HOFSTRA UNIVERSITY

v. August 2020

Biological Agent Research Registration & Risk Assessment

ADMINISTRATIVE USE ONLY:

Registration#:	**☐Pre-Clinical ☐Clinical**	**Date Received:**
☐ Requires Institutional Biosafety Committee (IBC) Review		**☐Requires IBC Notification**
Date IBC Review:		**Date Approved:**

SECTION I - CONTACT INFORMATION/PROJECT SUMMARY

Principal Investigator (PI):	Name:
	Office #:
	Cell#:
	Email:
Lead Researcher (if other than PI) ☐NOT APPLICABLE	Name:
	Office #:
	Cell#:
	Email:
Research Project Title	
Site of Research Project (list department and all laboratory areas where the biological agent will be)	Building:
	Room Number(s):

Provide a brief description of the research project(s) associated with the use of the biological agents described in this registration. Sufficient information must be provided for the IBC to understand the general scope of the work. The emphasis should be on the role of the agent in the work.	
As the PI, please provide information regarding your direct experience handling, transporting, and manipulating the agents listed in this registration. If you will not be directly handling the material, describe your role.	
List corresponding Institutional Animal Care and Use Committee (IACUC) Protocol(s) in which biological agent(s) described in this registration will be used. ☐ NOT APPLICABLE	
List corresponding Institutional Review Board (IRB) Protocol(s) in which biological agent(s) described in this registration will be used. ☐ NOT APPLICABLE	

SECTION II - BIOLOGICAL AGENT DESCRIPTION

Select the type of agent that will be used. Only one agent per registration.	**Name agent**
☐Recombinant or Synthetic Nucleic Acid Molecule (complete section A)	
☐Microorganism (e.g. bacteria, yeast/fungi, virus, parasites, etc.) (complete section B)	
☐Xenotransplantation or modified human cells (e.g. transplantation of virus infected human cells) (complete section C)	
☐ Biological Toxin (complete section D)	

A-1. RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES	
If you are requesting the use of any agents that fall under the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, please specify under what section the research falls. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules References are to the page # of the April 2019 version of the Guidelines.	
☐Section III-B (page 17)	Experiments that Require NIH Office of Biotechnology Activities (NIH/OBA) and Institutional Biosafety Committee Approval Before Initiation
☐Section III-D (page 18)	Experiments that Require IBC Approval Before Initiation
☐Section III-E (page 22)	Experiments that Require IBC Notice Simultaneous with Initiation
☐Section III.E.1 (page 23)	Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus

A-2. RECOMBINANT DNA EXPRESSION	**☐NOT APPLICABLE**
Is the expressed gene an oncogene or tumor suppressor? ☐Yes ☐ No If yes, describe:	
Is the expressed gene a miRNA? ☐ Yes ☐No If yes, describe:	
Will the expressed gene edit genomic DNA? ☐Yes ☐ No If yes, describe:	

B-1. BACTERIA ☐ NOT APPLICABLE
Is the biological agent a bacterium? ☐Yes ☐No
Has any recombinant DNA been inserted? ☐Yes ☐No If yes, describe:
Does this increase the virulence? ☐Yes ☐No If yes, describe and include the maximum volume of bacterial culture:

B-2. VIRUS OR VIRAL VECTOR ☐ NOT APPLICABLE
Is the biological agent a virus or viral vector? ☐Yes ☐No If yes, identify:
Please provide a brief description of the viral vector including any modifications that alter replication competence and the name of any expressed gene(s). Provide references and catalogue numbers if available.
Is the vector replication competent? ☐Yes ☐No
What generation (if a lentivirus)? ☐2 (see Guidance 2nd Generation Lenti under Reference Material & Templates on the Institutional Biosafety Committee (IBC) webpage) ☐3 ☐ 4 **Note:** Use of 1st generation lentivirus is prohibited.
What is the volume of the concentrated virus being produced? ☐ <100mL ☐ >100mL (Note: BSL2+ required)
Source of envelope glycoprotein (if retro- or lentivirus)?
Tropism (list of species virus infects)?
Will any virus be shed by the recipient? ☐Yes ☐No If yes for how long?

