SAM HOUSTON STATE UNIVERSITY
Notification of Use (NOU)
Biological Agents, Recombinant Materials, CDC and USDA Regulated Agents

The purpose of this document is to ensure adequate review of occupational health and safety precautions and the procedures for use, handling, storage and disposal of biohazardous agents. The Principal Investigator (P.I.) or Supervisor must be fully aware of the potential hazards associated with the agent(s) used in the work area.

NOU(s) expire after 5 years. Continuing reviews must be submitted annually [form sent by Environmental Health and Safety (EHS)]. Amendments to the NOU do not change the renewal date, the original approval dates apply. No human or animal pathogen can be studied without prior written approval of the Institutional Biosafety Committee.

THIS MAY BECOME A PUBLIC DOCUMENT: DO NOT INSERT PROPRIETARY OR SECURITY SENSITIVE INFORMATION.

Type of Submission: ☐ New ☐ Renewal ☐ Amendment (NOU #: _____)

Type of Agent: ☐ Biological agent, list agent(s): _____
☐ Recombinant material

Animals: ☐ Yes ☐ No ☐ Creation of transgenic animals

Arthropods: ☐ Yes ☐ No ☐ Creation of transgenic arthropods

Biosafety Level at which this agent will be used: ☐ BSL1 ☐ BSL2
(One biosafety level per NOU.)

Select the Risk Group (RG) for this agent: ☐ RG1 ☐ RG2
(RG definitions: https://osp.od.nih.gov/biotechnology/nih-guidelines/)

I am familiar with and agree to comply with the SHSU Safety Manual, the SHSU Risk Management, the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (current edition) and the NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.*

The information provided in this document is accurate to the best of my knowledge. I agree to abide by the provisions set forth in this plan as approved by the Sam Houston State University Institutional Biosafety Committee.

I acknowledge if an unexpected increase in virulence is observed, I will notify EHS immediately. I accept responsibility for providing all lab personnel with a copy of this NOU, and providing training for all lab personnel involved in the research project described in this NOU before commencement of work.

P.I. (Signature)	Title	Extension	Date Submitted
P.I. (Printed Name, Credentials)	SHSU ID#	Department	Route

Institutional Biosafety Committee Use Only

Date Approved _____ **Date for Resubmission** _____ **NOU Number** _____

DURC ☐ **Yes** ☐ **No**

☐ **A** ☐ **B** ☐ **C** ☐ **D1** ☐ **D2** ☐ **D3** ☐ **D4** ☐ **D5** ☐ **D6** ☐ **D7** ☐ **E** ☐ **F**
NIH categories

IBC Chairman Signature _____ **Print Name** _____

SECTION I: General information

1. **List agent(s) (include strains or generation; no abbreviations):**

Attach a copy of the pathogen safety data sheet if available, or supporting safety information (eg, manufacturer safety, data or fact sheet).
(eg, http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php, https://www.cdc.gov/az/a.html)

2. **Goal of the project (1-2 sentences):**

3. **Description of use (include techniques used for in-vitro, in-vivo and vector work. Do not copy detailed protocols or grant information; this section should be ¼ to ½ page long):**

4. **Location:**

Building(s)/Room Number(s): _____

5. Occupational Health

a. Are all personnel enrolled in the Employee Occupational Health Program?
☐ No ☐ Yes

b. Can this agent infect humans?
☐ No (proceed to question 6)
☐ Yes
☐ Unknown

c. Is the infection associated with replication in humans or is it abortive (no infectious progeny, for example viral replicons or defective adenoviral vectors)?
☐ Abortive (proceed to question 6)
☐ Unknown
☐ Replicative

i. Can the agent cause disease in healthy humans? ☐ No ☐ Yes ☐ Unknown

- If yes and no are both checked (e.g., multiple agents are listed in #1), provide an explanation:

ii. Can the agent cause disease in immunocompromised humans? ☐ No ☐ Yes ☐ Unknown
- If yes and no are both checked (e.g., multiple agents are listed in #1), provide an explanation:

d. Is medical surveillance recommended for the agent(s) prior to commencement of work, and/ or ongoing during project?

☐ No ☐ Yes

e. If yes, what type of surveillance is recommended?

