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|  | |  | | --- | | 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](https://www.selectagents.gov/SelectAgentsandToxinsList.html)

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](https://www.niaid.nih.gov/research/biodefense-biosafety-labs)

Indicate the biosafety level of the proposed work:

BSL 1  BSL 2  BSL 3



ABSL 1  ABSL 2  ABSL 3

1. 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:

1. Animal Use

Will this project involve the use of animals? Yes  No

If yes, please explain:

1. [Select Agents](https://www.selectagents.gov/selectagentsandtoxinslist.html)

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 Immanuela Onocha, Biosafety Officer or (336) 758-3427

Select Agents require federal registration and authorization prior to use

1. 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 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 |
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(BLDG/RM = Building/Room)

1. 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

1. Personal Protective Equipment (PPE)

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

Eye/Face protection  Automatic pipettors  Lab Coat

Head cover  Tyveks/Disposable gowns  Other

Shoe covers  Safety centrifuge/blender/grinder

Gloves  N95 particulate respirator (if yes, contact EHS)

Manual pipettors  PAPR (HEPA) respirator (if yes, contact EHS)

## 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**

1. Are you using human DNA? Yes  No

If yes, please also complete Section VIII

1. Give a brief summary of your proposed use of rDNA:
2. Please answer the following questions to determine if this project is exempt under the NIH Guidelines
3. Are any of the rDNA segment(s) placed inside a viable organism or virus? Yes  No  N/A
4. Are the entire rDNA segment(s) from a single non-chromosomal or single viral DNA source?

Yes  No  N/A

1. 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
2. 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
3. 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* | | |
|  | | |

1. 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
2. Does your use of rDNA molecules fall under one of the following categories in [Appendix C](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_APPENDIX_C._EXEMPTIONS) 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**

1. 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

1. Will you express any drug or immunological resistance genes? Yes  No

If yes, explain:

1. Will you express any oncogenic or pathogenic genes? Yes  No

If yes, explain:

1. Will you express any toxins? Yes  No

If yes, explain:

1. 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:

1. Which category of microorganism(s) is being used?

Bacteria  Virus  Parasitic worms

Fungi  Archaea

Protozoa  Unicellular Algae

1. List each agent, risk group, biosafety level and provider for rDNA work

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| --- | --- | --- | --- |
| Agent (genus, species, strain) | Biosafety Level | Risk Group Classification (if known) | Provider |
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1. Are you using transgenic animals? Yes  No
2. Are you using rodents? Yes  No
3. Does this rodent strain contain a transgenic element constitution >50% of an exogenous viral genome? Yes  No

If yes, explain:

1. 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:

1. Will you generate or use synthetic nucleic acid molecules (SNM)? Yes  No

If yes, explain:

* 1. Will the SNM contain more than 100 nucleotides? Yes  No
  2. Will the SNM possess biological properties that enable integrations into the genome? Yes  No
  3. Will the SNM have the potential to replicate in a cell? Yes  No
  4. 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.

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| --- | --- | --- | --- |
| Provider/Supplier | Agents | Safety Precautions | Types of Sharps |
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## 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:
2. Human blood/tissue/fluids/Cell lines/brain tissue Yes  No
3. 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

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

If yes, list names and dates in the table below:

|  |  |
| --- | --- |
| Name | Date |
|  |  |
|  |  |
|  |  |
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## 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 – Immanuela Onocha | (317) 531-6209 |
| Associate 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:                