Potentially Hazardous Biological Agents Risk Assessment Form (6A)

Required for research involving microorganisms, rDNA, fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids.
SRC/IACUC/IBC approval required before experimentation.

Student's Name(s) Theresa Haupt

Title of Project Mechanism of Outer Membrane Vesicle and Tube Formation in Francisella

To be completed by the QUALIFIED SCIENTIST/DESIGNATED SUPERVISOR in collaboration with the student researcher(s). All questions are applicable and must be answered; additional page(s) may be attached.

SECTION 1: PROJECT ASSESSMENT

1. Identify potentially hazardous biological agents to be used in this experiment. Include the source, quantity and the biosafety level risk group of each microorganism.
   See attached document.
2. Describe the site of experimentation including the level of biological containment.
   Stony Brook University, Center for Infectious Diseases, Biosafety Level 2 laboratory
3. Describe the procedures that will be used to minimize risk (personal protective equipment, hood type, etc.).
   See attached document.
4. What final biosafety level do you recommend for this project given the risk assessment you conducted?
   Biosafety Level 2
5. Describe the method of disposal of all cultured materials and other potentially hazardous biological agents.
   Biological material disposed in biohazard waste or disinfected before disposal.

SECTION 2: TRAINING

1. What training will the student receive for this project?
   Safety Training - See list on attached document.
2. Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable).
   More than 4 years

SECTION 3: For ALL CELL LINES, MICROORGANISMS AND TISSUES – To be completed by the QUALIFIED SCIENTIST or DESIGNATED SUPERVISOR - Check the appropriate box(es) below:

☐ Experimentation on the microorganisms/cell lines/tissues to be used in this study will NOT be conducted at a Regulated Research Institution, but will be conducted at a (check one) ☐ BSL-1 or ☐ BSL-2 laboratory. This study has been reviewed by the local SRC and the procedures have been approved prior to experimentation.

☑ Experimentation on the microorganisms/cell lines/tissues to be used in this study will be conducted at a Regulated Research Institution and was approved by the appropriate institutional board prior to experimentation; institutional approval forms are attached.
Origin of cell lines: Laboratory strain collection Date of IACUC/IBC approval 10-2-2018

☐ Experimentation on the microorganisms/cell lines/tissues to be used in this study will be conducted at a Regulated Research Institution, which does not require pre-approval for this type of study. The SRC has reviewed that the student received appropriate training and the project complies with ISEF rules.

CERTIFICATION – To be SIGNED by the QUALIFIED SCIENTIST or DESIGNATED SUPERVISOR

The QS/DS has seen this project's research plan and supporting documentation and acknowledges the accuracy of the information provided above. This study has been approved as a (check one) ☐ BSL-1/ ☐ BSL-2 study, and will be conducted in an appropriate laboratory.

David G. Thanassi — QS/DS Printed Name

David G. Thanassi — Signature

6/21/2019 — Date of review (mm/dd/yy)

SECTION 4: CERTIFICATION – To be completed by the LOCAL or AFFILIATED FAIR SRC

The SRC has seen this project's research plan and supporting documentation and acknowledges the accuracy of the information provided above.

SRC Printed Name

Signature

Date of review (mm/dd/yy)

Form 6A

Section 1: Project Assessment

1. Identify potentially hazardous biological agents to be used in this experiment. Include the source, quantity and the biosafety level risk group of each microorganism

Escherichia coli K12 (biosafety level 1) and Francisella novicida MFN245 (biosafety level 2). Bacteria are from laboratory stocks, volumes from 5-25 mL.

3. Describe the procedures that will be used to minimize risk (personal protective equipment, hood type, etc.).

Gloves, lab coat, and close toed shoes are worn at all times to prevent contact of biological agents with skin. Manipulation of Francisella bacteria is done in a class II biological safety cabinet.

