WAKE FOREST UNIVERSITY

For IBC use only:
New Biosafety Protocol No:
Date Received:
BSL:
ABSL:
IRB #:

Institutional Biosafety Application

Instructions: Please complete this application if you plan on using infectious agents, select agents, recombinant DNA, blood, body tissues or fluids as part of your research, teaching or testing activities at Wake Forest University.

Please note that if you plan on using or collecting biological agents, samples, etc. from live vertebrate animal sources, identifiable human sources or your research will involve radiation/radioactive isotopes you will also need to seek approval from the appropriate committee(s). Contact the Office of Research and sponsored programs for additional information.

Is this application being submitted as part of a(n):
IACUC Application Yes ☐ No ☐ If yes, Protocol # and Date submitted:
IRB Application Yes ☐ No ☐ If yes, Protocol # and Date submitted:

Protocol Title:
Type of Protocol: ☐ New
Amendment ☐ Protocol #
Resubmission ☐ Protocol #

Section I: Principal Investigator Information

Principal Investigator:
Position/Title:
Email Address:
Department:
Phone #:
Date of IBC Online Training:
Will this project be funded by a grant, contract, or any pending grants or contracts? Yes ☐ No ☐
(If yes, provide a copy of the project narrative submitted as part of your grant proposal)

List all personnel involved in the project, their respective roles:

Section II: List of Biological Materials

☐ Human Subjects (blood, tissue, or bodily fluid)
☐ Animal Use (blood, tissue, or bodily fluid)
☐ Sharps
☐ Transgenic and/or pathogenic plants
☐ Recombinant or synthetic nucleic acid molecules
☐ Non-recombinant DNA or RNA
☐ Infectious Agents

☐ Select Agents
☐ Radioactive materials
☐ Shipping of Biological materials - Note: The EHS Department MUST oversee the shipping of any biological material or hazardous substance.

Please provide an overall summary of the project, the specific aim(s) of the study and briefly explain in language understandable to the general public:

Section III: Research Identification

1. Biosafety Level
   Indicate the biosafety level of the proposed work:
   ☐ BSL 1 ☐ BSL 2 ☐ BSL 3
   ☐ ABSL 1 ☐ ABSL 2 ☐ ABSL 3
2. Human subjects
   Will this project involve human subjects? Yes ☐ No ☐
   If yes, please explain how they will be used:
   Does the research involve human gene therapy? Yes ☐ No ☐
   If yes, please explain:

3. Animal Use
   Will this project involve the use of animals? Yes ☐ No ☐
   If yes, please explain:

4. Select Agents
   Are any of your human, animal, or plant pathogens or toxins of biological origins classified as Select Agents? Yes ☐ No ☐
   If yes, STOP and contact the Biosafety Officer at (336) 758-3427 Select Agents require federal registration and authorization prior to use

5. Shipping requirements
   Will you be exporting/importing samples (tissues, blood, etc.), plasmids, or research products within and outside of the United States of America? Yes ☐ No ☐
   If yes, contact the Biosafety Officer for preparation and shipment.

Section IV: Facilities, Safety Equipment and Materials Storage

1. Authorized Research locations

Please list the building, room number for the lab, autoclave, handwashing sink and check applicable storage for research activities

Lab Location (BLDG/ RM)	Autoclave (BLDG/ RM)	Handwashing sink (BLDG/ RM)	Eye Wash Station (BLDG/ RM)	Fume hood		Biosafety cabinet		Physical Security	
				(BLDG/ RM)	Certification Date	(BLDG/ RM)	Certification Date	Door locked w/key	Badge Access
								☐	☐
								☐	☐

								☐	☐
								☐	☐
								☐	☐

(BLDG/RM = Building/Room)

2. Biological Materials Storage

Building	Room	Freezer		Refrigerator	Incubator	Other
		-80F	-20F			
		☐	☐	Yes ☐ No ☐	Yes ☐ No ☐	
		☐	☐	Yes ☐ No ☐	Yes ☐ No ☐	
		☐	☐	Yes ☐ No ☐	Yes ☐ No ☐	
		☐	☐	Yes ☐ No ☐	Yes ☐ No ☐	
		☐	☐	Yes ☐ No ☐	Yes ☐ No ☐	

-80F=minus 80 freezer, -20F=minus 20 freeze

3. Personal Protective Equipment (PPE)

Please check all of the PPE and equipment to be used by personnel

☐ Eye/Face protection
☐ Head cover
☐ Shoe covers
☐ Gloves
☐ Manual pipettors
☐ Automatic pipettors
☐ Tyveks/Disposable gowns
☐ Safety centrifuge/blender/grinder
☐ N95 particulate respirator (if yes, contact EHS)
☐ PAPR (HEPA) respirator (if yes, contact EHS)
☐ Lab Coat
☐ Other

