Draft Registration Document Test registration for rDNA plus pathogen+Animal +HBBF	rDNA/Pathogen	Accession Number 16348-135440936	
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Inactivated Registration		**Date Submitted** N/A	**Expiration Date**

Doc Ver: 231-238

Recommendations

Synopsis

Organism/Toxin:

Purpose:

Description:

Start Date of Project:

Duration of Project:

Points of Contact

None

Associated Laboratories

Building/Room	Last Survey Date
13/3W84	10/17/2016

Animal Laboratories

Building/Room	Last Survey Date
13/test	06/23/2010

Associated Researchers

Name	Badge ID	Email	Work Type	e-Signed
Capul, Althea	2001192834	althea.capul@nih.gov	RD, HPRD, HBBF, Animal	No
Clarkson, Adam J.	0012011253	ac480y@nih.gov	RD, HPRD, HBBF, Animal	No

Associated Registrations

None

Recombinant DNA

Sources of DNA:

Registration Document Approved by Biosafety Officer	Registration Document Approved by Chair, IBC	Registration Document Approved
		Not Yet Approved

Description of recombinant molecule(s) being used or created:

Research Product

Expression:

Expression Product:

Nature of Expression:

Product Exposed to:

Exposure Details:

Vector Use:

Proposed NIH Guidelines:

Pathogen and/or Toxin

Organism/Toxin:

Organism/Toxin Not in List:

Strain:

Volume > 10L:

Toxin Description:

Toxin Volume:

LD50 > 100 Nanograms:

Agent Inactivation:

Organism Concentration:

Containment:

Samples Repository:

Refrigerators/Freezers:

Cell Sorting/Tissue Grinding/Sonication:

Pathogenic or Toxic To:

Antibiotic Resistant:

Permit Required:

Select Agent:

Radiolabeled:

Prokaryote Hosts

Prokaryotic Host(s):

Description:

Uploaded Description:

Nature of Gene Sequence:

Percent Source Genome:

Vector Plasmid DNA/Virus:

Uploaded Vector Maps:

Proposed NIH Guidelines:

Proposed Prokaryotic BSL:

Eukaryote Cells

Nature of Experiment:

Uploaded Documents:

Uploaded Vector Maps:

Expression of Foreign Gene:

Additional Uploaded Vector Maps:

Cloning of Toxin Molecule:

Proposed NIH Guidelines:

Proposed Eukaryotic BSL:

Animal Use 1

Animal Species:

Species is not in list:

Uploaded ASP(s):

ASP Number:

ASP Title:

Assertions:

Routes of Administration:

All Researchers Trained:

Containment BSL:

Practices BSL:

HBBF/Tissue Use

Register to Work With:

Types of Material:

Manipulation Techniques:

PI Attestations

Decontamination Plan Posted:

Staff Trained in Waste Disposal:

Research Staff Provided:

PI Certification: Not certified

Technical Competency:

Mitigation Programs:

PI E-Signature: Registration is not complete

Dual Use Questionnaire

A. Will the intermediate or final product of your experiments:

1. enhance the harmful consequences of the agent or toxin? (for example, will it enable weaponization* of an agent or toxin, or enhance the virulence of a pathogen, or render a non-pathogen virulent?)

2. disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification? (for example, make a vaccine less effective)

3. confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies? (for example, confer a drug resistance trait to microorganism(s) in the study that could compromise the use of appropriate or conventional drugs to control or detect these microorganism(s) as disease agents in humans, veterinary medicine, or agriculture)?

4. increase the stability, transmissibility, or ability to disseminate the agent or toxin?

5. alter the host range or tropism of the agent or toxin?

6. enhance the susceptibility of a host population to the agent or toxin?

7. generate or reconstitute an eradicated or extinct agent or toxin?

B. Will synthetic biology** techniques be used to construct a pathogen, toxin or potentially harmful product?

C. Even if your planned research does not involve any of the aforementioned criteria, and realizing your work or results could conceivably be misused, is there the potential for your data/product to be readily utilized to cause public harm?

Please add any important additional information you would like to share to address potential concerns.

After considering the above answers, do you believe there is the potential for your research data/product to be readily utilized to cause public harm?

* In this context, weaponization refers to the enhanced dispersion, deliverability, survivability or pathogenesis of an agent or toxin.

** Synthetic biology includes, but is not limited to, techniques of molecular biology, chemistry and genetics that would allow for the de novo synthesis or reverse engineering of genes, gene products or entire functional organisms.