VECTOR PACKAGING
Will you be using packaging cell line and/or helper plasmid? ☐Yes ☐No If yes, then complete:
Name of packaging cell line(s), helper virus or plasmid:
If a lentivirus, indicate how many plasmids are being used to generate the virus? ☐2 ☐3 ☐4
Source(s) of cells

C. CELLS	☐ NOT APPLICABLE
☐Human ☐Non-human Primate ☐Other: Specify: Describe source and specific cell type:	
Have the cells been tested for panel of pathogens? ☐Yes ☐No If yes, describe:	
Are the cells irradiated? ☐Yes ☐No	
Are the cells transduced with a viral vector? ☐Yes ☐No If yes does the viral vector contain ☐ >2/3 of the viral genome ☐<2/3 of the viral genome	

D. TOXINS	☐ NOT APPLICABLE
Is the biological agent a toxin? ☐Yes ☐ No	
Is the biological agent subject to the Centers for Disease Control and Prevention (CDC) Select Agents and Toxins Regulations? ☐Yes ☐No See Select Agents list: **Note:** If select agent or toxin is above exempted quantities we must report to CDC Division of Select Agents and Toxins before research can initiate.	
Can the biological agent produce toxins? ☐Yes ☐No If yes, identify the toxin:	
Total quantity needed for proposed experiment under this IBC registration?	

SECTION III –HAZARD ASSESSMENT AND WORK PRACTICE

A. RISKS OF BIOLOGICAL AGENT(s)

☐ Agent Information must be attached, i.e. Agent Safety Data Sheet (SDS)	☐ Other pertinent references attached: Document(s):

Is the biological agent known to be transmissible via the following routes of transmission?

☐Inhalation ☐Ingestion ☐ Injection / sharps injury ☐ Skin ☐ Eyes

☐Unknown ☐ Other ☐Not known to be transmissible

Does the biological agent have the potential to cause injury or disease in healthy adult humans?

☐ Yes ☐ No If yes, indicate:

☐ Lung ☐ Skin ☐ Liver ☐ Eyes ☐ Carcinogenic ☐ Other: ☐ Unknown

Details (if applicable):

Do any of these following conditions increase the risk of the researcher?

If yes, identify: ☐ Pregnancy ☐ Immunocompromised ☐ Chronic Respiratory Illness

☐ Other:

A. ENGINEERING CONTROLS For Agent(s) Management

Indicate which engineering controls (implement physical change to the workplace, which eliminates/reduces the hazard on the job/task) **will be used. For:** ☐Receipt ☐ Transportation ☐ Preparation

☐Administration

Check all that apply:

☐Increased PPE ☐Negative pressure ventilation ☐Containment to a designated location

☐Fume hood ☐ Biosafety cabinet

Note: BSC is to be used when handling the agent in any way including manipulating or administering to animals.

B. DECONTAMINATION

Describe disposal of biological agent(s):

☐Regulated Medical Waste, describe:

☐10% bleach

☐Autoclave

☐Other, as per manufacturer's guidelines, describe:

Describe disposal of device(s) used:

☐Regulated Medical Waste

☐10% bleach

☐Other, as per manufacturer's guidelines, describe:

Describe the treatment for contaminated consumables

☐Autoclave

☐Decontamination with and Environmental Protection Agency (EPA) approved disinfectant:

☐Reprocess of surgical instruments with:

☐High-level disinfection ☐Sterilization ☐Other:

PPE available and appropriate to minimize exposure during decontamination. Check all that apply:

☐Gloves ☐Eye protection ☐Face shield ☐Mask ☐N95 Respirator

☐Impervious gown ☐ Laboratory coat with protective sleeves ☐ Other:

C. WORK PRACTICE

☐BSL1 ☐ BSL2

Note: The use of biological agents that fall under BSL3 or BSL4 are prohibited.

***If the Research Project falls under <u>BSL1</u> guidelines, SKIP to Section IV. STUDY PERSONNEL.**

***If the Research Project falls under <u>BSL2</u> guidelines, COMPLETE the entire document.**

D. POST PROCEDURE PRECAUTIONS ☐ NOT APPLICABLE

For personnel exposed to the agent described above, are there post-procedure precautions for follow-up care beyond standard precaution (i.e. airborne, contact, or droplet precaution): ☐Yes ☐No

If yes, describe:

For personnel exposed to the agent described above list any other considerations for follow-up care (i.e. duration of shedding or potential transmission to others by any means, exposure precautions)

☐Not Applicable

E. EXPOSURE PLAN

In the event of an exposure, is prophylaxis recommended? ☐Yes ☐ No

If yes, prophylaxis must be described in the SOP for the agent (attach to registration).

F. TRANSPORTATION OF AGENT(S)

Outline chain of custody from point of receipt to storage location (include the name(s) of who will be transporting the agent):

Outline chain of custody from storage location to administration location (identify the administration location):

Describe mode of transportation (how the agent will be transported) from the storage location to point of use:

Engineering Controls:

Is there a secondary container used for transport? ☐Yes ☐ No

If yes, describe:

Additional engineering controls? ☐ Yes ☐No

If yes, describe:

Administrative Controls: Changes in work procedures that have a goal of reducing the duration, frequency, and severity of exposure to hazardous materials, i.e. written safety policies, rules, training, etc.

