NAZARBAYEV UNIVERSITY

Biological and Chemical Safety Committee

Instructions for Completing the Biosafety Application and Authorization Review Process

Bio and Chemical Safety Committee (BCSC), exercises oversight for all Nazarbayev University research, classroom, and field activities involving biological agents or materials[1], to ensure that employees, students, the public and the environment are protected from biohazards associated with NU operations.

Complete this form to receive BCSC review and authorization for **3 years** for research involving: any biological agents, infected animals or tissues (including field work), recombinant or synthetic nucleic acid (rsNA) molecules, Select Agents & Toxins, and work with human blood, bodily fluids, tissues or cells in culture. Most of the biological research described in this application requires BCSC authorization **prior** to initiation.

Note that "any biological agents" even includes viral vectors that contain less than 2/3rds of the wild-type viral genome or that do not infect vertebrate cells. Examples of such vectors include:

- most defective retrovirus vectors (usually MLV-based)
- adeno-associated virus vectors (AAV vectors)
- baculovirus vectors

Registrations for biological research must be reviewed and approved by the BCSC every three (3) years or immediately if there are significant changes**. The Application must be completed electronically and submitted in hard copy after the approval will be received.** Handwritten, incomplete or illegible forms will be returned. The BCSC meets and reviews applications monthly.

If you have any questions, please contact: bcscsubmission@nu.edu.kz. Please visit the web page https://nu.edu.kz/research/office-provost/bio-chemical-safety to view and download all of the available support documents for the Campus Biological Safety Program.

Please contact bcscsubmission@nu.edu.kz in case you need to use BSL 3 or BSL 4.

Your Biosafety Application will only be reviewed if a completed electronic copy is sent to bcscsubmission@nu.edu.kz.

For any changes to your research that may occur during the 3 year approval period, you will need to submit the "Biosafety Update Form": bcscsubmission@nu.edu.kz.

Minor changes include personnel changes, room changes, termination of research, etc.

[1] Biological Agents and Materials are defined as: human blood, bodily fluids, tissues, organs, pathological specimens; human and animal cell culture materials, tumor cell lines or hybridomas; infected animals or tissues (including field work); bacteria, viruses (to include oncogenic viruses), parasites, other microorganisms; Select agents and biological toxins; all recombinant or synthetic DNA or RNA materials.

Biological and Chemical Safety Committee

Biosafety Application #_____ (Office Use Only)
Renewal for Application(s) #_____ (Office Use Only)
Title of Research Project_____
ABL-2

(Office Use Only)

☐ BIO ☐ BSC
☐ BBP ☐ SHIP
☐ rsNA ☐ ABL-1 ☐

Section I - Administrative Information

Principal Investigator_____ Office Rm. #_____

Email Address:_____ Phone:_____ Fax:_____

Department:_____ Building:_____ Lab Rm(s). # _____

Primary Lab Contact for biosafety lab inspections (such as a lab manager): _____

Section II – Type of Experiments *(Check all applicable boxes and complete attachments as directed).*

A. 1) Use of recombinant or synthetic nucleic acid molecules (e.g., Use of GFP inserts): ☐ Yes ☐ No

2) Use of genetically modified animals: ☐ Yes ☐ No
3) Development and production of genetically modified animals: ☐ Yes ☐ No
If yes to 1)complete Attachment I-A and Worksheet 1 2. If no, go to the next question.
Proposed Biosafety Level of Experiment: ☐ BSL1 ☐ BSL2

B. Use of biohazardous agentsoxins (chemical hazards/toxins should not be included here): ☐ Yes ☐ No **If yes, complete Attachment I-B.** If no, go to the next question.
Proposed Biosafety Level of Experiment: ☐ BSL1 ☐ BSL2

C. Use of CDC/USDA Select Agents/Toxins (see appendix 1): ☐ Yes ☐ No
If yes, complete Attachment I-B. If no, go to the next question.
Max. amount of toxin in your possession at any given time: _____

D. Use of laboratory animal subjects with:
1. chemotherapeutic drugs? ☐ Yes ☐ No
2. biological agents/cells/materials*? ☐ Yes ☐ No
***If yes to D.2, enter IACUC # and complete Worksheet 2.** If no, go to the next question.
Proposed Animal Biosafety Level of Experiment: ☐ ABSL1 ☐ ABSL2

Proposed location of experiments:
Building: _____ Room #: _____
Other location (include proposed building and room #): _____

E. Gene Therapy/Vaccine Experiment/Use of Human Research Participant: ☐ Yes ☐ No
If yes, complete Attachment I-A and provide IREC Number and date of approval .

