INSTITUTIONAL BIOSAFETY COMMITTEE
Biological† Use Application Form

FOR OFFICE USE ONLY
Application No. Status: ☐ Exempt ☐ Non-Exempt
Receipt Date:
Approval Date:

SECTION I: ADMINISTRATIVE INFORMATION

PRINCIPAL INVESTIGATOR INFORMATION	
Name:	Date:
Job Title:	Email address:
Phone:	
PROJECT INFORMATION	Proposed Biosafety Level: BSL- ← As entered in **Section IV. Part C**.
Project Title:	Anticipated Start Date: Anticipated End Date:
Funding Agency/Source:	
Approval of this protocol is needed for grant application deadline? Yes ☐ No ☐	Grant deadline date:
CATEGORY OF APPLICATION	This application is: ☐ Initial (New) ☐ Revised - Existing IBC approval will expire. Existing IBC #: Expiration Date: This application contains proprietary or confidential business information. ☐ Yes ☐ No

SECTION II: INSTITUTIONAL & REGULATORY APPROVALS/ REGISTRATIONS

OTHER INSTITUTIONAL REVIEWS/APPROVALS/PERMITS		
A. USE OF VERTEBRATE ANIMALS Does this biosafety activity involve the use of vertebrate animals?	☐ Yes ☐ No	**If Yes, attach IACUC approval.**
B. USE OF RADIATION Does this biosafety activity involve the use of radioactive materials?	☐ Yes ☐ No	
C. USE OF HUMAN SUBJECTS Does this biosafety activity involve the use of human subjects?	☐ Yes ☐ No	Attach a copy of an Institutional Review Board (IRB) permission to use human subjects in this research or a copy of Exempt Research Determination or other evidence of compliance with 45 CFR Part 46 and HHS Human Subject Regulations Decision Charts
D. FEDERAL PERMITS Does this biosafety activity require any Federal permits that are not included in A, B, or C above**?**	☐ Yes ☐ No Permits from Federal agencies (e.g., APHIS, CDC) are required for handling of toxins, pests, certain biological organisms, or to import exotic agents and organisms.	If yes, list issuing agency: ; permit number: ; and expiration date: Are there additional issuing agencies, permit numbers &/or expiration dates? ☐ Yes ☐ No If Yes, list below or on a separate page. If yes, list issuing agency: permit number: ; and expiration date: Notes: Please email a copy of the permit(s) to research@newmexicoconsortium.org Please contact Research Administration at (505) 412 - 4200 for assistance with permit application(s) or if any questions.

† Per NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, CDC's Biosafety in Microbiological and Biomedical Laboratories, 6th Edition and the NMC's Research Compliance/Laboratory Research webpage

SECTION III: LOCATION OF ACTIVITIES

LOCATION		
NMC	☐ Yes ☐ No	Facility address, name, and phone number of contact person at this location:

NON-NMC
Does any part of this activity occur at a non-NMC facility or site? ☐ Yes ☐ No
If Yes, complete all of the following information for each non-NMC facility.

Name and address of non-NMC Facility	Contact Name, Title, Phone Number

Provide names of NMC personnel physically participating in the activity at the non-NMC facility listed above?

Will the proposed activity involve the transfer of any biohazardous or recombinant DNA materials from and/or to this location? ☐ Yes ☐ No
If yes, specify what materials will be transferred

Do you have the necessary permits required for transfer of these materials? ☐ Yes ☐ No

Does this facility, or specific area where the work is conducted, have an IBC approval for work at the appropriate biosafety level? ☐ Yes ☐ No
If Yes, what is the approved BSL? ☐ BSL-1 ☐ BSL-2

Note: A copy of the non-NMC facility IBC, IRB or IACUC (as applicable) approval must be attached to this Application if the work involves recombinant DNA, vertebrate animals, human subjects, or BSL-2 work.

