RESEARCH PROTOCOL SAFETY SURVEY

VA PRINCIPAL INVESTIGATOR (PI):

PROJECT TITLE:

DATE OF SUBMISSION:

LIST VA AND NON-VA LOCATIONS IN WHICH PI CONDUCTS THIS RESEARCH:

1. DOES THE RESEARCH INVOLVE THE USE OF ANY OF THE FOLLOWING?

a. Biological Hazards (Microbiological or viral agents, pathogens, toxins, select agents as defined in Title 42 Code of Federal Regulations (CFR) 73, or animals) YES ( ) NO ( )

b. Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines) YES ( ) NO ( )

c. Recombinant deoxyribonucleic acid (rDNA, including synthetic nucleic acid molecules) YES ( ) NO ( )

d. Chemicals:

(1) Toxic chemicals (including heavy metals)
Chemicals: _____ YES ( ) NO ( )

(2) Flammable, explosive, or corrosive chemicals
Chemicals: _____ YES ( ) NO ( )

(3) Carcinogenic, mutagenic, or teratogenic chemicals
Chemicals: _____ YES ( ) NO ( )

(4) Toxic compressed gases
Chemicals: _____ YES ( ) NO ( )

(5) Acetylcholinesterase inhibitors or neurotoxins
Chemicals: _____ YES ( ) NO ( )

(6) Antineoplastic drugs
Chemicals: _____ YES ( ) NO ( )

e. Controlled Substances YES ( ) NO ( )

f. Ionizing Radiation (not including Standard of Care usage):

(1) Radioactive materials YES ( ) NO ( )

(2) Radiation generating equipment YES ( ) NO ( )

g. Nonionizing Radiation:

(1) Ultraviolet Light YES ( ) NO ( )

(2) Lasers (class 3b or class 4) YES ( ) NO ( )

(3) Radiofrequency or microwave sources YES ( ) NO ( )

If the answer to <u>any</u> of these questions is YES, complete all sections of this survey that apply.

If <u>all</u> answers are NO, a documented review by the local Subcommittee on Research Safety is still required prior to submission. If the research involves the use of human subjects or human tissues, Institutional Review Board (IRB) review is required. ***NOTE:*** *Use of animals also requires submission of an Institutional Animal Care and Use Committee (IACUC)-approved Animal Component.*

2. BIOLOGICAL HAZARDS

a. Does your research involve the use of microbiological or viral agents, pathogens, toxins, poisons or venom? YES ( ) NO ( )

If **NO**, skip to the section on **Cells and Tissue Samples (Section 3)**.

If **YES** FOR **Biological Toxins**, complete **Section 2(b).**

If **YES** FOR **Viral Agents or Pathogens**, list all Risk Group 2 and 3 agents used in your laboratory. It is the responsibility of each PI to:

(1) Consult either The National Institutes of Health (NIH)-Center for Disease Control and Prevention (CDC) publication entitled Biosafety in Microbiological and Biomedical Laboratories or (http://www.cdc.gov/biosafety/publications/bmbl5/)

(2) Identify the Risk Group for each organism/agent.
Enter it into the following table.

Organism, Agent, or Toxin	**Risk Group****

** For **each Risk Group 2 or 3 agent** listed, provide the information requested on the following page(s). (Description of Risk Group 2 and 3 can be found in Appendix A.)

Are any of the biohazardous agents listed above classified as a "Select Agent" by the Centers for Disease Control? YES ( ) NO ( )

b. Identify all biological toxins to be used in this research and their LD50 (if known)

Biological Toxin	**LD50*****

*** If known

c. Biological Hazards – Description of Use *NOTE: Duplicate this section, as necessary.*

a. Identify the microbiological agent or toxin (name, strain, etc.):
b. If this is a Select Agent (42 CFR 72.6), provide the CDC Laboratory Registration # and the date of the CDC inspection:
c. Indicate the largest volume and/or concentration to be used:
d. Indicate whether antibiotic resistance will be expressed, and the nature of this antibiotic resistance:
e. Describe the containment equipment (protective clothing or equipment, biological safety cabinets, fume hoods, containment centrifuges, etc.) to be used in this research:
f. Describe the proposed methods to be employed in monitoring the health and safety of personnel involved in this research:

3. CELLS and TISSUE SAMPLES

a. Will personnel work with animal blood, human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones? If yes, specify: YES ( ) NO ( )
If yes, specify which species and which hazard (eg. blood, urine, tissue type):
_____

b. Will research studies represent a potential risk for occupational exposure to a biohazard for research lab personnel? YES ( ) NO ( )

If yes, specify precautions employed to protect personnel working in the laboratory: universal precautions will be utilized; biohazard waste bins available to dispose waste appropriately, biohazard bags available to transport human serum to lab, PPE available for personnel use.