☐ **Initial** ☐ **Ongoing**

Please explain:

f. Is a vaccine available for the agent?
☐ No (proceed to question 6)
☐ Yes ☐ FDA approved ☐ Internationally available ☐ Experimental (IND)
List vaccine:

g. Is immunization recommended by the ACIP at the listed biosafety level?(Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov) ☐ No ☐ Yes

6. Agent Assessment (Answers are to be based on this scope of work *in-vitro*)

a. Provide the following:

i. Maximum volume to be cultured/handled at one time per container (e.g. flask, tubes, roller bottles): _____

ii. Maximum number of containers cultured/handled at one time: _____

If agent is abortive, skip to b.

iii. Maximum concentration to be cultured/handled at one time (units eg, pfu/mL):

iv. Will the agent be concentrated prior to experimental use? ☐ No ☐ Yes:

- Final total volume: _____
- Final concentration: _____
- Describe use of the concentrated material: _____

b. Will infectious material be manipulated outside of primary containment (eg., BSC)?

☐ No

☐ Yes, provide scientific justification:

c. Describe agent stability in the environment

i. Agent stability in regards to spill, fomites, survival outside of host:

ii. Susceptibility to decontamination as it pertains to the lab (heat, chemical inactivation):

d. Describe potential routes of lab transmission (including recombinant material).

☐ Inhalation ☐ Mucous membrane ☐ Ingestion ☐ Sharps (including needle sticks) ☐ Other: _____

e. What is the origin of the infectious material and from where will you specifically receive the agent?

☐ Existing stock
☐ Clinical isolate location:
☐ Field sample location:
☐ Commercially purchased
☐ Collaborator
☐ Other:

f. In the box below, describe pathogenicity for each agent, including disease incidence and severity in humans.

☐ Not infectious (proceed to question 7)

g. What is the infectious dose for each agent in humans? Provide reference. (If unknown, state whether or not the dose being used can be expected to cause infection and an explanation.)

h. If human data is not available, summarize from the most appropriate animal model studies (pathogenicity, infectivity and route of shedding from animals)?

7. Agent Inactivation

a. Will the project involve inactivating agent or samples?

☐ No (proceed to question 8)
☐ Yes

b. Reason for agent/sample inactivation

☐ To work at the same biosafety level
☐ To work at a lower biosafety level or on bench-top
☐ For shipment
☐ Other: Please describe below.

c. Inactivation and Verification Procedure(s)

No samples will be brought to a lower biosafety level prior to inactivation validation.

Please provide a detailed SOP* of the inactivation procedure(s) and validation procedure(s) for complete inactivation. This should also include the frequency of validation testing.

***Note: this must be attached to your IBC protocol documentation or available during inspection.**

9. Evaluation of Dual Use potential experiments of concern (US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern). If answer is "yes", please explain in detail.

a. Is it likely that the harmful consequences of the agent will be enhanced?

☐ No

☐ Yes, explain in detail:

b. Is it likely that the immunity or effectiveness of an immunization against the agent without clinical and/or agricultural justification will be disrupted?

☐ No

☐ Yes, explain in detail:

c. Is it likely that:

i. resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions will be conferred to the agent?

☐ No ☐ Yes, explain in detail:

ii. the agent's ability to evade detection methodologies will be facilitated?

☐ No ☐ Yes, explain in detail:

d. Is it likely that the stability, transmissibility, or the ability to disseminate the agent will be increased?
☐ No ☐ Yes, explain in detail:

e. Is it likely that the host range or tropism of the agent will be altered?
☐ No ☐ Yes, explain in detail:

f. Is it likely that the susceptibility of a host population to the agent will be enhanced?
☐ No ☐ Yes, explain in detail:

g. Is it likely that an eradicated or extinct agent will be generated or reconstituted?
☐ No ☐ Yes, explain in detail:

10. Agent Propagation

a. Will agent(s) be propagated on this study?
☐ No
☐ Yes

b. What systems (cells and bacteria) will be used with the agent(s) listed (e.g. propagation, transduction, etc.)?
☐ N/A (e.g. broth or agar)
i. Cells of arthropod or animal origin: _____
ii. Cells of human or nonhuman primate origin: _____
Human or nonhuman primate product NOU approval number(s): _____
iii. Bacteria: _____

11. Check the personal protective equipment (PPE) worn when handling agent(s) in-vitro:

☐ Lab coat or gown/gloves/eye & face protection as needed (BSL1)
☐ Lab coat/gloves/eye & face protection as needed (BSL2)

12. Respiratory Protection

N95 respirator explain when and why this is worn:

13. Additional PPE

☐ Face Shield, explain when and why this is worn: _____
☐ Surgical mask, explain when and why this is worn: _____

14. Check lab equipment used when handling agent(s) in-vitro:

☐ Centrifuge (Sealed lid and cups/bucket) Building/Room: _____
☐ Blender
☐ Homogenizer, type: _____
☐ Sonicator
☐ Shaker Building/Room: _____
☐ Chemical Fume Hood: Building/Room: _____
☐ Biological Safety Cabinet (BSC): Building/Room: _____
☐ Other specify: _____