SECTION IV. TYPE OF BIOLOGICALS AND BIOSAFETY ACTIVITY

A. BIOHAZARDOUS AGENTS: Check the box(es) that apply to this project.

1. ☐ Arthropod (e.g., mosquitoes, ticks)
2. ☐ Bacteria
3. ☐ Cells or tissues (Animal source)
4. ☐ Cells or tissues (Human or non-human primate source), blood, or body fluids, unfixed tissue including immortalized cell lines.
5. ☐ Fungi
6. ☐ Mold
7. ☐ Parasite (e.g., Plasmodium spp.)
8. ☐ Recombinant or synthetic nucleic acid molecules; refer to the NIH Guidelines
9. ☐ Toxin (☐ chemical or ☐ biological product)
10. Use of expression vectors
    - ☐ Yes - viral vector
    - ☐ Yes - cosmid, phagemid, plasmid vector
11. ☐ Virus - Animal (☐ exotic or ☐ endemic to NM)
12. ☐ Virus – Plant (☐ exotic or ☐ endemic to NM)
13. ☐ Yeast
14. ☐ Other, list material below (e.g., *dura mater* from human, non-human primate, livestock, rickettsia, etc.)

Mark the appropriate box(es) to indicate the sources of the BIOHAZARDOUS AGENTS listed above.

☐ A commercial vendor (ATCC or as part of a kit, i.e., Stratagene, Promega, etc.) If using a kit, provide the vendor or manufacturer and product number _____

☐ Isolation from environmental samples (e.g., water, soil, etc.) ☐ Isolated from a plant or animal ☐ Hospital or clinic

☐ Colleagues and collaborators in: ☐ Academia or ☐ Industry ☐ Other (specify) _____

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For each box marked in **Section IV. Part A**. above, provide the COMMON NAME, SCIENTIFIC NAME (i.e., Genus & species, strain and/or Manufacturer's kit name and product number) & SPECIFICS in the columns below. Also mark the applicable box(es) in the 'SPECIFICS' column. *Add more rows, as needed*.

COMMON NAME	SCIENTIFIC NAME (Genus & species, strain and/or Manufacturer's kit name and product number)	Yes No SPECIFICS
		☐ ☐ Certified BSC will be used for propagation / manipulation of agent. ☐ ☐ Vaccine is available (☐ licensed or ☐ IND*). ☐ ☐ Vaccination recommended. ☐ ☐ Special precautions to be used? (If yes, list below):
		☐ ☐ Certified BSC will be used for propagation / manipulation of agent. ☐ ☐ Vaccine is available (☐ licensed or ☐ IND). ☐ ☐ Vaccination recommended. ☐ ☐ Special precautions to be used? (If yes, list below):
		☐ ☐ Certified BSC will be used for propagation / manipulation of agent. ☐ ☐ Vaccine is available (☐ licensed or ☐ IND). ☐ ☐ Vaccination recommended. ☐ ☐ Special precautions to be used? (If yes, list below):
		☐ ☐ Certified BSC will be used for propagation / manipulation of agent. ☐ ☐ Vaccine is available (☐ licensed or ☐ IND). ☐ ☐ Vaccination recommended. ☐ ☐ Special precautions to be used? (If yes, list below):
		☐ ☐ Certified BSC will be used for propagation / manipulation of agent. ☐ ☐ Vaccine is available (☐ licensed or ☐ IND) ☐ ☐ Vaccination recommended. ☐ ☐ Special precautions to be used? (If yes, list below):
		☐ ☐ Certified BSC will be used for propagation / manipulation of agent. ☐ ☐ Vaccine is available (☐ licensed or ☐ IND). ☐ ☐ Vaccination recommended. ☐ ☐ Special precautions to be used? (If yes, list below):
		☐ ☐ Certified BSC will be used for propagation / manipulation of agent. ☐ ☐ Vaccine is available (☐ licensed or ☐ IND). ☐ ☐ Vaccination recommended. ☐ ☐ Special precautions to be used? (If yes, list below):

* Investigational New Drug Application

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B. RECOMBINANT DNA

Does this research involve the use of recombinant or synthetic nucleic acid molecules? ☐ Yes ☐ No

Provide details below; if needed, add lines or a separate page for more **SOURCES**.

SOURCE: What is the origin of DNA or nucleic acid sequence of interest? (Give the common name, scientific name, and how obtained):

What is the nature of the nucleic acid sequence of interest?

