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| **Institutional Biosafety Application** Wake Forest University |  | For IBC use only: New Biosafety Protocol No.:  Date Received:  BSL:  ABSL: |

This application contains proprietary/confidential information.

**PROTOCOL TITLE**:

**TYPE OF PROTOCOL:**  **NEW** **AMENDMENT**  **RESUBMISSION**

**TRANSGENIC RODENT REGISTRATION**

For Amendment or Resubmission, enter IBC #:       and highlight all changes or additions to the research since the original approval.

Does this application require expedited review? (e.g. NIH funding deadline?)

Yes  No Explain:

1. **PRINCIPAL INVESTIGATOR SECTION**

|  |
| --- |
| **PI Name/Title**       Email  Department       Department #       Phone#:  **Individual Completing Application:** Title:Phone#:  **Co-Investigator**       Email       Department       Department #       Phone #: |

**\*\*Note*:*** *If any documents are referenced in completing this application, please forward those documents along with your submission*.

1. **LIST OF BIOHAZARDOUS MATERIALS**  *(Check all that apply)*

|  |  |
| --- | --- |
| Human Subjects – ([Section 3](#Human))  Select Agents – ([Section 3](#Select))  Recombinant DNA – ([Section 5](#Recombinant))  Microorganisms – ([Section 5](#Recombinant))  Non-recombinant DNA or RNA – ([Section 6](#Non_Recombinant_Prions))  Culture of Cells or Cell Lines - Human or Non-Human Primate – ([Section 7](#Culture_Cells))  Tissue and Cell Culture – ([Section 8](#Tissue))  Pathogens – ([Section 9](#Pathogens))  Animals – ([Section 10](#Animals)) | |
| Please give a brief summary (200 words or more) of the research you will be conducting:  \*The summary should be written for a lay audience, should include the purpose and objectives of the research, as well as how/what will be performed. | | | | | |
| 1. **RESEARCH IDENTIFICATION** | | | | | |
| Check the appropriate box for each question in context of proposed research. | | | | | |
| **HUMAN SUBJECTS**?  Yes  No  If yes, how will they be used?  Are there going to be samples or will the human subjects be injected? Please explain:  Does the project involve human gene therapy?  Yes  No If Yes, explain: | | | **IRB #:**        **Date Submitted:** | | |
| **ANIMAL USE**?  Yes  No | | | **IACUC #:**       **Date Submitted:** | | |
| **CRISPR/Cas9 or similar technology**?  Will this project involve the use of CRISPR/Cas9 or a similar system?  Yes  No  If Yes, specify the experimental design including but not limited to:   * How the gRNA and Cas9 will be delivered to the cells or tissues * How was/were the targeting sequence(s) designed? * How was/were off-target site/s evaluated? * Will the project involve potential gene drive experiments? | | | | | |
| **SELECT AGENT USE?**  Yes  No   If **YES**, you must **STOP** and contact [Immanuela Onocha](mailto:onochaia@wfu.edu), Biosafety Officer, or (336) 758-3427.  Which agents are you asking to use? | | | | | |
| **SHIPPING REQUIREMENTS:** (*Check all that apply or N/A* ) Reference: [*Shipping Checklist*](http://wp-cdn.aws.wfu.edu/wp-content/uploads/sites/208/2017/06/21104311/Biological-Shipping-Form.pdf)  Material Transfer Agreement.  Contact Environmental, Health and Safety Department – Phone: (336) 758-3427  Purchased?  ATCC number:       Other:  Clinical isolate (If checked, provide sensitivity/resistance information):  Novel  PI Name  Campus Name | | | | | |
| What level of biocontainment will be used?  BSL-1  BSL-2  BSL-3 If another institution, please list:  ABSL-1  ABSL-2 If another institution, please list: | | | | | |
|  | 1. **AUTHORIZED USE LOCATIONS AND MATERIAL STORAGE**  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Choice Action** Use  **A or D**  **(A**dd) (**D**elete) | **LAB LOCATION** | **AUTOCLAVE** | **HANDWASHING**  **SINK** | **Physical Security** | | **Check Applicable Storage** | | | | |  | BLDG/  Room(s) | BLDG/  Room(s) | BLDG/  Room(s) | Door Key Locked | Badge Access | **F20** | **F80** | **R** | **LB** | |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |   ***F20****=Freezer,* ***F80****=Freezer,* ***R****=Refrigerator,* ***LB****=Lockbox*   1. **RECOMBINANT DNA SECTION**  Not Applicable  (*Go to next section)* | | | | | |