F. Use of human blood, infected or potentially infected human cell lines, tissue or bodily fluids, primary cells: ☐ Yes ☐ No
If yes, complete Attachment I-B. Provide IRB Number approval if obtaining specimens from research subjects _____

G. Use of animal cell lines, infected or potentially infected tissue or bodily fluids: ☐ Yes ☐ No
If yes, complete Attachment I-B.

H. Use of transgenic and/or pathogenic plants: ☐ Yes ☐ No
If yes, please contact the biosafety group at bcscsubmission@nu.edu.kz **for a supplemental form**

I. Use of radioactive materials: ☐ Yes ☐ No If yes, list approved isotopes: _____.
J. Will this project include export or import of hazardous biological materials outside KZ? ☐ Yes ☐ No If you answered "yes" to this question, please contact bcscsubmission@nu.edu.kz
K. Ship biological materials – may include infectious agents, rsNA, transgenic animals or plants, human blood, blood products, tissue or fluid, animal carcass, tissue or fluid: ☐ Yes ☐ No *****If yes, please highlight the names of lab personnel in the next section who will be shipping*****

Section III - Personnel

NAME	POSITION (Faculty, PostDoc, Graduate or Undergraduate Student)	E-MAIL	Have they completed all required trainings?
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

Section IV - Location of Research Experiment

Approval of the proposed experiment is given only for the locations listed below.

Room used for: (e.g.: general lab, Tissue culture, microscopy, etc)	BUILDING	ROOM	BIOSAFETY LEVEL (BSL-1, BSL-2)	SHARED ROOM
				☐ Yes
				☐ Yes
				☐ Yes

				☐ Yes
				☐ Yes

BIOLOGICAL MATERIALS STORAGE

BUILDING	ROOM	-70 FREEZER	REFRIGERATOR	INCUBATOR	OTHER	
		☐ Yes	☐ Yes	☐ Yes		
		☐ Yes	☐ Yes	☐ Yes		
		☐ Yes	☐ Yes	☐ Yes		
		☐ Yes	☐ Yes	☐ Yes		

Section V – Physical Containment Equipment - Biosafety Cabinets

BUILDING	ROOM			BSC # (listed on orange sticker)	DATE OF CERTIFICATION

Section VI – Safety Evaluation (Include any safety evaluation information in your scope of work narrative on the next page).

I. Experimental Risks

A. **Use of Sharps (parenteral inoculation hazard)** ☐ Yes ☐ No

If yes, check all used in experimental procedures

☐ needles & syringes ☐ razors ☐ scalpels ☐ blades ☐ Pasteur pipettes ☐ drills ☐ glass
☐ microtome probes ☐ other: _____

Sharps Mitigation- check all used

☐ sharps container ☐ engineered sharps (e.g. self sheathing needle) ☐ broken glass container
☐ other _____

B. **Aerosol Generating Procedures (Inhalation Hazard)** ☐ Yes ☐ No

If yes, check all performed experimental procedures

☐ centrifugation ☐ mixing ☐ blending ☐ grinding ☐ sonicating ☐ pipetting
☐ flow cytometry analysis /sorting ☐ other: _____

Aerosol Engineering Controls-check all applicable used to minimize the hazards

☐ Class II Biosafety Cabinet ☐ Fume Hood ☐ Sealed Vial ☐ Sealed rotor
☐ Centrifuge Cone ☐ HEPA Filtered Cage ☐ Local Exhaust-Snorkel ☐ other _____

C. Disinfectants used to clean the work area.

☐ chlorine (e.g.,10% bleach, 1-5-1 preparation of clydox) ☐ alcohols (e.g)70% ethanol, 70% isopropanol