15. Method for disposal of biohazardous waste:

☐ Placed in red bag for disposal.
☐ Autoclaved, then placed in the biohazard trash.
☐ Chemically disinfected, then placed in the biohazard trash.
☐ Chemical disinfection or autoclave of bulk liquid, then disposed of based on MSDS
☐ Autoclaved, then packaged for incineration. [for only ABSL-1/ABSL-2]
☐ Other: _____

16. List disinfectant(s) used for surface decontamination and spills:

☐ CaviCide ☐ MicroChem
☐ Bleach ☐ Other _____ %

17. If you are planning recombinant or synthetic nucleic acid molecules work, please fill out Section II ☐ **N/A**

If you are planning any animal work, please fill out Section III ☐ **N/A**

If you are planning any arthropod vector work, please fill out Section IV ☐ **N/A**

Section III: Animal Use

SUBMIT A SEPARATE ANIMAL USE SECTION FOR EACH SPECIES.
(Mice and rats may be submitted together)

IACUC Protocol #: _____ IACUC Approval date: _____
PI name if different from NOU PI: _____

1. **Animal Species:** ☐ Mouse ☐ Rat ☐ Cattle ☐ Aquatic species ☐ Chickens ☐ Horses ☐ Goats ☐ Other: _____

2. **Provide a project description specific to animal study; include procedures, treatments, challenge materials and sampling per species:**

3. **Will the infected animal present a human health risk after administration?**

   ☐ No ☐ Yes, provide the following information:

   Route of exposure: ☐ Respiratory ☐ Milk ☐ Urine ☐ Feces ☐ Saliva ☐ Blood ☐ Other: _____

4. **What animal facility/housing is recommended?**

☐ ABSL1 ☐ ABSL2 ☐ Other

5. **Check the PPE that will be worn (eye protection is to be used at all biosafety levels):**

☐ Standard PPE for the animal facility
☐ PAPR
☐ N95 respirator
☐ Other (specify): _____

6. **Check lab equipment that will be used:**

☐ Biological safety cabinet
☐ Chemical fume hood
☐ Other (specify): _____

7. **Dose per animal:**
   a. Maximum volume to be administered at one time: _____
   b. Maximum concentration to be administered at one time: _____

8. **Route of administration:**

☐ Intracranial	☐ Intraperitoneal	☐ Intradermal	☐ Intramuscular
☐ Intravenous	☐ Subcutaneous	☐ Intracardiac	☐ Intranasal
☐ Aerosol	☐ Gavage	☐ Topical	☑ Oral
☐ Bronchial	☐ Intrathecal	☐ Other: _____	

9. **Sampling:**

☐ Intravenous bleeds	☐ Feces	☐ Intracardiac bleeds
☐ IV Retro-orbital bleeds	☐ Urine	☐ Organs
☐ IV Saphenous bleeds	☐ Throat swabs	☐ Bronchoalveolar lavage
☐ IV Submandibular bleeds	☐ Nasal Swabs	☐ Other: _____

10. **Will any manipulations be performed without the animal under anesthesia?**
☐ No ☐ Yes (provide justification below and attach written protocol)

11. **Will tissue homogenization be performed?**
☐ No ☐ Yes (provide a written protocol)

12. **Please describe how body fluids from perfusions will be collected and treated for disposal.**
☐ **N/A, no perfusions are performed**

13. Will the study use:

a. **Recombinant material** ☐ Yes ☐ No

b. **Viral vectors** ☐ Yes ☐ No (if no go to 13.c)

i. Are the vectors replication deficient? ☐ Yes ☐ No

ii. Are there safety concern(s) associated with the vectors used; if so, please explain (please indicate if the vector is expected to shed within 72 hours).

ii. Are there any toxins, virulence factors or oncogenes associated with the expression of the transgene; if so, please explain.

c. **Gene transfer experiments** ☐ Yes ☐ No

d. **Creation of transgenic animals (other than maintaining BSL-1 breeding colonies)**
☐ Yes ☐ No

14. <u>Will infected animals be transported by laboratory staff out of or between the vivarium(s)?</u>

☐ No (proceed to question 15)
☐ Yes, please describe below:

a. Reason for removal:

b. Location of animal manipulation/necropsy:

c. Procedures for transportation of cages to and from vivarium:

d. PPE worn by all personnel present in the lab:

e. PPE worn by those handling animals:

15. Are there any deviations from standard facility procedures?

☐ No ☐ Yes , please describe below

If you are planning any arthropod vector work, please fill out Section IV. ☐ **N/A**