Section 2: Training

1. What training will the student receive for this project?

Safety Training - General fire safety, laboratory safety chemical and biological hazards, hazardous waste training, regulated medical waste

Stony Brook Research

Stony Brook University Institutional Biosafety Committee (IBC)

DATE:	September 28, 2018
TO:	David Thanassi, PhD
FROM:	Susan Gasparo, Assistant Director, Research Compliance
SUBJECT:	Institutional Biosafety Committee (IBC) Action Taken
STUDY TITLE:	[267209-19] Structure and function of the pilus usher/Mechanism of the usher in assembly and secretion of pili
IBC #:	2011-145-R1

SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
SUBMISSION APPROVAL DATE:	October 2, 2018
PROJECT EXPIRATION DATE:	October 1, 2019
REVIEW TYPE:	Administrative Review

The Continuing Review/Progress Report for the project referenced above which involves Recombinant or Synthetic Nucleic Acid Molecules (rsNAM), was approved by the Institutional Biosafety Committee (IBC) on October 2, 2018.

Only those individuals listed as study personnel on the approved IBC application are authorized to conduct this activity.

The approval for this project expires on October 1, 2019 after which time all rsNAM work relating to this project must cease and desist until renewed IBC approval has been secured.

PLEASE POST THIS LETTER IN A PROMINENT AREA WHERE THIS rsNAM ACTIVITY IS BEING CONDUCTED SO THAT ALL STUDY PERSONNEL ARE AWARE OF THE ABOVE-REFERENCED EXPIRATION DATE.

The experiments must be conducted at Biosafety Level BSL1, BSL2, BSL3. Specifics regarding proper procedures for this containment level is provided with this document.

IMPORTANT: You must renew this project by submitting an Application for Continuing Approval of Recombinant or Synthetic Nucleic Acid Molecules (rsNAM) Activities to the IBC, and obtain approval by October 1, 2019 if the study is to continue.

You are reminded:

- Any proposed amendment or revision to the approved activity must first be submitted and approved by the IBC prior to initiation.
- **As an IBC-approved investigator, you have mandated reporting responsibilities. Certain incidents regarding this work must be immediately reported to one of the following individuals:**

- Dr. Laurie Krug, Chair, IBC, laurie.krug@stonybrook.edu
- Mr. Christopher Kuhlow, Biosafety Officer, christopher.kuhlow@stonybrook.edu
- Ms. Susan Gasparo (on behalf of the IBC), susan.gasparo@stonybrook.edu

See the Incident Reporting Policy in section VI of the SBU Policy on Research Involving rsNAM for details.

If you have any questions, please do not hesitate to call me.

Stony Brook University
Institutional Biosafety Committee (IBC)
Institutional Animal Care and Use Committee (IACUC)
Stem Cell Research Oversight Committee (SCRO)
Registration Form

Submission Type: Continuing Review/Progress Report

Last edited by: David Thanassi

Last edited on: August 28, 2019

Initial	Subsequent Review	
☑	☐	IACUC
☑	☑	IBC
☐	☐	SCRO

[267209-23] Structure and function of the pilus usher/Mechanism of the usher in assembly and secretion of pili

I. Principal Investigator

Name: David Thanassi, PhD

Employee ID: 100331402

Department: Molecular Genetics and Microbiology

Email: david.thanassi@stonybrook.edu

Phone #: x2-4549

Fax #: x2-4294

Address: z = 5222

II. Co-Investigators/Additional Personnel

Name	Employee ID	Department	SBU Status
Nadine Henderson, MS	100339545	Molecular Genetics and Microbiology	Research Support Specialist
Peter Benziger, BS	111154711	Molecular Genetics and Microbiology	Graduate
Maheen Rashid, BS	110957519	Molecular Genetics and Microbiology	Graduate
Patrick McLaughlin, PhD	107428044	Molecular Genetics and Microbiology	Fellow
Jessica Johl, BS	110103978	Molecular Genetics and Microbiology	Graduate