☐ iodophors (e.g., 0.47% wescodyne) ☐ phenolics (e.g.,amphyl) ☐ quaternary ammonia compounds
☐ other _____

II. Mitigation of Other Risks

A. In case of using chemically hazardous materials please use Chemical Safety Application Form

B. Biological Waste Management- Check here the used and describe the disposal of biological waste in the Scope of Work narrative

☐ Sharps Container ☐ Red Bag ☐ Broken Glass Box ☐ other _____
☐ Autoclave Location: Building _____, Room _____and/or EH&S autoclave # _____

C. **Personal Protective Equipment (PPE):**

Check all used and include use of PPE in the narrative

☐ **safety eyewear:** ☐ safety glasses ☐ goggles ☐ faceshield ☐ surgical mask
☐ **respirator:** ☐ N95 ☐ PAPR ☐ other _____
**If wearing an N95 respirator for animal work, please schedule a fit-test appointment with Occupational Health and Safety
☐ **gloves:** ☐ latex ☐ nitrile ☐ other _____
☐ **lab coat:** ☐ reusable, laundered ☐ tyvek suit ☐ disposable
☐ **other: types of PPE used:** ☐ shoe covers ☐ head cover/bonnet ☐ ear plugs

D. Check safety equipment items available in the laboratory:

☐ deluge shower ☐ eyewash ☐ handwashing sink ☐ first aid kit
☐ fire extinguisher ☐ spill kit ☐ other _____

Section VII - Scope of Work Narrative:

This narrative must include two major components:

1) **The overall goal/aim of your experiment**
-this should be a descriptive narrative of your research in lay terms, including methods and equipment used in experimental procedures

2) **Safety/containment procedures**
-discuss biological waste disposal procedures
-include decontamination/disinfection processes
-address the potential sources of risk to personnel (aerosol generation, needle sticks, etc.) and/or the environment, and how these risks will be managed

Also, please indicate if over 10 liters of culture shall be generated, or if agents shall be concentrated.

Narrative:

BCSC Biosafety Application - Biohazard Control plan
Please complete this part of the Application using Word ("Unprotect Document")

The "Biohazard Control Plan" must be completed for research that involves Risk Group 2 agents; human blood, blood products, reagents derived from blood; human cell lines which are known or reasonably likely to contain or be infected with HIV, Hepatitis B virus, Hepatitis C virus, or that support HIV replication (e.g. HeLa, HEK 293, etc.); or field work that involves potential exposure to infectious agents like plague, hanta virus, rabies, etc.

1. Exposure determination:

Note: For research involving human blood, body fluids, and reagents derived from blood or body fluids, investigators are required to treat all materials as if known to be infectious for HIV, hepatitis B or hepatitis C virus and/or other blood-borne pathogens.

Describe the general types of experimental procedures that will be performed (e.g. cell culture, protein purification, drawing blood, etc).

2. Control methods:

a. List facility/facilities in which work is to be performed.

b. List who will have access to the facility and describe how access will be controlled (If relevant, describe signs, doors, type of lock, separation from corridors and other work areas, etc.)

c. How and when will facility be cleaned and decontaminated? Will Facilities Management custodial personnel have routine access, and if so, how will they be protected from hazardous materials?

d. List safety devices that will be used. These may include some or all of the following: biosafety cabinets, hand washing facilities, mechanical pipetting devices, puncture resistant sharps containers, splash guards, self-sheathing needles.

3. Vaccination: Will it be necessary to vaccinate workers against infectious agents? If so, describe plans for vaccinations.

4. Accidents: What procedures will be followed in case of an accident? Be sure to address how spills/exposures will be handled specifically in your lab (

5. Waste disposal: Describe provisions for disposal of hazardous materials. If all or part of hazardous material is to be decontaminated on site, specify procedures to be used.

Important to reliably be informed, what is available at NU

6. Labeling: Specify tags, labels, or bags that will be used to identify hazardous materials. If hazardous material is to be decontaminated on site, specify how material will be labeled to indicate that it is no longer infectious.