What host organism(s) will be used? (If using a commercial product, please specify the vendor and product name, e.g., Invitrogen *E. coli* Top10):

Vector name(s)	**Specify selection markers. (Provide a gene map or give a reference from literature or commercial supplier, if applicable.)**	**Will the foreign gene be expressed? If yes, indicate the protein that will be produced and identify promoters.**

C. PROPOSED BIOSAFETY LEVEL

What is the proposed Biosafety Level (BSL) for this activity?
☐ BSL-1
☐ BSL-2
☐ Plant Biosafety

- Biosafety Level 1 involves well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.
- Biosafety Level 2 involves work with agents of moderate potential hazard to personnel and the environment.

Sources: 2019 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition

D. CLASSIFICATION OF RECOMBINANT DNA WORK UNDER THE *NIH GUIDELINES*

[INSERT THE APPLICABLE CLASSIFICATION FROM SECTION III, EXPERIMENTS COVERED BY THE 2019 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules]

† Per NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, CDC's Biosafety in Microbiological and Biomedical Laboratories, 6th Edition and the NMC's Research Compliance/Laboratory Research webpage

SECTION V: DESCRIPTION OF ACTIVITY

A. LAY SUMMARY

*In lay language, use this page to describe the experimental design and research objectives of the activity, with **specific mention of the materials (i.e., the Biohazardous Agents &/or Recombinant DNA) listed in SECTION IV, Parts A. & B**. Provide details that will allow a non-scientist to understand your work and assess the hazards and risks. Please define all acronyms at first use.*

[INSERT LAY SUMMARY]

B. PROCEDURES

Research Methods/Procedures
*Use the space below to describe the procedures that you use for this activity, with the intent of providing the IBC with a clear understanding of what you are doing in terms of **materials (i.e., the Biohazardous Agents &/or Recombinant DNA) listed in SECTION IV, Parts A. & B**.*
Include any activities which may produce aerosols, or which may increase the hazard of working with the biohazardous agent(s). Include both standard procedures (referred to by common names such as PCR), and novel procedures or significant modifications to standard procedures, which should be clearly described and/or a referenced.

[INSERT PROCEDURES]

† Per NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, CDC's Biosafety in Microbiological and Biomedical Laboratories, 6th Edition and the NMC's Research Compliance/Laboratory Research webpage

C. SUBSTANCE DISPOSAL AND DECONTAMINATION PROCEDURES

Review the template language below describing the method of disposal (e.g., incineration, autoclaving, chemical disinfection) for Biohazardous Agents and Recombinant DNA transformed organisms. Mark the box(es) for all methods that may be used.

☐ **Inappropriate disposal of waste poses a potential for adverse environmental impact and regulatory enforcement action. We will follow facility-specific procedures and NMED Solid Waste Bureau regulations on disposal of solid lab waste, viable organisms and waste DNA and recombinant DNA materials.**

☐ **All personnel will be trained on Environmental Health & Safety in OSHA Hazard Communication and other topics required by hosting facility. Proof of training will be emailed to NMC HR: hr@newmexicoconsortium.org.**

☐ **At the facility, we decontaminate solid waste (transformation products, spent agar plates) by autoclaving so that all materials are subjected to sufficient conditions of steam, pressure, and time (temperature of at least 121°C, pressure of at least 15 pounds per square inch (psi), for at least 30 minutes). We record autoclave use in a logbook containing the following information for each load:**

- **The date and time the cycle is engaged.**
- **The operator's initials.**
- **Content (e.g., waste for decontamination, implements being sterilized, liquids being sterilized.)**
- **Volume of the load (e.g., bag size X number of bags).**
- **Cycle duration and type of load, i.e., 30-minute/liquid, 60-minute/dry.**
- **Results of a chemical integrator strip that visually indicates PASS/FAIL conditions and is attached to every bag of treated waste released to the regular trash.**

☐ **At the facility, we decontaminate liquid wastes and surfaces contaminated with liquid waste or cultures using bleach (10ml/3.75L) ~200ppm. We understand that the hypochlorite solution will break down within 24 hours, so we prepare a fresh solution as needed.**

