University of Central Missouri Institutional Biosafety Committee
Protocol Registration Form

Principal Investigator:_____

Department:_____ **Email:**_____

Office Location:_____ **Phone:**_____

Lab Location:_____ **Emergency Phone:**_____

Co-Investigator:_____

Department:_____ **Email:**_____

Office Location:_____ **Phone:**_____

Lab Location:_____ **Emergency Phone:**_____

Project Title:_____

Application Status: **New** ☐ **Renewal** ☐ **Protocol change** ☐

Previous IBC Registration Number:_____

Funded? Yes ☐ No ☐ Source:_____ Grant#:_____

Start Date:_____ End Date:_____

Title:_____

Required Sections for ALL applications	**Completed?**
Sections 1-3: Indicating additional requirements and associated guidelines	☐
Section 4: Describing the host cell(s), vector(s), and insert(s)	☐
Section 5: describing project, experimental design, risk assessment, and disposal	☐
Any section associated with provided answers in sections 1-3	☐
Section 10: Project Roster	☐
Section 12: Principal Investigator Responsibilities and Certification	☐

Section 1: Research requiring accompanying protocol registrations. Please provide these documents with registration.

Section(s)	Research Component(s)	Yes	No
6, 11	Use of microbial agents pathogenic to humans, animals, or plants? (Pathogen registration form(s):_____"attached" or the registration #)	☐	☐
6	Use of animal derived materials: non-primate and non-human primate blood, tissue, primary cell culture? (IACUC protocol number(s):_____)	☐	☐
6	Use of human derived materials: blood, tissue, cell lines, etc.? (IRB protocol number(s):_____)	☐	☐
6, 7, 11	Use of transgenic/knockout animals or the introduction of any of the following into animals: r/sNA, human-derived materials, animal-derived materials, infectious agents, toxins or select agents? (IACUC protocol number(s):_____)	☐	☐
9	Involves an Investigational New Drug (IND)? (FDA approval #:_____)	☐	☐

Section 2: Experiments covered by DURC (USG), CDC, and *NIH Guidelines*

DURC Guidelines: Biosafety and Biosecurity Policy - Office of Science Policy (nih.gov)

Check all that apply		Section(s)
☐	Can the research reasonably produce one or more of the seven experimental categories and/or effects outlined by DURC?	6.2.1, 6.2.2

CDC Guidelines: BMBL 6th Edition

Check all that apply		Section(s)
☐	Use of biological toxins or federally regulated select agents/toxins. [Section 6]	VIII, Appendices F, I
☐	Storage and/or use of drugs, chemicals, and/or biologics that may be considered hazardous.	Appendix A

NIH Guidelines: NIH Guidelines

Check all that apply		Section(s)
☐	Involve the transfer of drug resistance trait to disease-causing microorganisms not known to acquire the trait naturally that could compromise the ability to control disease (in humans, veterinary medicine, and/or agriculture) or alter the host range, transmission, or virulence. **Engineering resistance against the same drug used to treat the disease requires NIH approval.**	III-A, III-A-1-a
☐	Involve the use/cloning of genes for biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of less than 100 ng/kg body weight (e.g., botulinum toxins, etc.). **Requires NIH approval.**	III-B-1, Appendix F
☐	Administration of r/sNA molecules into humans (human gene therapy studies, gene transfer studies). **Requires NIH/RAC, FDA, and IRB approval. Refer to Appendix M and contact the IBC.**	III-C-1, Appendix M
☐	Introduction of r/sNA into Risk Group 2 agents or Restricted Agents.	III-D-1-a
☐	Cloning of genes from Risk Group 2 or Risk Group 3 agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.	III-D-2-a
☐	Use of infectious or defective DNA or RNA viruses (defective eukaryotic viruses contain less than 2/3 of the genome) in the presence of helper virus in tissue culture systems. (Influenza viruses fall under III-D-7)	III-D-3
☐	Experiments involving transgenic or knockout animals.	III-D-4
☐	Experiments involving whole plants containing r/sNA molecules (to create, propagate, use for other experimental purposes, use with microorganisms or insects containing r/sNA molecules)	III-D-5
☐	Experiments culturing organisms containing r/sNA molecules at volumes exceeding 10 liters in a single growth vessel.	III-D-6
☐	Cloning and/or vector construction in non-pathogenic prokaryotes and non-pathogenic lower eukaryotes.	III-E, III-F
☐	Generation or use of cDNA/genomic libraries.	III-E, III-F

Section 3: Experiments that are exempt per NIH Guidelines but still require IBC approval.