NOTE: *If these studies involve animals, the Animal Component of Research Protocol (ACORP)must be completed.*

4. RECOMBINANT DNA

a. Are procedures involving recombinant DNA (including the usage of transgenic animals) used in your laboratory
(Check **YES** if any section from 4.b-e. is checked yes)? YES ( ) NO ( )

NOTE: To be assured of whether the proposed work can be defined as involving recombinant DNA and which experimental category for the work, it is the PIs responsibility to consult the current NIH Guidelines for Research Involving Recombinant DNA Molecules which can be found at the Internet site https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html

b. Do recombinant DNA procedures used in your laboratory involve administration of synthetic nucleic acids (siRNA, shRNA, etc.) to cells, tissues or animals? YES ( ) NO ( )

Details of synthetic nucleic acid experiments:

(1) Is the synthetic nucleic acid molecule a chimera of two other nucleic acid molecules? YES ( ) NO ( )
If YES, can it replicate in cells? YES ( ) NO ( )
If YES, which molecules? _____
From which species? _____

(2) Have the synthetic nucleic acid molecules to be used been chemically modified? YES ( ) NO ( )
If YES, what modification? _____
How does this impact the synthetic molecule? _____

(3) Target of the synthetic nucleic acid (protein encoded by RNA targeted):

(4) Cell type, tissue or animal to be administered synthetic nucleic acid:

(5) Methods of introduction of synthetic nucleic acid to experimental model:

c. Are recombinant DNA procedures used in your laboratory limited to amplification of DNA segments (e.g. plasmids) in bacteria? YES ( ) NO ( )
Do these expression vectors express antibiotic resistance genes? YES ( ) NO ( )

Description of DNA Amplification Procedures:

(1) Biological source of DNA insert or gene:

(2) Function of the insert or gene:

(3) Vector(s) used or to be used for cloning (e.g., pUC18, pCR3.1):

(4) Host cells and/or virus used or to be used for cloning (e.g., bacterial, yeast or viral strain, cell line):

d. Do the recombinant DNA procedures used in your laboratory involve expression of cloned DNA in mammalian cells by plasmid, viral (e.g. adenovirus, retrovirus) or yeast vectors? YES ( ) NO ( )

Description of Recombinant DNA Procedures:

(1) Identify the NIH classification (and brief description) for these recombinant DNA studies:
(2) Biological source of DNA insert or gene:
(3) Function of the insert or gene:
(4) Vector(s) used or to be used for cloning (specify backbone of vector and genes deleted (if viral vector) if vector is rendered replication deficient/incompetent:

_____

(5) Host cells to be used for cloning or propagation (e.g., bacterial, yeast or viral strain, cell line):

e. Are transgenic animals used in your laboratory? YES ( ) NO ( )
For transgenic animal rDNA classification, see https://ehs.unc.edu/files/2015/08/csp_rdna.pdf

Description of Transgenic animals:

(1) Name of animal species and strain:
(2) Biological source of DNA insert or gene:
(3) Function of the insert or gene:

Description of transgenic animal procedures:

(1) Are the transgenic animals only subject to colony maintenance? (i.e. no cross-breeding)? YES ( ) NO ( )

(2) Will the transgenic animals be cross-bred with other transgenic strains? YES ( ) NO ( )
If **YES**, your recombinant DNA studies fall under category III-F-3 (for BSL-1 strains) or III-D-4-B (if generating a BSL-2 strain) as described in the NIH Guidelines for Research Involving Recombinant DNA Molecules.

5. USE OF CHEMICALS (*NOTE:* *Submission of the laboratory chemical inventory is required for local review)*

a. Has the use of chemicals in your laboratory been submitted for review by an appropriate committee or subcommittee in the past 12 months? YES ( ) NO ( )
b. Are personnel knowledgeable about the special hazards posed by:
(1) Carcinogens?_____NA ( ) YES ( ) NO ( )
(2) Teratogens and Mutagens? _____NA ( ) YES ( ) NO ( )
(3) Toxic gases? _____NA ( ) YES ( ) NO ( )
(4) Neurotoxins? _____NA ( ) YES ( ) NO ( )
(5) Reactive and potentially explosive compounds? _____NA ( ) YES ( ) NO ( )

6. CONTROLLED SUBSTANCES

a. Does your research involve the use of any substance regulated by the Drug Enforcement Agency? YES ( ) NO ( )

If yes, list controlled substances to be used:

(1) _____

(2) _____

(3) _____

b. Are all Schedule II and III drugs stored in a double-locked vault? NA ( ) YES ( ) NO ( )

c. Location of Vault_____

NOTE: *The schedule of controlled substances can be found at the Internet site* https://www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf

7. RADIOACTIVE MATERIALS

Does your research involve the use of radioactive materials? YES ( ) NO ( )

If YES, provide the following:

a. Identity of radioactive source (s):

b. Radiation Safety Committee Approval Number (if applicable, or date):

8. PHYSICAL HAZARDS

a. Are physical hazards addressed in the facility Occupational Safety and Health Plan? YES ( ) NO ( )

b. Do employees receive annual training addressing physical hazards? YES ( ) NO ( )

Acknowledgement of Responsibility and Knowledge

I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of, biohazardous materials, chemicals, radioisotopes, and physical hazards. I further certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA)-regulated hazardous chemicals is attached to this survey.

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Principal Investigator's Signature **Date**

Certification of Safety Officer's Approval

A complete list of chemicals to be used in the proposal has been reviewed. Appropriate occupational safety and health, environmental, and emergency response programs will be implemented on the basis of the list provided.

_____

Safety Officer's Signature **Date**

Certification of Research Approval

The safety information for this application has been reviewed and is in compliance with Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. Copies of any additional surveys used locally are available from the Research and Development (R&D) Office.

_____

Chair, Subcommittee on Research Safety **Date**

_____

Chair, Research & Development Committee **Date**

_____

Radiation Safety Officer (if applicable) **Date**

_____

Facility Safety Officer **Date**