7. Training: Describe how workers will be trained to handle all hazardous materials (biological, chemical and radioactive). For training in biological lab safety, blood-borne pathogens, biological safety cabinets, animal biosafety, and shipping biological materials, please visit our website (https://nu.edu.kz/research/office-provost/bio-chemical-safety) or contact bcscsubmission@nu.edu.kz

NAZARBAYEV UNIVERSITY

BIO AND CHEMICAL SAFETY COMMITTEE (BCSC) APPLICATION

PRINCIPAL INVESTIGATOR'S STATEMENT OF AGREEMENT

FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES AND BIOLOGICAL AGENTS

I certify that the information contained in the BCSC application is accurate to best of my knowledge.

I agree to comply with all University and BCSC requirements with regard to the use, handling, storage and disposal of biological agents and recombinant or synthetic nucleic acid molecules.

I agree to follow the current *Nazarbayev University Guidelines for Research* and the recommendations from the CDC/NIH handbook, *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition.*

I ensure that all research personnel listed on this application have or will complete all biosafety training modules and they are familiar with the hazards and symptoms of exposure relevant to the biological materials used within the laboratory. All laboratory personnel have been briefed on emergency procedures, good laboratory work practices, and the safe operation of laboratory equipment prior to the initiation of experimental work. Prior to the initiation of experimental work all vaccinations or medical surveillance requirements recommended by the BCSC and EH&S will be met.

Personal protective equipment, necessary for experimental procedures, will be provided to all laboratory workers. All biosafety cabinets shall be maintained properly and certified ***annually*.**

I will notify the Bio and Chemical Safety Committee Secretary (bcscsubmission@nu.edu.kz) in the event of the following:

1. Accident resulting in inoculation, ingestion, and inhalation of biological agents or recombinant or synthetic nucleic acid molecules or any incident causing serious exposure of personnel or danger of environmental contamination within 24 hours.

2. Malfunction of biological and physical containment safety equipment (biosafety cabinet), or facility failure, which may compromise building engineering controls and the safety of the workers in the lab.

3. All experimental work has been completed.

4. Near misses, mishaps and situations that did not result in accidents, but could potentially have.

I will not proceed with the experiment until I have received an official notice of approval from the BCSC unless otherwise specified. I acknowledge that BCSC approval granted by this application is non-transferable to any other CU Boulder researcher.

Principal Investigator signature: _____ Date: _____

(We MUST have a signature on file to be able to review this application. You may sign this application electronically and send it to bcscsubmission@nu.edu.kz)

Attachment I - Section A: Recombinant or Synthetic Nucleic Acid Molecules (rsNA)

Nazarbayev University requires that the BCSC review the following information as a pre-requisite of approval of any recombinant or synthetic nucleic acid molecule experiment. Review the following example of a C. elegans experiment and include the appropriate information of your experiment in your application form:

EXAMPLE:
Agent Characteristics: *non pathogenic vectors are used*
Routes of Exposure: *non pathogenic to humans*
Host: *Caenorhabditis elegans, E-coli*
Vector: *pUC19*
Nature of inserted sequences: marker, gfp cDNA, antibiotic resistance, ampicillin and kanamycin
Source of inserted sequences: *bacterial*
Types of manipulation: *standard tissue culture, growth of worms occur using E-coli agar gel plates*
Attempt to express foreign gene: *yes, AmpR, KanR, bacterial resistance, gfp*
Protein produced: *Green Florescent Protein*
Containment: *BSL1*
Section of Guidelines: *(Section III-D-4-a): Experiments Involving Whole Animals*

.....

Agent Characteristics:
Routes of Exposure:
Host:
Vector:
Nature of inserted sequences:
Source of inserted sequences:
Types of manipulation:
Attempt to express foreign gene:
Protein produced:
Containment:
Section(s) of Guidelines:

I-A.1. Description of Gene(s), include but not limited to: genes over-expressed, expressed in transgenic animals and/or silenced by RNA interference (and antibiotic-resistance genes).