| 1. Is this research exempt?  Yes  No *(If exempt, go to next question.)*   Refer to the link: [*rDNA* Guidelines](https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf)  or refer to the full text version: [*NIH Guidelines for Research Involving Recombinant DNA Molecules*](https://osp.od.nih.gov/biotechnology/nih-guidelines/)  ***RECOMBINANT DNA MOLECULES***  If Yes, list exemption category:   1. Will you express any drug or immunological resistance genes?  Yes  No   If Yes, list:  c. Will you express any oncogenic or pathogenic genes? Yes  No  If Yes, list:  d. Will you express any toxins? Yes  No If Yes, list:  e. Which category of microorganism(s) is being used? *(Check all that apply)*   |  |  |  | | --- | --- | --- | | Bacteria | Fungi | Protozoa | | Archaea | Unicellular Algae | Parasitic Worms | | Virus |  |  |  1. List each agent and its risk group, biosafety level, and provider (use additional sheet if necessary). Refer to [Risk Group Classification for Infectious Agents](https://my.absa.org/Riskgroups) for details.  |  |  |  |  | | --- | --- | --- | --- | | Agent (genus, species, strain) | Risk Group | BSL | Provider | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  |  1. Are you producing or receiving vector virus? Yes  No If Yes, please describe any safety features that prevent the generation of recombinant virus and methods of safety testing that have been performed or will be conducted:   Type of manipulations planned:  Source of inserted DNA sequences (e.g. species):  Will an attempt be made to obtain expression of a foreign gene, and if so, the protein that will be produced:  Containment conditions to be implemented:  h. Are you using transgenic animals? Yes  No  i. Does this rodent strain contain a transgenic element constituting > 50% of an exogenous viral genome? Yes  No If Yes, list:  j. Does this rodent strain use a non-mouse promoterto express a transgene, such as a functional retroviral (LTR) promoter (e.g., murine leukemia virus, feline leukemia virus, xenotropic murine leukemia-related virus)? Yes  No If Yes, list:  k. Will you generate or use synthetic nucleic acid molecules (SNM) in your experiments?  Yes  No   * Will the SNM contain more than 100 nucleotides   Yes  No   * Will the SNM possess biological properties that enable integration into the genome   Yes  No   * Will the SNM have the potential to replicate in a cell   Yes  No   * Will the SNM have the ability to be translated or transcribed   Yes  No  Please explain how the synthetic nucleic molecules will be used.  l. Please select the NIH category for your rDNA experiments. *(Select any or all that apply)*  Refer to: [NIH Guidelines](https://osp.od.nih.gov/biotechnology/nih-guidelines/) for complete details.  Section III-A (Transfer of drug resistance genes into microorganisms that are not known to acquire the trait naturally)  Section III-B (Cloning of toxins with LD50 < 100ng/kg body weight)  Section III-C (Transfer of rDNA, DNA, or RNA derived from rDNA into human subjects)  Section III-D (rDNA from Risk Group 2, 3, 4, or restricted agents as vector systems; Infectious or defective DNA or RNA viruses; Whole animals and plants; Large volumes)  Section III-E (rDNA involving < 2/3 of the genome of any eukaryotic virus in the absence of helper virus or plasmids; Whole plants; Transgenic rodents) | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Complete table below using one column per construct (deletion or mutation series of a gene may be listed in one column; use additional sheet if necessary). | | | | | |
|  | **Construct 1** | **Construct 2** | **Construct 3** | **Construct 4** | **Example** |
| **Name and**  **Provider of Gene** |  |  |  |  | green  fluorescent  protein from  Clontech |
| **Gene Function** |  |  |  |  | Example:  marker |
| **Vector Name** |  |  |  |  | Example:  pKH-WSU24 |
| **Vector Type /**  **Species and Strain** |  |  |  |  | Example:  Viral /  Adenovirus  serotype 5 |
| **Expression**  **control elements**  **(promoters,**  **enhancers, etc)** |  |  |  |  | Example:  CMV  promoter |
| **Conc/titer of**  **rDNA (i.p./ml)** |  |  |  |  | Example: 1 X  108 to 1  X1012  infectious  particles/ml |
| **Host and Strain, if**  **applicable** |  |  |  |  | Example: E.  coli, SureTM,  Mouse heart  cells, in vivo |
| **Largest**  **Production**  **Volume of Host** |  |  |  |  | Example:  1 liter |
| **Host Range**  **(including any**  **genetic alterations**  **to host range)** |  |  |  |  | Example:  amphotropic,  broad  mammalian  host range |
| **Is recombinant**  **made in your lab?**  **If not, where?** |  |  |  |  | Example:  UVA |
| **If vector is a**  **genome, what %**  **has been deleted**  **or substituted?** |  |  |  |  | Example:  10% |