Section V: Recombinant DNA

1. Will your project involve rDNA work? Yes ☐ No ☐
   If yes, please complete this section
   If your project **does not** involve rDNA, Please **go to the next section**

2. Are you using human DNA? Yes ☐ No ☐
   If yes, please also complete Section VIII

3. Give a brief summary of your proposed use of rDNA:

4. Please answer the following questions to determine if this project is exempt under the NIH Guidelines
   i. Are any of the rDNA segment(s) placed inside a viable organism or virus? Yes ☐ No ☐ N/A ☐

ii. Are the entire rDNA segment(s) from a single non-chromosomal or single viral DNA source?
Yes ☐ No ☐ N/A ☐

iii. Are the entire rDNA segment(s) from a prokaryotic host (including indigenous plasmids or viruses) and only propagated in that host? Yes ☐ No ☐ N/A ☐

iv. Are the entire rDNA segment(s) from a single eukaryotic host (including chloroplasts, mitochondria, plasmids – **but excluding viruses**) and only propagated in that host?
Yes ☐ No ☐ N/A ☐

v. Do the rDNA molecules consist entirely of DNA segments from one or more of the following species that exchange DNA by known physiological processes (though one or more of the segments may be a synthetic equivalent): Yes ☐ No ☐ N/A ☐

Genus Escherichia	Genus *Shigella*	Genus *Salmonella* including *Arizona*
Genus *Enterobacter*	Genus *Citrobacter* including *Levinea*	Genus *Klebsiella* including *oxytoca*
Genus *Erwinia*	*Pseudomonas aeruginosa*	*Pseudomonas putida*
Pseudomonas fluorescens	*Pseudomonas mendocina*	*Serratia marcescens*
Yersinia enterocolitica	Bacillus subtilis	*Bacillus licheniformis*
Bacillus pumilus	*Bacillus globigii*	*Bacillus niger*
Bacillus nato	*Bacillus amyloliquefaciens*	*Bacillus aterrimus*
Streptomyces aureofaciens	*Streptomyces rimosus*	*Streptomyces coelicolor*
Streptomyces griseus	*Streptomyces cyaneus*	*Streptomyces venezuelae*
Streptococcus sanguis	*Streptococcus pneumoniae*	*Streptococcus faecalis*
Streptococcus pyogenes	*Streptococcus mutans*	
One way transfer of *Streptococcus mutans* or *Streptococcus lactis* DNA into *Streptococcus sanguis*		

vi. Does your research involve genomic DNA molecules that have acquired a transposable element which does not contain any recombinant and/or synthetic DNA? Yes ☐ No ☐ N/A ☐

vii. Does use of rDNA molecules fall under one of the following categories in Appendix C determined by the NIH Director as “those that do not present a significant risk to health or the environment”?
Yes ☐ No ☐ N/A ☐
If yes, explain:

Exemptions from the NIH Guidelines does not indicate that the PI is exempt form IBC Policies, other federal and state standards of biosafety or from completing this application

5. Please Select the NIH category for the rDNA experiments.
   ☐ Section III-A Transfer of drug resistance genes into microorganisms that are not known to acquire the trait naturally)
   ☐ Section III-B Cloning of toxin molecules with LD50 <100 Ng/kg body weight
   ☐ Section III-C Deliberate transfer of rDNA, DNA, or RNA derived from rDNA into one or more human research participants
   ☐ Section III-D DNA from risk Group 2,3,4 or restricted agents as host-vector systems; use of infectious or defective DNA or RNA viruses; whole animal and plants; large volumes and Influenza viruses.
   ☐ 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

6. Will you express any drug or immunological resistance genes? Yes ☐ No ☐
   If yes, explain:
7. Will you express any oncogenic or pathogenic genes? Yes ☐ No ☐
   If yes, explain:
8. Will you express any toxins? Yes ☐ No ☐
   If yes, explain:
9. Will you be using hosts, vectors or inserts? Yes ☐ No ☐
   If yes, describe what they are, how they will be used and safety features that prevent the generation of recombinant virus and methods of safety testing:
10. Which category of microorganism(s) is being used?
    ☐ Bacteria ☐ Virus ☐ Parasitic worms
    ☐ Fungi ☐ Archaea
    ☐ Protozoa ☐ Unicellular Algae
11. List each agent, risk group, biosafety level and provider for rDNA work