☐ **yes** ☐ **no**

Gene Sources (organism-genus, species, strain, e.g., E-coli, K12)	**Gene Name and Protein Produced** (acronym & full name, e.g., GFP, green florescent protein)	**Gene category ***	**Expression of construct in Host**	
			In vitro cultured Cells - define	**In vivo Animals Define species**

*Examples of gene category: structural, enzymatic proteins, metabolic enzymes, cell growth/housekeeping, cell cycle/cell division, DNA replication, membrane proteins, tracking genes (GFP, luciferase), toxins, regulatory genes, oncogenes

I-A.2. Viral Vectors used - check all that apply (PROVIDE MAPS) ☐ yes ☐ no

☐ **Other, please list:**
☐ **Adenovirus, list genes deleted if applicable:**
☐ **Adeno-Associated virus (AAV); helper virus used ☐ Yes ☐ No**
☐ **Epstein-Barr Virus (EBV)**
☐ **Herpesvirus: ☐ HSV-1 ☐ HSV-2**
☐ **Retrovirus:** ☐ **ecotropic ☐ amphotrophic**
☐ **pseudotype virus, (e.g, VSV Glycoprotein Envelope expressed):**
☐ **MMLV**
☐ **Lentivirus:** ☐ **HIV ☐ SIV ☐ Other:**
☐ **helper virus used**
☐ **genes separated on separate plasmids**
☐ **pseudotype use of VSV-G**
☐ **Poxvirus -Vaccinia Virus**
☐ **Sindbis (alpha) virus ☐ helper virus used**
☐ **Baculovirus**

I-A.3. Vector Description

Vector backbone (organism-genus, species, strain)	**Vector name** (e.g. PBr322)	**Gene Transfer Method** (e.g. gene gun, transfection)	**Host to be used** (e.g. E. coli K-12)	**Expression**	
				Stable	**Transient**
				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐
				☐	☐

Attach a construct map and clearly indicate what viral sequences are being deleted from the wild-type vector, and the description and location of inserted viral or cellular sequences.

I-A.4. Packaging Cell Line(s) for Production of Virus Particles (with details of replicating genes) Fill out only, if your answer to question I-A2 is yes

Name of Cell Line(s) and helper plasmids (co-transfection) (e.g., HEK 293)	**Source(s)** (e.g. viral, human)	**Source of envelope glycoprotein** If retro-or lentivirus (e.g. vsv-g pseudotype in retroviral system)	**Characterization with respect to host range** (e.g. retro - ecotropic, amphotrophic or lentivirus)	**Host Cells**

Attachment I - Section B: Biohazardous Agents & Toxins

*A Biohazard Control Plan must be completed for all Risk Group 2 Agents and includes Human or Human Derived Materials (including cell lines)

1. Bacteria, including Rickettsia: ☐ yes ☐ no

Species and strain	Pathogen			Select Agent		Risk Group*
	Human	Animal	Plant	CDC	USDA	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	

*** For Risk Group classification, go to: http://www.absa.org/riskgroups/index.html**

Bacterial Cultures over 10 liters: ☐ Yes ☐ No

2. Virus: ☐ yes ☐ no

Name	Pathogen			Select Agent		Risk Group*
	Human	Animal	Plant	CDC	USDA	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	

***For Risk Group classification, go to: http://www.absa.org/riskgroups/index.html**

3. Fungi: ☐ yes ☐ no

Genus: _____ Species: _____ Risk Group*:_____
Genus: _____ Species: _____ Risk Group*:_____

4. Parasites: ☐ yes ☐ no

Genus:_____ Species:_____ Risk Group*:_____
Genus: _____ Species: _____ Risk Group*:_____

5. Toxins: ☐ yes ☐ no

Toxin Common Name	Source	Pathogen			LD_{50} or LDL	Target organ
		Human	Animal	Plant		
		☐	☐	☐		
		☐	☐	☐		
		☐	☐	☐		

6. Use of human derived biological material (note: all human cell lines are considered Risk Group 2) ☐ yes ☐ no

Please check all that apply:

☐ Human tissue, including scrapings, secretions, body fluids, bones or teeth (add details)
☐ An organ culture or primary cell line derived directly from human tissue
☐ An established cell line derived from human tissue
☐ Human blood or blood products like serum, plasma or cell preparation

Name of biohazardous agent, cell line used	Risk Group*		
	1	2	
	☐	☐	

	☐	☐	
	☐	☐	
	☐	☐	

7. Use of animal cell lines, infected or potentially infected animal tissue or bodily fluids (note: all non-human primate cell lines are considered Risk Group 2) (Add details)
☐ **yes** ☐ **no**

Please check all that apply:
☐ Animal tissue, including scrapings, secretions, body fluids, bones or teeth
☐ An organ culture or primary cell line derived directly from animal tissue
☐ An established cell line derived from animal tissue
☐ Animal blood or blood products like serum, plasma or cell preparation

Name of biohazardous agent, cell line used	Risk Group*		
	1	2	3
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	

Risk Group*:

RG-1 Agent that is not associated with disease in healthy adult humans.

RG-2 Agent that is associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

RG-3 Agent that is associated with serious or lethal human disease for which preventative or therapeutic interventions may be available (high individual risk but low community risk).

RG-4 Agent that is likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available (high individual risk and high community risk).

Risk Group 3 and 4 agents are not permitted at NU.

Worksheet 1
RECOMBINANT OR SYNTHETIC NUCLEIC ACID (rsNA) MOLECULE EXPERIMENTS QUESTIONNAIRE
CLASSIFICATION OF EXPERIMENTS THAT REQUIRE REVIEW AND APPROVAL

Source: ***NIH Recombinant or Synthetic Nucleic Acid Molecules Guidelines,*** dated March 2013

This section **MUST** be completed if you are working with ANY recombinant or synthetic nucleic acid molecules. Please check the appropriate **Yes** box if the NIH category accurately describes your experiment. BCSC applications are required for experiments that may be classified as Section III-F.

SECTION III-A

Proposals that require BCSC approval *BEFORE* initiation of the experiments.

Major Actions Under the NIH Guidelines.
Experiments considered as Major Actions under the NIH Guidelines. The NU Biosafety Committee will determine the level of containment at the time of approval.

Yes

☐ **III-A-1-a** Deliberate transfer of a drug resistance trait to microorganisms that are known to acquire it naturally, if such acquisition could compromise the use of the drug to control disease agents in human or veterinary medicine or agriculture.

SECTION III-B

Proposals that require BCSC approval *BEFORE* initiation of the experiments.

Yes

☐ **III-B-1** Deliberate formation of recombinant or synthetic DNA containing genes for the biosynthesis of toxin molecules lethal at an LD50 of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as tetanus toxin, botulinum toxin).

SECTION III-C

Proposals that require BCSC approval and Institutional Research Ethics Committee (IREC) approval, *before* Research Participant Enrollment

Yes

☐ **III-C-1** Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants.

SECTION III-D

Proposals that require BCSC approval *BEFORE* initiation of the experiments.

Yes

☐ **III-D-1** *Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems (see Section II-A, Risk Assessment)*

☐ **III-D-2** Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.

☐ **III-D-3** Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems

☐ **III-D-4** Experiments Involving Whole Animals
This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant or synthetic nucleic acid

molecule-modified microorganisms tested on whole animals. For the latter, other than viruses which are only vertically transmitted, the experiments may not be conducted at BSL1-N containment. A minimum containment of BSL2 or BSL2-N is required.

☐ **III-D-5** Experiments Involving Whole Transgenic Plants

☐ **III-D-6** Experiments Involving More Than 10 Liters of Culture

☐ **III-D-7** Experiments Involving Influenza Viruses

Section III-E

Experiments that Require BCSC Notice Simultaneous with Initiation (The recommended containment level is BSL1; recombinant or synthetic nucleic acid molecule experiments of higher risk and subsequently higher containment, are categorized in Section III-D)

Yes

☐ **III-E-1** Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus

Recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family being considered identical [see Section V-J, Footnotes and References of Sections I-IV]) may be propagated and maintained in cells in tissue culture using BSL1 containment. For such experiments, it must be demonstrated that the cells lack helper virus for the specific Families of defective viruses being used. If helper virus is present, procedures specified under Section III-D-3, Experiments Involving the Use of Infectious Animal or Plant DNA or RNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems, should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

☐ **III-E-2** Experiments Involving Whole Plants

☐ **III-E-3** Experiments Involving Transgenic Rodents

This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BSL1 containment are covered under this section; experiments that require BSL2, BSL3, or BSL4 containment are covered under Section III-D-4, Experiments Involving Whole Animals.