**6.** **NON-RECOMBINANT OR SYNTHETIC DNA/RNA; Prions Section**   
 Not Applicable  (*Go to next section)*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| a. Are you handling DNA or RNA from pathogenic microorganisms?  Yes  No  If Yes, list: | | | | | | | |
| 1. Are you handling oncogenic DNA sequences?  Yes  No   If Yes, list: | | | | | | | |
| c. Are you handling DNA containing drug resistance genes?  Yes No  If Yes, list: | | | | | | | |
| d. Are you working with any prions?  Yes  No  If Yes, complete the following table (use additional sheet if necessary):   |  |  |  |  | | --- | --- | --- | --- | | **Name of Prion** | **Pathogenic PrP Isoform** | **Disease** | **Natural Host** | |  |  |  |  | |  |  |  |  | |  |  |  |  |   If **YES** to questions 6 a-d, please answer the following: | | | | | | | |
| e. List the provider(s) of the agents: | | | | | | | |
| f. Explain what safety steps you will take to avoid percutaneous and mucous membrane exposure of laboratory personnel and contamination of the environment. | | | | | | | |
| g. What types of sharps will be used and how will they be disposed of? | | | | | | | |
| h. Provide manufacturer and order number: | | | | | | | |
|  | | | | | | | |
| **7.** | **CULTURE OF CELLS OR CELL LINES - HUMAN OR NON-HUMAN PRIMATE**  **TISSUE SECTION** (Not Applicable  (Go to next section) | | | | | | |
| 1. Are you handling:   Human tissue /fluids/cell lines/brain tissue  Yes  No Non-human primate tissue/fluids/cell lines/brain tissue?  Yes  No (prompt for [Herpes B Occupational Health Program](http://www.wakehealth.edu/IC_Office-of-Research/Occupational-Health.htm))  If Yes, explain (include species):  b. What is the source and provider of the tissue(s)?  c. Are the tissues known or suspected to be infected?  Yes  No | | | | | | | |
| If Yes, describe:  d. Has your staff taken the blood borne pathogen program?  Yes  No  If Yes, list names and dates:  e. Cloning and vector construction in bacteria and yeasts?  Yes  No  f. Expression of products in cultured cells?  Yes  No  If Yes, could toxic products be produced and released from the cells?  If Yes, could an agent that is potentially infectious to plants or mammalian hosts be produced and released from the cells? (e.g., the use of viral vectors or agents including replication defective viral vectors.) Explain:  Based on the agents you are using, is there any need for an occupational health program?  Yes  No  **8.** **TISSUE AND CELL CULTURE** Not Applicable  (Go to next section)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Tissues** | **Provider** | **Catalog Number** | **Type of Cells** | **Infectious Agents? (List)** | **Biosafety Level** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | If any tissues or cells are listed, are they resistant to any form of exposure (e.g. antibiotics or other chemicals)? Explain: | | | | | | | | | | | | | |
|  | |  | | | | | |
| **9.** | | | **PATHOGENS AND POTENTIAL PATHOGENS:** | **Yes** | | **No** | |
| Does the protocol involve the use of potentially infectious microbes? *agents, pathogens?* | | | |  | |  | |
| Are animals exposed to pathogenic organisms?  If yes, route of exposure: | | | |  | |  | |
| Are tissues or cells transplanted between species?  If yes, is it:  animal tissue into human  human tissue into animal  animal to animal | | | |  | |  | |
| **10.** | | | **CONTACT WITH ANIMALS** | | **Yes** | | **No** |
| Name the species: | | | | |  | |  |
| Small laboratory animals species: | | | | |  | |  |
| Large laboratory animals species: | | | | |  | |  |
| Non-human primates: | | | | |  | |  |
| Wild animals species: | | | | |  | |  |
| Transgenic animals species:   1. Will a Gammaretrovirus be used during breeding? If so, please list:   (FeLV, GALV, HERV-W, MLV, PERV, XMRV)   1. Will ≥ 50% of the genome of an exogenous eukaryotic virus be present? 2. Will the transgenic animal need to be maintained at BSL 2 or 3? | | | | |  | |  |
| Knock-out species: | | | | |  | |  |
| Animals that are potential reservoirs of zoonotic diseases (non-human primates, sheep, wild animals, etc.) Please specify: | | | | |  | |  |
| Infectious Agents in Animals: List  a. Dose of infectious agent:       (e.g. cfu/pfu)  b. Frequency of administration:  c. Route of administration: | | | | |  | |  |
| Human or primate cells in Animals | | | | |  | |  |
| Immuno-compromised animals: | | | | |  | |  |
| Provide a description of procedure: | | | | |  | |  |
|  | | | | |  | |  |
| **11. ANIMAL CARE FACILITY** (check all that apply) | | | | | **Yes** | | **No** |
| Biological containment in:  Airborne  Blood  Feces  Urine  Not Applicable | | | | |  | |  |
| Will any carcass, cage or cage contents require special disposal procedures  (Other than ARP disposal)?  If yes, describe:  Carcass disposal:  Bedding disposal:  Cage sanitation: | | | | |  | |  |
| Describe any special precautions for animal care personnel. | | | | | | | |
| How long after administration will the animal be infectious (duration of health hazard to animal care staff)? | | | | | | | |
| Feeding and watering of animals: ARP StaffStudy Staff  Cage changing: ARP StaffStudy Staff  Use of BSC? Yes No | | | | | | | |
| **12. GENE TRANSFER INTO NON-HUMAN SOMATIC CELLS** | | | | | **Yes** | | **No** |
| Does the project involve gene transfer into non-human somatic cells? | | | | |  | |  |
| If yes, could toxic products be produced and shed by the animal or plant?  (The definition of toxic is: LD50 of <100 micrograms per kilograms body weight.) | | | | |  | |  |
| If yes, could an agent that is potentially infectious to plants or mammalian hosts be produced and shed by the animal/plant? (e.g. the use of viral vectors or agents including replication defective viral vectors) Explain: | | | | |  | |  |

