[ ]  Use of four plasmids lentivirus expression system (BSL2) | [ ]  No | [ ]  Yes |
|  | (b) | If yes, list the name of packaging cell lines and specify the expression system:  |
| (3) | Is the host strain eukaryotic (for example, use adenoviral vector or mammalian vector)? If yes, complete the following.  | [ ]  No | [ ]  Yes |
|  | (a)  | Is the strain a virus, clone viral genome, pro-virus, or other? If other, specify: |
|  | (b) | Can it infect human cells?  | [ ]  No | [ ]  Yes |
|  | (c) | Is a helper virus required?  | [ ]  No | [ ]  Yes | List the name of the helper virus/helper plasmids  |
|  | (d) | If a viral vector, what % of the viral genome remains? | [ ]  N/A | or % |
| c. TARGET RECIPIENT |
| (1) | Specify the target recipient of the vector-recombinant DNA or vector-synthetic nucleic acids combination (indicate animal species or Cell lines):  |
| d. SYNTHETIC NUCLEIC ACIDS  |
| (1) | Research with genetically modified virus or a vector derived solely by synthetic nucleic acid techniques  [ ]  No [ ]  Yes |
| (2) | Synthetic nucleic acids that can replicate or generate nucleic acids in any living cell  [ ]  No [ ]  Yes |
| (3) | Synthetic nucleic acids are designed to integrate into DNA  [ ]  No [ ]  Yes |
| (4) | Synthetic nucleic acids produce a toxin that is lethal for vertebrates at an LD50 of <100 ng/kg body wt  [ ]  No [ ]  Yes |
| (5) | Clinical Research involves the transfer of synthetic nucleic acids (> 100 nucleotides) into human subject  [ ]  No [ ]  Yes |

**13. Safety and Protection**

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| a. SOP |
| SOP #       is followed. Submit a new SOP if there is any deviation from the standard SOP. |
| b. BIOHAZARDS/HAZARDOUS DRUGS | BUILDING | ROOM | Biosafety Level | QTY/VOL | Biosafety Cabinet/Fume Hood  | USES (“x” all that apply) |
| Type | Date Certified | Stored | Prep’d | Used |
| (1) |       |       |       |       |       |       |       |       |       |       |
| (2) |       |       |       |       |       |       |       |       |       |       |
| (3) |       |       |       |       |       |       |       |       |       |       |
| (4) |       |       |       |       |       |       |       |       |       |       |
| (5) |       |       |       |       |       |       |       |       |       |       |
| c. SHIPPING |
| Will hazardous materials be shipped, transferred or transported? [ ]  No [ ]  YesDangerous goods shipment training, IBO notification and IBC approval are required prior to any shipment, transfer and transportation. |
| d. HAZARDOUS DRUG(S), example chemotherapeutic drugs |
| Will hazardous drugs be used in this protocol? [ ]  No [ ]  YesHazardous drugs safety training is required for PI, Co-I, and lab workers. |
| e. PI has trained all workers and animal care providers (if applicable) in SOP#       Date:       **[ ]**  No **[ ]**  Yes |
| f. OCCUPATIONAL HEALTH REQUIREMENT |
| (1) | Are there any special groups of workers at risk of infection or disease from the use of the biohazard(s)/ [ ]  No [ ]  Yeshazardous drug(s) (e.g. pregnant, immuno-compromised, allergic, etc.)? If yes, describe below.      |
| (2) | Are any special immunizations necessary for personnel involved in the research (e.g. Hepatitis B, Tetanus/Tdap, etc.)? If yes, describe below. [ ]  No [ ]  Yes |

**14. Whole Animal Use**

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| **a. SUMMARY CHART** |
| SPECIES(include the names of transgenics and knockouts) | HAZARD (biological agent or hazardous drug) | BUILDING | ROOM(holding and procedure) | LOCATION TYPE(animal facility, lab, other) | ROUTEADMINISTERED(ip, iv, etc.) |
| (1) |       |       |       |       |       |       |
| (2) |       |       |       |       |       |       |
| (3) |       |       |       |       |       |       |
| (4) |       |       |       |       |       |       |
| **b. NARRATIVE AND CHECKLIST** |
| (1) |

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| --- | --- | --- | --- |
| Will the use of the hazard in animals be intermittent or one time only? If once, indicate how long the hazardous condition will last. If more than once, indicate the frequency of use and how long the hazardous condition will last when used. |  | [ ]  N/A | [ ]  Once [ ]  >Once |

please explain  |
| (2) |

|  |  |  |
| --- | --- | --- |
| Will special signage indicating the hazards be needed for rooms/cages? Door signage is approved by IBO for use of BSL2 biological agents & animals.  |  [ ] No | [ ]  Yes |

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**15. Any other relevant information**

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**16. Declarations**

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| - I certify the information provided in the *Biosafety Registration* form is complete and accurate and understand my responsibilities as noted in it. No changes will be made without advance approval from the Institutional Biosafety Officer.- I acknowledge my responsibility for the safe conduct of this research in accordance with NSU Biosafety Guidelines. I will inform all associated personnel of the nature and risks of this work, as well as necessary precautions and safe practices. I also agree to comply with the requirements for the shipment and transfer of recombinant DNA materials.- I further acknowledge my responsibility to ensure compliance with the following: (1) Work surfaces will be appropriately decontaminated at least daily and immediately after working with biohazardous materials. (2) All personnel involved will wash thoroughly with soap and water after working with biohazardous materials. Clothing will be changed as needed. (3) All contaminated materials will be discarded appropriately according to guidelines (e.g. as Biohazard waste, as Hazardous drug waste, as Chemotherapeutic waste). (4) The Institutional Biosafety Officer will be immediately notified of all spill or incidents occurring in lab spaces operating under Biosafety Level 2l containment. (5) In the event of an incident where there is a risk of infection or other consequences to incident, affected personnel will be counseled to seek appropriate medical attention. |

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| **Name (PI/ Co-PI/ Co-I)** | **Signature** | **Date** |
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*Add additional cells above as needed for additional the research personnel and members of the research team as identified.*

**Submittal**

When the foregoing proposal document is completed and signatures provided, the entirety of the proposal, including required supporting materials, is to be submitted to the Chairperson of the NSU Biosafety Committee through the Office of Research-NSU (Admin Building Rm 625). Provide one hard copy to the Office of Research-NSU and send the electronic copy to mostafizur.rahman09@northsouth.edu, CC to bio.safety@northsouth.edu