Section III-E-3-a. Experiments involving the breeding of certain BL1 transgenic rodents are exempt under Section III-F, Exempt Experiments (See Appendix C-VIII, Generation of BSL1 Transgenic Rodents via Breeding).

Section III-F

The following experiments require submission to BCSC.

Yes

☐ **III-F-1** Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.

☐ **III-F-2** Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.

☐ **III-F-3** Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.

☐ **III-F-4** Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.

☐ **III-F-5** Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species). Page 24 - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (November 2013)

☐ **III-F-6** Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), Major Actions). See Appendices A-I through A-VI, Exemptions under Section III-F-6--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.

☐ **III-F-7** Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.

☐ **III-F-8** Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions). See Appendix C, Exemptions under Section III-F-8 for other classes of experiments that are exempt from the NIH Guidelines.

Worksheet 2
ANIMAL EXPERIMENT QUESTIONNAIRE

Part 1 –these questions address the intrinsic nature of the work with animals and biological agents.

Species of Animal Used _____	**Species of Animal Used _____**	**Species of Animal Used _____**
Materials Used - Biological material introduced to animal: ☐ Biological agent(s) _____ ☐ Recombinant or synthetic DNA _____ ☐ Human or Animal Cell Lines:_____ ☐ Human or Animal Blood ☐ Other: _____ Concentration or titer used: _____	**Materials Used -** Biological material introduced to animal: ☐ Biological agent(s) _____ ☐ Recombinant or Synthetic DNA _____ ☐ Human or Animal Cell Lines:_____ ☐ Human or Animal Blood ☐ Other: _____ Concentration or titer used: _____	**Materials Used -** Biological material introduced to animal: ☐ Biological agent(s) _____ ☐ Recombinant or synthetic DNA _____ ☐ Human or Animal Cell Lines:_____ ☐ Human or Animal Blood ☐ Other: _____ Concentration or titer used: _____
Potential Risks with Agent Use - Release or Shedding through: ☐ Feces/Urine ☐ Bloodborne ☐ Respiratory Secretion ☐ Fomite/Cutaneous ☐ Other: _____ ☐ none Physical Risks ☐ Sharps/Laceration ☐ Ocular ☐ Bite/Scratch ☐ Respiratory/Allergen ☐ Other: _____ ☐ none	**Potential Risks with Agent Use -** Release or Shedding through: ☐ Feces/Urine ☐ Bloodborne ☐ Respiratory Secretion ☐ Fomite/Cutaneous ☐ Other: _____ Physical Risks ☐ Sharps/Laceration ☐ Ocular ☐ Bite/Scratch ☐ Respiratory/Allergen ☐ Other: _____	**Potential Risks with Agent Use -** Release or Shedding through: ☐ Feces/Urine ☐ Bloodborne ☐ Respiratory Secretion ☐ Fomite/Cutaneous ☐ Other: _____ Physical Risks ☐ Sharps/Laceration ☐ Ocular ☐ Bite/Scratch ☐ Respiratory/Allergen ☐ Other: _____

Part 2 - this completed section will be the basis for the SOP for your animal experiments. A copy of this must be given to the Institutional Animal Care and Use Committee Secretary.

Hazardous Agent Use in Animal Research ● Standard Operating Procedures for Experiments
LAB (Building/Room (e.g. MCDB A2B10) _____ Agent(s): _____

Instructions: Insert specific details pertaining to your research.