☐ **At the facility, if chemical disinfectant other than a 10% dilution of 6.0% sodium hypochlorite is used, state the chemical and concentration here:**

☐ **At the facility, we practice good housekeeping and package sharps in puncture-resistant containers manufactured for the purpose of sharps disposal and contain our waste in lined, rigid containers.**

☐ **We contact (fill in vendor here) for arrangements to pick up chemical waste and full sharp containers.**

*[INSERT ANY ADDITIONAL PROCEDURES BELOW: Specify any waste handling, decontamination, and disposal operations **not** described in **Section V. Part** **C. SUBSTANCE DISPOSAL AND DECONTAMINATION PROCEDURES** above.]*

† Per NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, CDC's Biosafety in Microbiological and Biomedical Laboratories, 6th Edition and the NMC's Research Compliance/Laboratory Research webpage

D. EQUIPMENT		
Do you use a biological safety cabinet (BSC) for this activity?	☐ Yes	☐ No
Do you use a clean air bench (CAB) for this activity?	☐ Yes	☐ No
Do you use an autoclave for decontamination of laboratory waste?	☐ Yes	☐ No

If Yes in Section V. Part D. EQUIPMENT above, please mark the appropriate box(es) and fill in the information requested below. If needed, insert lines.

Equipment	Building	Room	Identification Information (i.e., Manufacturer, Model, Serial Number)	Certification/Test Date
☐ BSC ☐ CAB ☐ Autoclave				
☐ BSC ☐ CAB ☐ Autoclave				
☐ BSC ☐ CAB ☐ Autoclave				

SECTION VI: PERSONNEL

A. PERSONNEL

List the names and titles (i.e., faculty, staff, post-doc, grad student, undergrad student, technician, or other discipline) of personnel working on this project and provide the following information:

(1) *Experience relevant to the proposed research; list equipment, methods, procedures and experience at BSL-1 or BSL-2;* ***If no prior experience, provide a brief description of how training will be given in the space below.***

(2) *Where obtained (NMC or other), and*

(3) *Number of years' experience working in a laboratory at biosafety level 1, 2, or 3.*

a. Name and Title: _____
(1) _____ (2) _____ (3) _____

b. Name and Title: _____
(1) _____ (2) _____ (3) _____

c. Name and Title: _____
(1) _____ (2) _____ (3) _____

d. Name and Title: _____
(1) _____ (2) _____ (3) _____

e. Name and Title: _____
(1) _____ (2) _____ (3) _____

Note: For any additional personnel, please add lines or attach a separate page providing the above information.

[***As applicable: if no prior experience, provide a brief description here of how personnel will be trained.]***

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B. REQUIRED TRAINING (*for all personnel): Provided by the Hosting Laboratory Facility**)							
Name	LSP**	GHS HAZ COMM**	PPE**	IWDs**	BBP** Awareness	Carcinogen Safety	Eye & Face Protection

Note: For additional personnel, insert rows or attach a sheet providing the above information.
*The Hosting Laboratory must provide training to all personnel. **Copies of all personnel training must be attached here and forwarded to:** hr@newmexicoconsortium.org
**LSP: Laboratory Safety Program; GHS HAZ COMM: Globally Harmonized System of Classification and Labeling of Chemicals; PPE: Personal Protective Equipment; IWDs: Integrated Work Documents; BBP: Bloodborne Pathogens

SECTION VII: SAFETY PLANS

Established Exposure Response Procedures	
Accidental Exposure*: Indicate that you agree with the text below by **marking the appropriate box** ☐ OR **deleting the text** below and describing your alternative exposure response.*	
Material (rDNA, Bacteria, Virus etc.)	Response Procedure
	Available evidence suggests that materials used in this research ☐ are / ☐ are not (mark the appropriate box with an "X") implicated in occupational illness due to exposure in a research environment. Our response to an occupational exposure to DNA, rDNA, or *E. coli* K-12 derivatives, pathogens, or potentially infectious agents via splash to exposed skin is to wash the affected area with mild soap and warm water. For mucosal (i.e., eyes, nose, or mouth) exposures our response is to flush with warm water generally for 15 minutes for the eyes or nose, or 5 minutes for the mouth, or as determined by the specific contaminant. All exposure events, including sharps exposures and other occupational injuries are reported to HR at hr@newmexicoconsortium.org or by notifying the CEO at buelow@newmexicoconsortium.org
The Principal Investigator will submit an Incident Report Form from the New Mexico Consortium's Forms webpage, detailing occupational exposures and spills of research materials to NMC Human Resources, hr@newmexicoconsortium.org.	