Staff transporting agent were trained, including emergency spill procedures? ☐ Yes ☐ No

Other specific training requirements? ☐ Yes ☐ No
If yes, list the required training:

Specific labelling requirements? ☐Yes ☐ No
If yes, list the required labels:

PPE to be used to minimize exposure. Check all that apply:
☐Gloves ☐Eye protection ☐Face shield ☐Mask ☐N95 Respirator
☐Impervious gown ☐Laboratory coat ☐Other:

G. ADMINISTRATION OF AGENT

Location where agent will be administered:

Describe and include any device used for administration:

The following safety features are provided in the administration area:
☐ Sink ☐ Eye wash ☐ Shower ☐ Biosafety cabinet ☐Sharps containers ☐Medical waste containers ☐ Spill kits ☐ Other .

PPE must be worn to minimize exposure when administering agent. Check all that apply:
☐Gloves ☐ Eye protection ☐Face shield ☐Mask ☐N95 Respirator
☐ Impervious gown ☐ Laboratory coat with protective sleeves ☐ Other:

IV. STUDY PERSONNEL

1. HAZARD COMMUNICATION PROCESS

Indicate individual and contact information (telephone number and e-mail address) for reporting incidents/spills/emergencies:

SAFETY & EMPLOYEE HEALTH SERVICES CONTACTS

	Name	Telephone number	Email
Chemical Hygiene Officer	Wendy Hom	516-463-5541	**Wendy.hom@hofstra.edu**
Public Safety		516-463-6789	
Laboratory Director			

2. STUDY PERSONNEL

Instructions: List all persons involved with the work detailed in this registration/risk assessment.
Note: All personnel listed must complete biosafety program participation and research compliance requirements. If the agent is to be shipped, DOT-IATA trained personnel must be consulted.

Name		
Title		
Department		
Contact information	**Telephone #:** 3-	**Email:**
List tasks involving biological agents	☐Study Supervisor/Administrative Oversight ☐Receiving/Transporting ☐In vitro Use ☐ Animal use ☐Disposal ☐Decontamination Other:	

Name		
Title		
Department		
Contact information	**Telephone #:**	**Email:**
List tasks involving biological agents	☐Study Supervisor/Administrative Oversight ☐Receiving/Transporting ☐In vitro Use ☐ Animal use ☐Disposal ☐Decontamination Other:	

Name		
Title		
Department		
Contact information	**Telephone #:**	**Email:**
List tasks involving biological agents	☐Study Supervisor/Administrative Oversight ☐Receiving/Transporting ☐In vitro Use ☐ Animal use ☐Disposal ☐Decontamination Other:	

Name		
Title		
Department		
Contact information	**Telephone #:**	**Email:**
List tasks involving biological agents	☐Study Supervisor/Administrative Oversight ☐Receiving/Transporting ☐In vitro Use ☐ Animal use ☐Disposal ☐Decontamination Other:	

3. PRINCIPAL INVESTIGATOR ATTESTATION

- I AND all persons working and/or performing research in my laboratory are trained in the proper handling of all biological agents, including the proper use of all safety and bio-containment equipment, PRIOR to the initiation of any experiments.

- I attest that the information contained in this registration concerning research involving the use of biological agents is accurate and complete.

- I attest that I have read, understand and will comply with the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules.

- I am familiar with and agree to comply with the current Federal, State, Local and Institutional regulations and policies.

- I am familiar with and I agree to comply with the requirements pertaining to shipment and transfer of all biological agents requested herein.

- I am familiar with the policies and procedures for safe storage, handling, utilization, shipment and disposal of all requested biological agents. I will conduct my research in conformance with these regulations, policies and principles.

- I will seek and obtain approval for this registration prior to initiation, and will report promptly to the Institutional Biosafety Committee any unanticipated deviation from the protocol described herein.

- Any unusual illnesses or reactions of any personnel engaged in this research will be immediately reported to Employee Health Services.

- Written reports will be submitted as outlined in the SOP concerning:
  1. Any accident or illness as the result of inoculation, ingestion, and inhalation of biological agents; any incident causing serious exposure of personnel or danger of environmental contamination.
  2. Any problems pertaining to operation and implementation of biological and physical containment safety procedures or equipment or facility failure.
  3. Documentation of the quantities of the agent(s) on hand and maintained quantities will be at or below the regulatory quantities allowable.

Signature of Principal Investigator ***(required when submission is approved)***	**Date:**