III. Research Funding

☑ Internal Funds

☑ External Funds

☑ Seeking Funding

☐ No Internal or External Funds Required

Grant Title	Sponsor	Status	RF Account #
Mechanism of the Usher in Assembly and Secretion of Pili	NIH/NIGMS	Awarded	1134949-1-75977
Modulation of host cell responses by Francisella tularensis	NIH/NIAID	Awarded	1154425-1-84935
REACH: Peptide inhibitors of Porphyromonas gingivalis fimbrial assembly for the prevention of periodontal disease	Long Island Bioscience Hub	Awarded	1145734-1-73538

If externally funded or seeking funding:
Did any investigators listed above indicate having one or more significant financial interests (for themselves or members of their immediate families) on the Investigator Disclosure Form Part I that was submitted in COEUS to the Office of Sponsored Programs?

☑ No ☐ Yes

For all projects:
Do any investigators listed above, or members of their immediate families, have a vested personal interest in the future commercial success of the drug, device, etc. under study (e.g., was involved in discovery, patent, licensing, IND/IDE filings etc.)?

☑ No ☐ Yes ☐ Not Applicable (There is no drug, device, etc. under study.)

IV. IACUC

N/A ☐

Use of live vertebrate animals? ☐ No ☑ Yes

Locations where procedures involving live animal subjects will be conducted:

☑ DLAR facility (main or satellite)

☑ Investigator laboratory:

Building: CMM
Floor: 1 and 2
Room(s): 150, 260, and 270

☑ Off-campus site: Public Health Research Institute (PHRI)
Newark, NJ

Proposed species:

Species	Pain/Distress Category
Mice	These studies will cause no pain or distress to the subjects involved (Category A).
Mice	These studies will cause pain or distress that will be relieved by appropriate means (Category B).
Mice	These studies will cause pain or distress that is not relieved (Category C).

If Category C is selected, explain why relief from pain/distress is not appropriate or available:

Some experiments will compare virulence of wild-type and mutant strains of Francisella tularensis and Yersinia pestis in wild-type or genetically-altered mice. In a subset of these experiments, death of the animal will be the endpoint. From our own experience, it is clear that in some instances, euthanasia of what seemed to be moribund animals would have been premature, since mice that appeared to be very ill actually recovered from the infection. Thus, in order to measure virulence accurately, we really need to let the animals die on their own, and we will not interfere by using euthanasia. We also cannot interfere by administering analgesics, since these would alter the immune status of the animal (e.g., by lowering fever or preventing the production of prostaglandins). According to DLAR, unassisted death is considered a form of distress, and that is why we have checked Category C for some of the studies proposed herein. The majority of mice to be used fall within Categories A and B, and we have designed our studies to keep the number of mice in Category C to the absolute minimum.

Do you propose any of the following?

- ☐ Food/water restriction
- ☑ Non-survival surgery
- ☐ Survival surgery
- ☐ Multiple survival surgeries
- ☐ Multiple manipulations/procedures requiring anesthesia (other than survival surgeries)
- ☐ Physical restraint
- ☐ Use of paralytics
- ☑ Biohazard use
- ☐ Controlled Substances (e.g. ketamine, pentobarbital, buprenorphine, morphine, valium, etc.)
- ☐ Keeping animals outside of DLAR for >12 hours
  - Building:
  - Floor:
  - Room(s):
- ☐ Not Applicable

V. IBC

N/A ☐

Use of rsNAM? ☐ No ☑ Yes

Biosafety Level(s): ☑ BSL 1 ☑ BSL 2 ☑ BSL 3

(If more than one BSL, specify in the IBC application which activities will be conducted at each level.)

Locations where rsNAM activities will be conducted:

Building: CMM

Floor: 1 and 2

Room(s): 295, 283, 277, 270 and 260

Will radiological material be used? ☑ No ☐ Yes

Permit holder: **Permit #:**

(Contact Environmental Health and Safety at 632-6410 if no permit # is available.)