**13.** **ENGINEERING CONTROLS/SAFETY PRECAUTIONS**

|  |  |  |
| --- | --- | --- |
| If operations will be performed in a laboratory fume hood or biological safety cabinet, please provide the information show below. | | |
| **Biological Safety Cabinet(s)?**  Yes  No  *Refer to Proper Use of* [*Biological Safety Cabinets*](http://ehs.wfu.edu/files/2014/08/ehs-wfu-chemical-hygiene-plan.pdf) | | **Autoclave?**  Yes  No |
| Cabinet #1 Type:  Location:  Re-certification Date: | | Type:  Location(s): |
| Cabinet #2 Type:  Location:  Re-certification Date: | | **Hand washing sink available?**  Yes  No  Location(s): |
| Cabinet #3 Type:  Location:  Re-certification Date: | | **Personal Protective Equipment Used:**  Yes  No Nitrile Gloves  Yes  No Lab coats, sleeve covers, aprons  Yes  No Protective Eyewear  Yes  No Respiratory protection  Surgical Mask  Respirator  (If yes, you must contact EH&S to arrange for “Fit Testing”.)  Other (List) : |
| **Eye Wash Station?** Yes No | |  |
| Lab/Room #:  If not in lab, list nearest location: | |  |
| **Fume Hoods**  Yes  No | | **Safer Sharps Devices** Yes No |
| Type:  Location:  Date of last certification of face velocity: | | Needles and syringes  Scalpels    Routes of Administration:  Needles for implant. Location: |
| **14.** | **SAFETY PROCEDURES SECTION** | |
|  | 1. Will you work with biohazardous agents in any of the following aerosol-producing devices or procedures? Yes  No (check all that apply)  |  |  |  | | --- | --- | --- | | Aspirators | Intranasal Inoculation | Pressurized Vessels | | Blenders | Large Volumes (>10L) | Shakers | | Centrifuges | Necropsy | Sonicators | | Homogenizers | Pipetting Infectious Liquids | Vortexers |   If YES to any of the above, describe how you will contain the aerosol?    If using sonicator, how will you provide hearing protection to all workers in the area?     1. Do you concentrate the biohazardous agents?  Yes No  |  |  |  | | --- | --- | --- | | Centrifugation | Filtration | Precipitation | | Other, please list: | | |   If Yes, which agent is being concentrated?   1. Are you using a vacuum supply with the biohazardous agents?  Yes No   If Yes, which agent is being used?  If Yes, select method for protecting the vacuum source:   1. At any time during the procedures, will biohazardous agents be moved from a higher safety level to a lower one?  Yes  No   If Yes, provide a justification and describe method of inactivation for this step:     1. How do you generally inactivate the biohazardous agents described in this application?      1. How do you disinfect surfaces in the laboratory? *(Any items used in conjunction with infectious material must be decontaminated by wiping with either 5% (v/v) diluted bleach or 70% ethanol.* | |

**15. EMERGENCY PROCEDURES**

**Any injury to a laboratory worker shall be reported immediately to [*the Principal Investigator:***     **].**

How will you handle an injured lab worker?

Complete a [First Report of Injury](http://ehs.wfu.edu/files/2014/08/ehs-form-first-report-incident.pdf) then go or send employee to Novant Health Urgent Care & Occupational Medicine.

**SPILLS**

Call 5911 on Reynolda Campus and (336) 713-1568 at Wake Downtown B60, report the spill and notify EH&S at (336) 758-3427. All major spills must be reported to ***[the Principal Investigator:***     ***].***

Please provide a detailed biological spill procedure.

**All spills of any nature must be described in your laboratory notebook.** The description must include: 1) the type of spill, 2) the time and date it happened, 3) the time and date it was cleaned up, and 4) the time and date you autoclaved the waste from the spill.

A **major spill** (>10mL) is one in which:

* hazardous materials contact the skin, eyes, etc.
* a break in the skin occurs
* the spill splashes over an area larger than one foot in diameter
* the extent of the spill is undetermined or
* the spill involves an aerosol

Refer to the [WAKE](http://www.wfubmc.edu/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=1392) FOREST UNIVERSITY BIOSAFETY PLAN for spill information:

* Inside of a containment device – (*Appendix G*)
* Spills of infectious material outside of a containment device – (*Appendices H and I*)

For Radioactive emergencies/spills, the Radiation Safety Office (336-716-1201) should be notified.

**16. WASTE GENERATION SECTION**

|  |  |  |
| --- | --- | --- |
|  | 1. Are you generating biological waste?  Yes  No   Refer to: [Biohazard Waste Management Plan](http://ehs.wfu.edu/files/2017/01/Biohazard-Waste-Management-Plan-2017.pdf)  If yes, specify type:   1. Are you generating mixed waste?  Yes  No (check all that apply)   Biological  Chemical  Radiological Hazard   1. How will the waste be disposed? 2. Are you generating chemical waste?  Yes  No   If yes, specify type:   |  | | --- | |  | |

# 17. GENERAL LAB RULES

Please provide standard and additional lab policies for this application:

For general information regarding policies and procedures in labs, click on the following links as reference:

[Environmental, Health and Safety Laboratory Safety](http://ehs.wfu.edu/lab-safety/)

[Wake Forest University Chemical Hygiene Plan](http://ehs.wfu.edu/files/2014/08/ehs-wfu-chemical-hygiene-plan.pdf)  
[Prudent Practices in the Laboratory](http://ehs.wfu.edu/files/2014/08/ehs-13-prudent-practices-laboratory.pdf)

# 18. EMERGENCY PHONE NUMBERS AND PROCEDURES

|  |  |
| --- | --- |
| Police - Reynolda Campus  Wake Downtown B60 | 336-758-5911 or 5911  336-713-1568 or 9-911 |
| Fire and Medical Emergencies – Reynolda Campus  Wake Downtown B60 | 336-758-5911 or 5911  336-713-1568 or 9-911 |
| Principal Investigator’s Home Phone | [     ] |
| Novant Health Urgent Care & Occupational Medicine | 336-759-0700 |
| Environmental Health and Safety | 336-758-3427 |
| Biosafety Officer – Immanuela Onocha | 336-758-3427 |
| IBC Contact - Bernadette Menuey | 336-716-6440 |

**19. DISCLAIMER**

**PI Statement of Responsibility:** I accept responsibility for the safe conduct of work with the agents described in this application. The information in this application is accurate and complete.

**PI Name:** **Signature:**

**20. AUTHORIZED USERS - LABORATORY PERSONNEL SECTION**

|  |  |  |
| --- | --- | --- |
| List Only those individuals involved in THIS research working with biohazardous materials in your laboratory under your supervision. Attach additional sheets if necessary*.* ***Note:*** *Individuals under 18 years of age are not allowed to work with biohazardous materials.*  Each student and / or employee is required to complete either classroom or online “[Lab Compliance Training](https://wfu-ss.multimedia.wfu.edu/vportal/VideoPlayer.jsp?ccsid=C-6de013ce-a924-45fd-ba92-f277cd412f0a:2)”. Training records should be maintained in Lab Compliance Kit. | | |
| *The undersigned individual(s) are involved in this project and have read this application. They also understand that the agents used in this research are infectious to humans. Furthermore, they agree to understanding the Biosafety Manual and agree to attend and/or have required training prior to handling samples or working with this research.* | | |
| **USE ADDITIONAL SHEET IF NECESSARY** | | | |
| **Name** | **Signature** | **Date** | |
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