

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					

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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