NIH Guidelines: NIH Guidelines

Check all that apply		Section(s)
☐	No organisms or viruses	III-F-1
☐	Using only the exact r/sNA segment from a single source.	III-F-2
☐	DNA from a prokaryotic host when propagated only in that host or when transferred to another host by well-established physiological means.	III-F-3
☐	DNA from a eukaryotic host when propagated only in that host.	III-F-4
☐	DNA segments from different species that exchange DNA by known physiological processes.	III-F-5
☐	Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any r/sDNA.	III-F-7
☐	Experiments that do not present a significant risk to health or the environment. Refer to Appendix C, Exemptions under III-F-8 for exempt experiments.	III-F-6, III-F-8

Section 4: Description and sources of host cell(s), vectors, and inserts.

Host cell(s)

List the host species and/or cell line lineage to be used for r/sNA expression and/or propagation (e.g. E. coli, Human Immortal Cervical Cancer).

List strain(s) and/or cell line name (e.g. DH5α, HeLa).

Are host cell(s) pathogenic or potentially hazardous to humans, animals, or plants? Yes ☐ No ☐

If yes, list the antibiotics used to treat disease.

Proposed containment for experiments: **BSL-1** ☐ **BSL-2** ☐

Sources for host cell(s) (external academic institution, commercial, environmental, etc.):

Vector(s)

List and describe the vector(s) used (e.g. pKD4, pCVD442, pGEM)

Do any vectors contain inserted nucleic acid sequences that retain more than 2/3 of genome of any eukaryotic virus?
Yes ☐ No ☐

If yes, list the name of the virus:			
Is viral replication competent (wild-type)?	Yes ☐	No ☐	N/A ☐
Is vector replication defective?	Yes ☐	No ☐	N/A ☐
Is a helper virus or packaging system involved?	Yes ☐	No ☐	N/A ☐
List the antibiotic resistant genes contained in the vector if applicable:			
If host cell(s) are pathogenic, does the vector contain genes that are resistant to the antibiotics used to treat disease?	Yes ☐	No ☐	
If yes, list all antibiotics that can be used to treat infection/disease caused by the new or used recombinant strain:			
Sources for vector(s) (external academic institution, commercial, generated at UCM):			

Insert(s)

List the gene/biological source (genus, species, strain), gene function, protein expressed, and any toxic or oncogenic potential if applicable:		
Will the r/sNA molecule contain more than 2/3 of the genome of any eukaryotic virus?	Yes ☐	No ☐
If transcription will be controlled, describe the promotor (native, alternative, inducible).		
Include a map of the construct and/or sequence.		

Section 5: Project summary, experimental design, risk assessment, and disposal

Project Summary: Provide a brief overview of the proposed work including the purpose and value of the research.

Experimental Design: Provide a detailed description of all materials and methodologies/protocols in adequate detail but in lay terms. Highlight r/sNA methodology, protocols, and methods for using transgenic animals.

~~Risk Assessment:~~ All risks specific to the research need to be identified and discussed. Any work associated with hazardous biological agents, sharps usage, and aerosol generating procedures needs to be included. Identify and describe all pathogenic microorganisms and/or viral vectors and the associated mitigation measures and biosafety procedures and containment. **For each microorganism, please use the template provided to complete an individualized risk assessment.**

Biological Waste Disposal: Methods for disposing of both liquid and solid biological and r/sNA waste should be identified and described. Include the planned disinfectants for use within the lab.

Laboratory and biological safety acknowledgement.	Yes	No
Post-exposure procedures are understood and included in the lab-specific manual?	☐	☐
Emergency response plans are included in the lab-specific manual?	☐	☐
The lab is equipped with all necessary and appropriate disinfectants and PPE?	☐	☐

Section 6: Potentially hazardous materials and biological agents involved in research with or without the use of r/sNA molecules.