Biohazard information with regard to animals	*Provide known hazards to humans and physical description, color, odor characteristics, etc.*
Preparation	*List procedures used. Be specific about the physical form (solid, liquid, etc.) and locations for work (bench top, fume hood, biosafety cabinet), and be very specific about personal protective equipment (PPE) to be worn when handling the material.*
Transportation	*Discuss the precautions that will be taken if the agent is to be transported; if all work will be done within the same lab, this section is not applicable.* Infected animals will be housed for _____ hours after injection.

Use	*List specifics; include information regarding PPE and location of work.* How long will the animal be shedding the biological agent? _____ in Room _____ If applicable, please list any PPE that is required to be worn in addition to the standard PPE for the facility: Decontaminate surfaces and equipment with:
Disposal *If unsure, contact EH&S at 492-6025 to determine proper disposal procedures.*	All used Sharps must be placed immediately into a rigid sharps container. Do not overfill the container. These containers should be properly sealed/closed, autoclaved, and then tagged as Hazardous Waste. All lab debris should be collected in a red biohazard bag in a rigid container that has a step activated lid or cover within Rm. _____ Will it be necessary to autoclave the animal bedding prior to disposal? _____
Spill response and emergency procedures	*Include a brief description of how an accidental spill will be handled. Example:* Insert text from MSDS if available: (e.g.,) For lentivirus: **Susceptibility to disinfectants:** Susceptible to many disinfectants - 1% sodium hypochlorite, 2% glutaraldehyde, formaldehyde, ethanol…70% ethanol would be appropriate.
Hazard communication, signs, cage cards, etc.	All researchers handling this material should read this document. When animals have been treated with/administered this agent, all cage cards should be labeled appropriately with the name of the agent and a hazard warning (e.g. biohazard) for ____ hours and this SOP should be posted in a plastic sleeve on the door of Rm._____ to notify Animal Care staff and other personnel. Also have the Animal Care/Facility manager review and initial below prior to posting.
Unique instructions	*Please include any special instructions here, if applicable.* Coordinate use of Rm._____ with appropriate Animal Care staff.
Additional information or references	

Principal Investigator: _____

THIS SPACE IS FOR BCSC USE ONLY

Biosafety Application # _____

Principal Investigator: _____

Pre-review:

Biosafety lab audit has been completed: ☐ Yes ☐ No ☐ N/A

Biosafety cabinet has up to date certification: ☐ Yes ☐ No ☐ N/A

Application Reviewed by: Full Committee ☐ Yes *Administrative Approval: ☐ Yes

Approval is valid for 3 years from date of approval.

Review Date: _____ Renewal Due Date: _____ Approval Date: _____

Biohazards: _____

_____

_____

Biosafety Level Required: ☐ Exempt ☐ BSL-1 ☐ ABL-1 ☐ BSL-2 ☐ ABL-2 BSC Required: ☐ Yes ☐ No
☐ **Approved** ☐ **Modifications Required for Approval** ☐ **Deferred** ☐ **Denied** ☐ **Sent to full committee review**

Biohazards: _____

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Biosafety Level Required: ☐ Exempt ☐ BSL-1 ☐ ABL-1 ☐ BSL-2 ☐ ABL-2 BSC Required: ☐ Yes ☐ No
☐ **Approved** ☐ **Modifications Required for Approval** ☐ **Deferred** ☐ **Denied** ☐ **Sent to full committee review**

Biohazards: _____

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Biosafety Level Required: ☐ Exempt ☐ BSL-1 ☐ ABL-1 ☐ BSL-2 ☐ ABL-2 BSC Required: ☐ Yes ☐ No
☐ **Approved** ☐ **Modifications Required for Approval** ☐ **Deferred** ☐ **Denied** ☐ **Sent to full committee review**

Biohazards: _____

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Biosafety Level Required: ☐ Exempt ☐ BSL-1 ☐ ABL-1 ☐ BSL-2 ☐ ABL-2 BSC Required: ☐ Yes ☐ No
☐ **Approved** ☐ **Modifications Required for Approval** ☐ **Deferred** ☐ **Denied** ☐ **Sent to full committee review**

*Applications reviewed administratively can be: approved, approved with modifications required, or sent to the full committee for review.

_____ _____

BCSC Chair Signature Date

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