Work proposed with select agents? ☐ No ☑ Yes

*(If Yes, you **must** contact Environmental Health and Safety at 632-6410 for additional requirements.)*

Dual use research? ☑ No ☐ Yes

VI. SCRO

N/A ☑

Use of stem cells or totipotent/pluripotent lines? ☑ No ☐ Yes

Are the cells pluripotent? ☐ No ☐ Yes

If no, is inducing pluripotency an objective? ☐ No ☐ Yes

(Complete SCRO application.)

If cells are pluripotent or if inducing pluripotency is an objective, indicate the type(s) of research:

☐ Research involving human embryonic stem cells

hESC listed in NIH Registry? ☐ No ☐ Yes

Cell lines:

☐ Research involving introduction/transplantation of human pluripotent cells from any source into any non-human recipient or animal at any stage of development
(Note: IACUC approval must be obtained before submission to SCRO.)

☐ Introduction of human pluripotent cells or embryonic stem cells into humans
(Note: CORIHS approval must be obtained before submission to SCRO.)

☐ Other research involving the use of human embryos or human embryonic stem cells

Describe:

INSTRUCTIONS TO RESEARCHERS

Review the contents of this form for accuracy and completeness before submitting this package to the appropriate committee(s).

REGISTRATION FORM COMPLETE!

You will need to finish constructing your submission package by adding some required documents if you have not done so already. This one submission package can be used for one, two, or all three committees (IBC, IACUC, SCRO). Just print out and follow these simple directions (also available in the Instructions for IACUC/IBC/SCRO Investigators).

FOR ALL COMMITTEES:
Upload a copy of the grant(s) that support the activity (and that are referenced in the registration document you just completed). This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer.

AND

For IACUC:

Download the IACUC application, which is located in the IACUC Library of the Designer (see 'Select a Library' in Step 1). Once you have completed it and saved it to your computer, upload it back into your submission package. This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer.

For IBC:
Download the IBC application, which is located in the IBC Library of the Designer (see 'Select a Library' in Step 1). Once you have completed it and saved it to your computer, upload it back into your submission package. This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer.

For SCRO:
Download the SCRO Sheet, which is located in the SCRO Library of the Designer (see 'Select a Library' in Step 1). Once you have completed it and saved it to your computer, upload it back into your submission package. This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer.

THEN:

Follow Instructions for IACUC/IBC/SCRO Investigators to obtain all necessary signatures, and submit your package to all appropriate committees.

SUBMISSIONS THAT DO NOT INCLUDE THE REGISTRATION FORM, THE APPROPRIATE APPLICATION, AND ALL OTHER REQUIRED MATERIALS WILL BE CONSIDERED INCOMPLETE AND WILL NOT BE FORWARDED TO THE COMMITTEES FOR ACTION. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT THE OFFICE OF RESEARCH COMPLIANCE AT 631-632-9036.

Stony Brook University

Renaissance School of Medicine
Department of Microbiology and Immunology
Center for Infectious Diseases

October 30, 2019

To Whom It May Concern:

Theresa Haupt worked in my laboratory at Stony Brook University this past summer. My lab has been granted approval by the Institutional Biosafety Committee of Stony Brook University for all of our work. Attached is the documentation for this, which includes the Approval and the Registration form, for October 2018-2019. Maheen Rashid, who was Theresa's designated supervisor, is listed on the registration form. In my lab, Theresa was always under the supervision and guidance of Maheen. Maheen's approval covers the high school and undergraduate students who work under her supervision. Therefore, because of this, we did not submit a prior approval form, as it had already received documented approval from the SBU IBC (please see attached).

Please note that at no time did Theresa work in a BSL-3 area, enter a BSL-3 area, or do any BSL-3 level work. The BSL-3 lab is physically isolated from the BSL-1 and BSL-2 areas, and entrance is restricted. In addition, Theresa also never worked with any vertebrate animals. Even though my laboratory IBC protocols include approvals for this type of work, at no time did Theresa perform vertebrate animal work or was she in an area where such work was occurring.

Sincerely,

David G. Thanassi, Ph.D.
Professor and Chair

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