† Per NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, CDC's Biosafety in Microbiological and Biomedical Laboratories, 6th Edition and the NMC's Research Compliance/Laboratory Research webpage

SECTION VIII: Principal Investigator Statement

The PI must mark each box to indicate that:

☐ I agree to comply with all requirements pertaining to the use, handling, storage and disposal of biohazardous agents and recombinant DNA molecules. I also agree to follow the current *NIH Guidelines for Research Involving Recombinant DNA Molecules*, referred to as the NIH Guidelines, and the CDC recommendations from the CDC/NIH handbook, *Biosafety in Microbiological and Biomedical Laboratories*, referred to as the BMBL 6th Edition

☐ I have read, understand, and will follow applicable NMC's IBC Policies and Procedures and the Hosting Facility's Policies and Procedures. I have ensured that all laboratory workers under my supervision have received or will receive biosafety training and that they are familiar with the hazards and symptoms of exposure relevant to the biological materials used within the lab. These individuals have been briefed on emergency procedures, good laboratory work practices, and the safe operation of laboratory equipment prior to the initiation of the experimental work.

☐ I will select and provide personal protective equipment to all lab workers as necessary for the procedures required in the experiment. If I must use a biosafety cabinet (BSC) while working with biological materials, then I will ensure that the BSC is certified annually and maintained properly. Any vaccinations or medical surveillance requirements as determined by the IBC will also be met prior to the initiation of experimental work.

☐ I will immediately notify the NMC by submitting an Incident Report to hr@newmexicoconsortium.org or by notifying the CEO, buelow@newmexicoconsortium.org in the event of either:

1. Any accident that results in inoculation, ingestion, and/or inhalation of biohazardous agents or recombinant DNA or any incident causing serious exposure of personnel or danger of environmental contamination.
2. Any problem pertaining to the operation of biological and physical containment safety equipment, i.e., a biosafety cabinet, or facility failure, i.e., a power outage, which may compromise building engineering controls and subsequently, the safety of the laboratory workers.

☐ If this work involves other Institutional or Federal Regulatory Review/Approvals/Permits, or involves the use of any CDC or USDA Select Agents and Toxins List, or materials that are regulated under OSHA's Bloodborne Pathogens Standard, I will not proceed with the activity until I have submitted all relevant documentation, and have received an official notice of approval from the IBC.

☐ I acknowledge that the IBC approval granted by this application is **not transferable** to any other NMC PI researcher. If the PI on a project changes, a new application form must be submitted to the IBC. I also acknowledge that I will not transfer or receive biological materials from vendors, other NMC staff or collaborators, until IBC approval is granted. The IBC will verify that the receiving researcher has appropriate IBC approval to use the agents.

☐ I further understand that the duration of IBC approval of an application is for **three years** and that I must submit an IBC Activity Modification Form to the IBC if and when the project changes significantly in terms of experimental activities, facilities, or for any personnel change during the approval period. It is my responsibility to submit an activity modification report in a timely manner to avoid research delays.

† Per NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, CDC's Biosafety in Microbiological and Biomedical Laboratories, 6th Edition and the NMC's Research Compliance/Laboratory Research webpage

To the best of my knowledge, the information contained in this Application is accurate and complete.

_____ _____

Principal Investigator (signature) **Date**

If submitting this application as an electronic copy, type name and date above, then mark box: ☐

Note: If this is a revision of a submitted Application, please Date Here: _____

SECTION IX: IBC APPROVAL

*The content of this signed form represents the final application reviewed and approved by the NMC IBC for a period of **three** years. To continue this work, an updated application must be submitted prior to expiration of this application's approval.*

_____ _____

IBC Chair (printed name & signature) **Date**

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