Select Agents and Toxins	Yes	No
Is the agent on the CDC/USDA Select Agent and Toxins list? https://www.selectagents.gov/sat/list.htm	☐	☐
If yes, list the name of the agent or toxin and quantity used/stored:		
Is the agent on the CDC/USDA Select Agent and Toxins Exemptions list? https://www.selectagents.gov/sat/exclusions/index.htm	☐	☐
If yes, list the name of the agent or toxin and quantity used/stored:		
Does the experiment use a select toxin that is not regulated under the Federal Select Agent Program due to permissible toxin amounts? https://www.selectagents.gov/sat/permissible.htm	☐	☐
If yes, list the name of the agent or toxin and quantity used/stored:		
Does the experiment use a biological toxin that is not regulated under the Federal Select Agent Program?	☐	☐
If yes, list the name of the agent or toxin and quantity used/stored:		

Infectious Agents		
List any pathogenic microorganisms that will be used during the research:		
Do any of the microorganisms produce toxins?	☐	☐
If yes, list the toxin(s) and indicate if it will be used within the research:		

	Yes	No
Will any microorganisms be cultured at a volume >10 liters?	☐	☐
Will any pathogenic microorganisms be introduced into animals?	☐	☐
If yes, list the animal species and housing location:		

Human-Derived Materials

List all human-derived materials to be used and where the materials will be obtained from (e.g. blood, serum, bodily fluids, cell culture, tissue, etc.):

Are the materials known to contain an infectious agent?	☐	☐
Will any animal cells/tissues, modified or unmodified, be introduced into animals?	☐	☐
If yes, list the animal species and housing location:		

Animal-Derived Materials

List all animal-derived materials to be used, the species of animals, and where the materials will be obtained from (e.g. blood, serum, primary cell culture, tissue, etc.):

Are the materials known to contain an infectious agent?	☐	☐
Will any animal cells/tissues, modified or unmodified, be introduced into animals?	☐	☐
If yes, list the animal species and housing location:		

Potentially hazardous chemicals, biologics, and/or drugs

Will experiments involve the use of potentially hazardous chemicals, biologics, and/or drugs?	☐	☐
If yes, list he name and quantity of substance(s) used/stored. Indicate the location of storage and containment.		

Will potentially hazardous chemicals, biologics, and/or drugs be introduced into animals?	☐	☐
If yes, indicate the animal species and house location.		

Section 7: Use of r/sNA molecules in animals and/or experiments involving transgenic animals.

	Yes	No
Does the research involve the transfer of r/sNA or biological agents containing r/sNA into animals?	☐	☐
If yes, list the species and the animal housing location:		
Proposed containment level for r/sNA experiments with animals? **ABSL-1** ☐ **ABSL-2** ☐		
Will rDNA be propagated in live animals?	☐	☐
Will live animals be infected with any microorganisms that contain rDNA?	☐	☐
Is vertical transmission of r/sNA to offspring possible?	☐	☐
Is transmission of r/sNA to persons or the environment possible?	☐	☐
Will the study involve transgenic animals?	☐	☐
What is the genotype and phenotype of the transgenic animals:		
If purchasing, what is the source of the transgenic animals?		
If generating, what is the location these animals will be generated?		
Will you breed these animals to maintain a colony?	☐	☐
Will r/sNA molecules be transferred into transgenic animals?	☐	☐

Section 8: Seven classes of potential Dual Use classified by NSABB

Research may be classified "Dual Use" if any of the following are applicable:	**Yes**	**No**
Demonstrates how to render a vaccine ineffective?	☐	☐
Confers resistance to antibiotics or antiviral agents currently used for therapeutics?	☐	☐
Enhances the virulence of a pathogen or transfers virulence to a non-pathogen?	☐	☐
Enhances transmission of the pathogen between hosts or from the vector?	☐	☐
Alters the host range of the pathogen?	☐	☐
Allows for the development of evasion strategies from host/therapeutic defenses?	☐	☐
Alters the biological agent or toxin to be potentially weaponized?	☐	☐

Section 9: Investigational New Drugs

FDA approval #:
Indicate the facility and contact information for manufacturing of the drug, including Good Laboratory Practices, Good Manufacturing processes, and quality assurance:
How will the drugs be tested for sterility?

Section 10: Roster

Project Roster: PI and all personnel working with r/sNA molecules or any biological agents

Required Training Modules (CITI, EHS, Lab specific)
List the date of completion under each module acronym. Full name of modules listed below table.

Name	UCM ID	Position/Title	CITI				EHS		Lab
			BBS	DEC	RCR	ABSL	LCS	RCRA	BIO

CITI Training Modules	
BBS	Biosafety and Biosecurity Series
DEC	DECON Methods
RCR	Responsible Conduct of Research
ABSL	Working with Mice in Research Settings
UCM EHS Training (BB)	
LCS	Laboratory Chemical Safety
RCRA	RCRA Hazardous Waste Training
Lab Specific Training	
BIO	Research Specific Biological Agents

Section 11: Infectious Agents

List infectious agents that will be used in research with or without r/sNA molecules

Organism Type	Species and Strain	Biosafety Level (1-2)	Room(s) the agent will be used	Room(s) the agent will be stored	Culture amount >10 liters in a single container?
					Yes ☐ No ☐
					Yes ☐ No ☐
					Yes ☐ No ☐
					Yes ☐ No ☐
					Yes ☐ No ☐
					Yes ☐ No ☐

Section 12: Principal Investigator Responsibilities and Certification.

- Do not initiate any research requiring prior approval from the IBC before approval has been granted (Sections III-A, Sections III-B, III-C, III-D, III-E).
- Agree to an initial and periodic inspection of the laboratory that will be used to conduct the proposed research to ensure adequate biocontainment and appropriate equipment and facilities.
- Ensure that all SOPs are readily available to laboratory personnel.
- Report any significant problems, violations of *NIH Guidelines*, any significant research-related accidents, and illnesses to the Greenhouse/Animal Facility Director (if applicable), IBC, NIH OSP, and other appropriate authorities within 30 days. Send to NIHGuidelines@od.nih.gov
- Report any new information relating to the research to the IBC, which will report to NIH OSP.
- Be adequately trained in good microbiological techniques.
- Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination.
- If the PI wants certification of a new-host vector system (Appendix I-II), to petition for proposed exemptions to *NIH Guidelines*, or petition for containment regulations, or propose research that require prior authorization from NIH OSP, this information should be submitted to NIH OSP.
- Complete risk assessments on all biological agents to be used.
- When the PI submits proposed research to IBC, include the following information.
    - A research proposal with appropriate microbiological practices and laboratory techniques to be used for the research.
    - An initial determination of required levels of physical and biological containment that follows *NIH Guidelines*.
    - A signed and dated registration document that includes all appropriate and relevant information as outlined in the document. This document is required for BSL-1 and BSL-2 level agents and containment levels.
    - Experiments that are exempt from *NIH Guidelines* and registration with the IBC are in Section III-F. The PI must provide their reasoning for exemption and refer to the appropriate subsection to support their reasoning.
    - Risk assessments.
- Prior to initiating research, ensure all laboratory staff have access to protocols that describe the potential biohazards, the necessary precautions to be taken, and are appropriately trained in practices and techniques required for the research and procedures for accidents.
- During research the PI is responsible for the following:
    - Supervision of safety practices, techniques, and safety performance of laboratory personnel.
    - Correct any actions or conditions that have the potential to release r/sNA materials.
    - Monitor and ensure the integrity of BSCs and biological containment (e.g. purity and genotypic and phenotypic characteristics).
    - Remain in communication with the IBC.
    - If there are concerns or problems relating to operation and implementation of containment, investigate and report these to the Greenhouse/Animal Facility Director, IBC, NIH OSP, and other appropriate authorities. Reports sent to NIHGuidelines@od.nih.gov.

Principal Investigator Certification:

I certify that the information provided is complete and correct to the best of my knowledge. I am familiar with and agree to abide by the provisions of current guidelines outlined in *NIH Guidelines*, the Biosafety in Microbiological and Biomedical Laboratories, 6th Edition, and any other granting or federal agency that has oversight on components of the proposed research, as well as requirements established by UCM EHS and IBC. I understand it is my responsibility to ensure laboratory personnel are appropriately trained in all biosafety and risk assessments associated with this research.

_____ _____

Principal Investigator (Signature) **Date**