Agent (genus, species, strain)	Biosafety Level	Risk Group Classification (if known)	Provider

12. Are you using transgenic animals? Yes ☐ No ☐
13. Are you using rodents? Yes ☐ No ☐

14. Does this rodent strain contain a transgenic element constitution >50% of an exogenous viral genome? Yes ☐ No ☐
    If yes, explain:
15. Does this rodent strain use a non-mouse promoter to express a transgene, such as a functional retroviral (LTR) promoter? Yes ☐ No ☐
    If yes, explain:
16. Will you generate or use synthetic nucleic acid molecules (SNM)? Yes ☐ No ☐
    If yes, explain:
    a. Will the SNM contain more than 100 nucleotides? Yes ☐ No ☐
    b. Will the SNM possess biological properties that enable integrations into the genome? Yes ☐ No ☐
    c. Will the SNM have the potential to replicate in a cell? Yes ☐ No ☐
    d. Will the SNM have the ability to be translated or transcribed? Yes ☐ No ☐

Section VI: Non-recombinant or Synthetic DNA/RNA

Are you handling DNA or RNA from pathogenic microorganisms? Yes ☐ No ☐
If yes, please explain:
Are you handling oncogenic DNA sequences? Yes ☐ No ☐
If yes, please explain:
Are you handing DNA containing drug resistance genes? Yes ☐ No ☐
If yes, please explain:
Are you working with any prions? Yes ☐ No ☐
If yes, list the name of prion, pathogenic PrP Isoform, disease and natural host :
Please list the provider/supplier of the non-recombinant or synthetic DNA/RNA agents, safety precautions and types of sharps.

Provider/Supplier	Agents	Safety Precautions	Types of Sharps

Section VII: Infectious Agents

Will your project use agents that are infectious to humans (excluding host for rDNA work)?
Yes ☐ No ☐ (If yes, please complete this section)

Agent 1
Name of Agent:
Strains/isolates:
Biosafety Level:

Risk Group Classification
How will you use the agent? ☐ In vitro
☐ In vivo in animals
☐ In vivo in plants
☐ Other
What methods of inactivation will be used? ☐ Autoclave
☐ Incineration
☐ Chemical
☐ Other
Please give a brief summary of the use and source of the agent:

Agent 2
Name of Agent:
Strains/isolates:
Biosafety Level:
Risk Group Classification
How will you use the agent? ☐ In vitro
☐ In vivo in animals
☐ In vivo in plants
☐ Other
What methods of inactivation will be used? ☐ Autoclave
☐ Incineration
☐ Chemical
☐ Other
Please give a brief summary of the use and source of the agent:

(Please use the above format for additional agents)

Section VIII: Blood, Body Fluids, Cell lines and Tissues

1. Do you plan to use:
   a. Human blood/tissue/fluids/Cell lines/brain tissue Yes ☐ No ☐
   b. Non-human primate tissue/fluids/cell lines/brain tissue Yes ☐ No ☐

If you don't plan to use any of the above, go to next section

2. Describe the specific origin (source and provider), uses and infectious potential of 1a and/or 1b:
3. Describe how you plan to minimize the risk of infection (list procedures for inactivation/decontamination):
4. Have all personnel taken the Bloodborne Pathogen Training? Yes ☐ No ☐
   If yes, list names and dates in the table below:

Name	Date

Section IX: Biohazard Control Plan

Please provide a biohazard control plan and include the following:

- The general types of experimental procedures that will be performed
- Addressing the potential sources of risk (aerosol generation, needle sticks etc.) to personnel and /or the environment and how these risks will be managed
- Describe safety devices that will be used
- Decontamination/disinfection processes
- Plans for disposing generated biological waste

Section X: 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 Emergency – Reynolda Campus Wake Downtown B60	(336) 758-5911 or 5911 (336) 713-1568 or 9-911
Principal Investigator's Home Phone	
Environmental, Health and Safety (8 AM – 5PM)	(336) 758-3427
Biosafety Officer & IBC Contact	(336) 758-3427
Director & IBC Contact – Steve Fisenne	(336) 830-9394

Section XI: Principal Investigator Agreement

PI Statement of Responsibility: I accept responsibility for the safe conduct of work with the agents described in this application. I confirm that the information in this application is accurate and complete. I confirm that all individuals working on this protocol have completed the required Biosafety training and Bloodborne pathogen training. I will immediately report any biological hazard spills to EHS.

PI Name:

Signature: