Boston Children's Hospital

Date: Friday, September 9, 2016 9:26:20 AM

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Boston Children's Hospital Institutional Biosafety Committee (BCH IBC)

It is Boston Children's Hospital policy that all biological research must be submitted to the Boston Children's Hospital Institutional Biosafety Committee (BCH IBC) for review and approval prior to initiation. IBC protocols are approved for 3 years and are subject to an annual verification.

Biological Research is defined as follows:

Laboratory research involving the use of:

- Recombinant and Synthetic Nucleic Acids in cells, organisms and viruses

  Recombinant and synthetic nucleic acids are defined as:
  (i) Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
  (ii) Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
  (iii) Molecules that result from the replication of those described in (i) or (ii) above.

  (E.g. viral vectors, plasmids in E.coli, transduced cell lines, generation of transgenic or knockout animals by recombinant or synthetic nucleic acid molecules.)

  * Please note that the chemical synthesis of recombinant or synthetic nucleic acid molecules does not require an IBC registration.

- Biological agents regardless of pathogenicity to humans. This includes bacteria, viruses, parasites, rickettsia, fungi, microbial toxins and prions.
  (E.g. Staphylococcus aureus, Psuedomonas aeruginosa, Listeria monocytogenes, Diphtheria toxin, Staphyloccocal enterotoxin)

- Human and non human primate blood, unfixed tissues, or cell lines (established or primary) or other potentially infectious materials (OPIM).

Human subject research involving the use of:

- Recombinant and Synthetic Nucleic Acids

  Human gene transfer is the deliberate transfer into human research participants of either:
  (i) Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
  (ii) Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules,that meet any one of the following criteria:
  a. Contain more than 100 nucleotides; or
  b. Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
  c. Have the potential to replicate in a cell; or
  d. Can be translated or transcribed.

- Biological agents regardless of pathogenicity to human, examples include bacteria, viruses, parasites, rickettsia, fungi, biological toxins and prions.

- Xenotransplantation/xenografts

For more information regarding the IBC Meeting Schedule and Policies please go to:
http://web2.tch.harvard.edu/resops/mainpageS2785P108.html

If you have any questions regarding the IBC review, approval or oversight please contact the Biosafety Officer, Despina Felis at Despina.felis@childrens.harvard.edu or 617-919-2288.

Title: test

General Information

1 * **Short Title:**
test

2 **Full Protocol Title:**
test

3 * **Provide a brief description of your project using non-technical terms that will be understood by the members of the IBC with non-scientific background (i.e. support staff or IBC community members). Include broad goals**

and potential benefits of the research. (4-6 sentences).
test

4 * **Please describe the specific methods, procedures and techniques that will be conducted in this protocol. Include all laboratory bench, animal or clinical experiments as applicable. Include all biological agents (e.g. biological organisms, toxins, human materials and recombinant and synthetic nucleic acid molecules) as well as equipment that will be used for the experiments. Include the biohazard potential of the proposed experiments. If multiple experiments will be conducted include a project subtitle with each summary of experimental design.**
test
Note: You may copy and paste the text from a word document.

5
* **Principal Investigator (PI):**Myriam Armant

PI's Home Institution: Boston Children's Hospital

NOTE: To add/Update PI's Home Institution, please go to PI's Account Profile.

NOTE: The Principal Investigator (PI) must have a Harvard faculty-level appointment, with an academic appointment at the level of at least Instructor and cannot be a resident or research fellow. The PI is responsible for the health and safety of their staff and compliance with all local, state and federal laws and regulations applicable to their research. All PI's must complete the CHB IBC Training. If you cannot find the Principal Investigator's name on this list please contact the Biosafety Office at 617-919-2288.

6 * **Does this research involve a human clinical trial (e.g. human gene transfer study)?**
(●) **Yes** ( ) No

7 ***Select the option(s) below that apply to your research:**
- [x] Will your research involve the use of biological organisms or toxins of biological origin (e.g. wild-type or attenuated viruses, bacteria, parasites, fungi, prions, biological toxins etc.)?
- [x] Will your research involve the use of recombinant or synthetic nucleic acid molecules (e.g. genome editing tools, viral vectors such as lentivirus or adenovirus, plasmid vectors, mammalian expression vectors, bacterial artificial chromosomes, shRNA)?
- [x] Will your research involve the use of human materials (cell lines, blood, unfixed tissues or other potentially infectious materials)?
- [x] Will your research involve the use of non human primate (e.g. macaque) materials (cell lines, blood, unfixed tissues or other potentially infectious materials)?
- [x] Will your research involve the use of tissues or substances of biological origin which may be infected with human pathogens? (eg.culturing bacteria from feces)
- [x] Will your research involve the use of animals (e.g. mice, rats, sheep, swine etc.)?
- [x] Will your research involve the use of arthropods (e.g. mosquitos, drosphila melanogaster)?
- [x] Will your research involve the use of plants?

Title: test

Research Staff

1 **Please add the staff members that will be working on this protocol. Please note that only research personnel on this registration may work on this protocol.**

	Name	CHB ID#	Institution	Role On IBC Study	Editor	Protocol Specific Training	Protocol Specific Training Date	Research Safety Training	IBC Training	Vaccine (Date)
View	Milena Di Meo	164782		Research Staff	no	yes	5/17/2013	06/6/2014	No Training Available	

2 **PI:** Myriam Armant

Completed Training Courses & Laboratory Inspection:

Research Safety Training	IBC Training	Laboratory Inspection
Research Safety Training (6/20/2014)	IBC Training (5/29/2013)	Lab Inspection (8/20/2015)

NOTE: The Completed Training Courses required for IBC approval include IBC Training within the last 3 years and Research Safety Training within the last year. A Laboratory Inspection is required within the last year.

Title: test

Biological Organisms or Toxins

1 * **Please list all biological agents (e.g. viruses, bacteria, parasites, fungi, prions and toxins of biological origin) in the research study. Do not include viral vectors in this section. Vector and plasmid information should be entered in the Recombinant DNA section of the registration form.**

	Genus Species	Agent Type	RG
View	Actinobacillus lignieresii	Bacteria	RG-2

Note: If you are using multiple Biological organisms or toxins please add them one at a time.

Title: test

NIH Guidelines

NOTE: The full NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (NIH GUIDELINES) can be found on the following website:
http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

The NIH Guidelines require that Principal Investigators select the appropriate sections of the NIH Guidelines that apply to their research proposal.

1 Please cite the Sections of the NIH rDNA Guidelines that apply to this project.

1.1 * **Section III-A - Experiments must be reviewed by the NIH Recombinant Advisory Committee (RAC), and approved by the NIH Director as well as the IBC before initiation.**

III-A-1 - The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture.

Consideration should be given as to whether the drug resistance trait to be used in the experiment would render that microorganism resistant to the primary drug available to and/or indicated for certain populations, for example children or pregnant women.

○ Yes ◉ **No**

1.2 * **Section III-B - Experiments must be reviewed by the NIH/OBA and approved by the IBC before initiation.**

III-B-1 -Deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and Shigella dysenteriae neurotoxin).

○ Yes ◉ **No**

1.3 * **Section III-C - Experiments require IBC and IRB approvals and RAC review before research participant enrollment begins. III-C-1 - Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants human gene transfer is the deliberate transfer into human research participants of either: 1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or 2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria: a. Contain more than 100 nucleotides; or**
b. Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
c. Have the potential to replicate in a cell; or
d. Can be translated or transcribed.

○ Yes ◉ **No**

1.4 * **Section III-D - Experiments require IBC approval before initiation.**

These experiments involving the introduction of recombinant or synthetic nucleic acid molecules comprise of the bulk of the experiments reviewed by the IBC and include the use of Risk Group 2 through 4 agents and restricted pathogens, or defective pathogens in cell culture, animals, plants, arthropods, and large scale experiments (work with >10 liters of rDNA culture).

For more information on risk groups, click here.

◉ **Yes** ○ No

If YES:

1.4.1 Please select all that apply.

- ☑ **III-D-1 - Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems (e.g. Risk Group 2 agents such as Herpes Simplex Virus, Adenovirus or Risk Group 3 agent such as HIV).**
- ☐ III-D-2 - Experiments in Which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
- ☐ III-D-3 - Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
- ☐ III-D-4 - Experiments Involving Whole Animals (e.g. viral vectors into animals, transduced cells into animals)
- ☐ III-D-5 - Experiments Involving Whole Plants (e.g. genetically engineering plants by recombinant DNA methods, use plants for other experiments (e.g. response to stress), propagate plants, use plants together with microorganisms or insects containing recombinant DNA)
- ☐ III-D-6 - Experiments Involving More than 10 Liters of Culture in one single vessel.

☐ III-D-7 - Experiments Involving Influenza Viruses (e.g. influenza viruses generated by recombinant methods (e.g., generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations).

1.5 * **Section III-E - Experiments require IBC notice simultaneous with initiation.**

These experiments are a category of research that allows the PI to initiate the work at the time of submission of a recombinant or synthetic nucleic acid molecule registration form to the IBC. The protocol will be reviewed by the IBC and any new information from the review will be provided following the IBC meeting.

III-E- Experiments involve the formation of recombinant or synthetic nucleic acid include research that involves less than 2/3 of the genome of Risk Group 2 agents. Experiments involving Risk Group 3 or 4 pathogens or from restricted agents are not included. The creation or production of transgenic rodents qualifies as a III-E experiment. Work with whole plants that involve the use of noxious weeds, non-exotic agents, and exotic agents that won't threaten the ecosystem are also included as III-E experiments.

○ Yes ◉ **No**

If YES:

1.5.1 Please select all that apply.

☐ III-E-1 - Experiments Involving the Formation of Recombinant DNA or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus.

☐ III-E-2 - Experiments Involving Whole Plants (This section covers experiments involving nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-D, or III-F).

☐ III-E-3 - Experiments Involving Transgenic Rodents (e.g. the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or BL4 containment are covered under Section III-D-4, Experiments Involving Whole Animals.

1.6 * **Section III-F - Are exempt experiments. They represent recombinant or synthetic nucleic acid molecules that do not pose a significant risk. The BCH IBC requires review and registration of III-F experiments.**

○ Yes ◉ **No**

If YES:

1.6.1 Please select all that apply.

There are no items to display

Title: test

Recombinant or Synthetic Nucleic Acid Molecules

Recombinant and Synthetic Nucleic Acid Molecules are defined as:
(i) molecules that:
a) are constructed by joining nucleic acid molecules and
b) can replicate in a living cell (i.e. recombinant nucleic acids);

(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids);
or
(iii) molecules that result from the replication of those described in (i) or (ii) above.

Note: At least one vector group must be populated.

1 **Please add the viral vectors (e.g. adeno-associated virus, adenovirus, lentivirus ext.) that will be used in this study.**

Viral Vector(s)	
View	Lentivirus human immunodeficiency virus 1 (HIV 1)
View	Adeno-associated virus (AAV)

Note: If you are using multiple viral vectors, please add one vector at a time.

2

Please add the bacterial plasmid, mammalian plasmids, bacterial artificial chromosomes, yeast artificial chromosomes, oligonucleotites, siRNA or other recombinant or synthetic nucleic acid molecules that will be used in this study.

Bacterial plasmid, bacterial artificial chromosome, yeast artificial chromosome, oligonucleotide, siRNA or other recombinant or synthetic nucleic acid molecules

View test

Note: If you are using multiple plasmids or other recombinant or synthetic nucleic acid molecules, please add one group at a time.

Title: test

Human Materials

1 **Please select the human materials that apply to your study:**

1.1 * **Human cell lines (primary or established)**

○ Yes ◉ **No**

If YES:

1.1.1 **Please list the type of cell lines that will be used. Please indicate if they are primary cell lines or established cell lines:**

1.2 * **Human blood, human blood components, and products made from human blood**

◉ **Yes** ○ No

1.3 * **Human embryonic stem cells**

○ Yes ◉ **No**

1.4 * **Other potentially infectious materials (OPIM).**

- The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

○ Yes ◉ **No**

If YES:

1.4.1 **Please describe:**

1.5 * **Induced pluripotent stem cells**

○ Yes ◉ **No**

If YES:

1.5.1 **Please describe how these are made.**

2 * **Is it possible to ascertain the identity of the person from whom the human materials originated?**

○ Yes ◉ **No**

If YES:

2.1 **Please list IRB approval #.**

3 * **Will any of the above materials be fixed (e.g. heat killed, immersion into formalin)?**

○ Yes ◉ **No**

If YES:

3.1 **Please list which materials will be fixed and how (e.g. heat or chemical and contact time) are they fixed.**

Title: test

Non Human Primate Materials

1 **Please select the non human materials that apply to your study:**

1.1 * **Non human primate cell lines**

○ Yes ◉ **No**

If YES:

1.1.1 Please specify species and cell line(s) that will be used:

1.2 * **Non human primate blood, blood components, and products made from blood**

○ Yes ◉ **No**

If YES:

1.2.1 Please specify species.

1.3 * **Non human primate tissue**

○ Yes ◉ **No**

If YES:

1.3.1 Please specify the species and tissues from each.

2 * **Will any of the above materials be fixed (e.g. heat killed, immersion into formalin)?**

○ Yes ◉ **No**

If YES:

2.1 Please list which materials will be fixed and how are they fixed.

Title: test

Exposure Control Plan

1 * **Will any of the human and/or non human primate material be known to be infected with a bloodborne pathogen (e.g. HIV, hepatitis B, hepatitis C, herpes B virus)?**

○ Yes ◉ **No**

If YES:

1.1 Please specify what human pathogen(s) are known to be present.

2 * **Will any of the human or non human primate material be tested for bloodborne pathogens prior?**

◉ **Yes** ○ No

If YES:

2.1 Please specify what bloodborne pathogens the material is tested for. Please include the method that was used to test for the bloodborne pathogens.

test

Note: Testing does not ensure the absolute absence of transmissible biological agents. It is also not possible to test for every bloodborne pathogen. Universal precautions must always be used when working with human or non human primate materials regardless of suspected or confirmed infection status.

3 * **Have the staff been offered the hepatitis B vaccine?**

◉ **Yes** ○ No

4 * **Please describe the tasks and procedures in which occupational exposure to human or non human primate materials (e.g. cutting human tissue samples, tissue culture, use of needles or homogenizing cell lines) may occur.**

test

5 * **Please describe the exposure control plan for eliminating or reducing exposure to bloodborne pathogens. Include universal precautions, engineering controls (e.g. Biosafety Cabinet), and work practice controls, personal protective equipment (e.g. lab coat, safety glasses, gloves, face shield) and housekeeping procedures that will be used.**

test

6 * **Please specify how the human or non human primate material will be inactivated on surface.**

☑ **10% Bleach**

☑ **70% Ethanol**

☑ **Tuberculocidal disinfectant**

☑ **Virucidal disinfectant**

☐ Other

If OTHER:

6.1 Please describe:

7 * **Please specify how the solid waste will be disposed of.**

☐ Autoclave and then dispose of in Red Biohazard Waste Container

☑ **Red Biohazard Waste Container**

☐ Other

If OTHER:

7.1 Please describe:

8 * **Please specify how the liquid waste will be inactivated and disposed of.**

☑ **1:10 bleach, let sit for 20 minutes and sink disposal**

☐ Autoclave and then sink disposal

☐ Other

If OTHER:

8.1 Please describe:

Title: test

Material Infected or Potentially Infected With Pathogen

1 * **Please select the genus and species of the source material.**

	Genus/Species	Tissue/Material	Material Procured From
View	test	test	test

Note: Please add infected or potentially infected material one at a time.

Title: test

Animal Research Study

1 * **Please add the animal research model(s) in this study.**

	Species	Biological Agents	Recombinant or Synthetic Nucleic Acid Molecules	Human or Non Human Primate Materials	Other
View	Fish	Actinobacillus	test	test	test

NOTE: Please add one animal research model at a time. For each animal research model include the biological microorganisms, biological toxins, recombinant and synthetic nucleic acid molecules, human or non human primate materials and other biological material that will be administered to the specific animal research model. Please ensure that the dose and route of exposure for the administration of biological agents are reconciled with a submitted or approved animal protocol.

2 **If available, please add the related animal protocol number(s) and project title(s):**

Title: test

Arthropod Study

1 * **What types of arthropods will be used?**

☑ **Mosquito**

☐ Drosophila melanogaster

☐ Musca domestica

☐ Other

If OTHER:

1.1 Please describe:

2 * **What biological agents or recombinant DNA will be used?**
test

3 * **How will the arthropods be infected?**
test

4 * **How will the arthropods be prevented from escaping containment?**
test

5 * **How will the arthropods be euthanized and disposed of?**
test

Title: test

Plant Research

1 * **What type of plants will be used? Please include genus and species.**
test

2 * **What biological agents or rDNA will be used in the plants? Please describe how the plants will be infected.**
test

3 * **Infected plants will be housed in:**
- ☑ **Growth Chamber**
- ☐ Green House
- ☐ Other

If OTHER:
3.1 Please describe:

4 * **Describe the procedures for containment of infected plants.**
test

5 * **Describe how infected plant materials will be rendered non-infectious.**
test

Title: test

Human Studies

1 * **What are the potential biosafety concerns of this clinical study?**
test

2 * **Where will the agent be stored?**
test

3 * **Where will the agent be prepared for administration?**
Children's Hospital Boston Pharmacy

If OTHER:
3.1 Please specify:

4 * **How will the agent be prepared?**
test

4.1 * Please attach standard operating procedure.

Name	Date Last Modified	Version Number	Owner
How Do I Access IBC Training in Netlearning.pdf	9/9/2016 9:25 AM	0.01	Irine Breytburg

5 * **What are the expected number of subjects to be enrolled at CHB?**
6

6 * **Will other institutions be involved in this study?**
○ Yes ◉ **No**

If YES:

6.1 Please select all that apply:

- ☐ Dana-Farber Cancer Institute # of subjects expected:
- ☐ Brigham and Women's # of subjects expected:
- ☐ Beth Israel Deaconess Medical Center # of subjects expected:
- ☐ Mass General Hospital # of subjects expected:
- ☐ Other # of subjects expected:

If OTHER:

6.1.1 Please describe:

7

*** Which IRB will review this study?**

- ◉ **Children's Hospital Boston Institutional Review Board (CHB IRB)**
- ○ Dana Farber Cancer Institute/ Harvard Cancer Center Institutional Review Board (DFCI/HCC IRB)
- ○ Other

If OTHER:

7.1 Please specify:

8 * What is the IRB protocol number?

test

9 * What is the status of the IRB Review?

test

10 Please attach the following as applicable:

Protocol

Name	Date Last Modified	Version Number	Owner
There are no items to display			

Investigator's Brochure

Name	Date Last Modified	Version Number	Owner
There are no items to display			

Informed Consent

Name	Date Last Modified	Version Number	Owner
There are no items to display			

Appendix M (if applicable)

Name	Date Last Modified	Version Number	Owner
There are no items to display			

Correspondence and review from the NIH OBA-RAC (if applicable)

Name	Date Last Modified	Version Number	Owner
There are no items to display			

Other

Name	Date Last Modified	Version Number	Owner
There are no items to display			

11 Enter the IND (FDA) number:

12 Enter RAC number:

Title: test

NIH Guidelines Assurances

1 * I will comply with all requirements of the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules.

◉ **Yes** ○ No

Title: test

Principal Investigator Assurances

1 * **I will comply with the Policies and Procedures set forth by the Boston Children's Hospital Institutional Biosafety Committee (IBC). I will comply with all NIH, CDC, OSHA, and other local, state and federal regulations and laws relevant to this research.**
◉ **Yes** ○ No

2 * **I will ensure that my laboratory has appropriate facilities, equipment, and work practices to conduct this work safely.**
◉ **Yes** ○ No

3 * **I will ensure that all personnel associated with this project have completed all relevant training required.**
◉ **Yes** ○ No

4 * **The information I have submitted regarding this project is accurate and complete. I will maintain this IBC protocol to accurately describe my current research. I will amend my registration or submit a new registration prior to beginning any new research involving biological agents human materials, non-human primate materials and recombinant or synthetic nucleic acid molecules.**
◉ **Yes** ○ No

5 * **I will comply with all federal transport regulations (DOT, ICAO, IATA) pertaining to shipment and transfer of biological materials.**
◉ **Yes** ○ No

6 * **I will immediately (within 24 hours) report incidents involving materials recombinant or synthetic nucleic acid molecules, human materials and non-human primate materials and biological agents including loss, theft, release, or human exposure to the Biosafety Officer at 617-919-2288. Examples of reportable events include the escape of a transgenic mouse or a needlesticks with biological material. I will also immediately report any exposure to biological material to Occupational Health Services (857-218-3046).**
◉ **Yes** ○ No

7 * **I will be responsible for assuring compliance for all biological work conducted under this registration, including all investigators and locations listed.**
◉ **Yes** ○ No

8 * **I will ensure, if applicable, that all research staff on this protocol are offered the available medical surveillance prior to and during the project.**
◉ **Yes** ○ No

9 * **I understand and acknowledge that the commencement of work with live animals must be authorized and approved by both the IBC and the Institutional Animal Care and Use Committee (IACUC). The IACUC has the ultimate authority for authorizing work with live animals. In addition, I will ensure work that is submitted to both the IBC and the IACUC for approval each contain complete and congruent listing of biological agents and procedures.**
◉ **Yes** ○ No

Research Staff

1 **Please add research personnel that will work on this protocol and assign privileges.**

1.1 * **Person - Choose a team member.**
Milena Di Meo

1.2 * **Editor - Indicate if this person should be allowed to edit the online forms, correspond with the IBC office, and be alternate contact when the PI is away.**
○ Yes ◉ **No**

NOTE: It is recommended that one or two persons, other than the PI, are listed as Editors. All Editors of an IBC protocol must complete CHB IBC Training.
Click here for instructions on how to access the IBC training in NetLearning.

2 * **Indicate the individual's role on the study.**
Research Staff

3 * **Has this person received specific training regarding the proposed work in this study?**
◉ **Yes** ○ No

If YES:

3.1 **Please enter the completion date:**
5/17/2013

3.2 **Please indicate who provided the training:**

NOTE: All research personal on an IBC protocol must receive training on the hazards and work practices & procedures of the proposed work. The training may be conducted by the Principal Investigator, designated knowledgeable staff member or the Biosafety office.

4 Completed Training Courses & Laboratory Inspection:

Program	Date Completed
Research Safety Training	6/6/2014
Lab Inspection	10/24/2013
New Employee Research Safety Training	5/17/2013

NOTE: All research staff members are required to have completed New Employee Safety Training and Annual Safety Refresher Training there after.

The New Employee Safety Training and Annual Safety Training schedule can be found on the BCH internal website at: http://web2.tch.harvard.edu/resops/mainpageS2785P1.html

5 Medical Surveillance

Vaccine	Date Completed
Anthrax Vaccine	
DTaP Vaccine	
Hepatits A Vaccine	
Hepatits B Vaccine	
Haemophilus Influenzae Vaccine	
Influenza Vaccine	
Rabies Vaccine	
Streptococcus Pneumoniae Vaccine	
Vaccinia (Smallpox) Vaccine	
Yellow Fever Virus Vaccine	

ID: VIEW4C658F334F400
Name: IBC Research Staff with Current CHB ID#s

Add Biological Organism or Toxin

1 Select the biological agent.
Actinobacillus lignieresii

NOTE: If you are unable to find the desired biological agent in the list, please contact the IBC Office at 617-919-2288.

2 What is the source(s) of the biological agent?
ATCC

If Another Laboratory:

2.1 Indicate Institution and PI:

If OTHER:

2.2 Please specify:

2.3 Please upload order information, Safety Data Sheet or other available information regarding the source of this agent.

Name	Date Last Modified	Version	Owner
There are no items to display			

3 Is this an attenuated strain?
No

If YES:

3.1 Describe how the strain is attenuated.

NOTE: For strains that require verification, include your plan for verification. Attenuated strains that have a wild type strain that are a higher biosafety level will likely need to be verified prior to use at lower containment level.
For questions, contact the Biosafety Office at 617-919-2288.

3.2 Upload validation documentation.

Name	Date Last Modified	Version	Owner
There are no items to display			

4 What is the host range of this organism:
Birds

If OTHER:

4.1 Please specify:

NOTE: The host range of organisms may be found on the Pathogen Safety Data Sheets and Risk Assessment (http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php).

5 **Does the agent contain any foreign or altered genetic material?**
No

If YES:

5.1 Please specify foreign gene products or gene functions targeted:

6 **Is there a post exposure prophylaxis and/or vaccine available that may mitigate the disease or risk of transmission?**
No

If YES:

6.1 Please specify:

7 **Does the organism have any known antibiotic resistance? Include any antibiotics used as selectable markers.**
No

If YES:

7.1 Please specify:

8 **Will experiments result in acquisition of new characteristics such as enhanced virulence, infectivity, drug or antibiotic resistance, or change in host range?**
No

If YES:

8.1 Please explain:

9 **Will you perform procedures to concentrate the organism (e.g. centrifugation)?**
No

If YES:

9.1 Please describe. Include anticipated initial and final volumes, estimated concentration, and specify the units that are used.

10 **Please specify how the organism will be inactivated on a work surface (e.g. laboratory bench):**
70% Ethanol

If OTHER:

10.1 Please describe:

11 **Please specify how the solid waste will be disposed of:**
Red Biohazard Waste Container

If OTHER:

11.1 Please describe:

12 **Please specify how the liquid waste will be inactivated and disposed of:**
Autoclave and then sink disposal

If OTHER:

12.1 Please describe:

If this is a select agent or permissible toxin please answer questions 13 and 14.

13 **How much of the select agents or permissible toxin will be stored in lab?**

14 **How will the select agent or permissible toxin be stored in the lab? How will security be maintained?**

ID: VIEW4CE8AD1B0AC00
Name: View Biological Agent_Microorganism latest

Viral Vectors

1 * **Please select the vector that will be used in this study:**

- ○ Adeno-associated virus (AAV)
- ○ Adenovirus
- ○ Baculovirus
- ○ Epstein-barr virus (EBV)
- ○ Herpes simplex virus type-1 (HSV-1)
- ○ Lentivirus equine infectious anemia virus (EIAV)
- ○ Lentivirus feline immunodeficiency virus (FIV)
- ◉ **Lentivirus human immunodeficiency virus 1 (HIV 1)**
- ○ Lentivirus human immunodeficiency virus 2 (HIV 2)
- ○ Lentivirus simian immunodeficiency virus (SIV)
- ○ Moloney murine leukemia retrovirus (MMLV)
- ○ Murine stem cell virus
- ○ Pseudorabies virus
- ○ Sendai virus
- ○ Sinbus virus
- ○ Vaccinia virus
- ○ Vesicular stomatitis virus (VSV)
- ○ Other

1.1 * **Please describe the selected viral vector. As applicable, for the selected vector please indicate the vector backbone, serotype, generation (e.g. 1st, 2nd, 3rd, 4th), tropism (ecotropic or amphotropic) that you will be using. Include associated plasmids that will be used to prepare the viral vector.**

The lentiviral (LV) vector used is a 3rd generation self-inactivating lentiviral vector, pCCLChimGp91s (aka G1XCGD), which directs gp91phox expression from a codon-optimized form of the CYBB gene preferentially to myeloid cells, with a modified WPRE (PRE4).The G1XCGD lentiviral vector will be packaged by transient transfection of 293T cells with plasmids encoding HIV-1 gag and pol region proteins and the VSV-G membrane protein

1.2 * **What is the source of the viral vector?**

- ☐ Another Laboratory
- ☐ ATCC
- ☐ Bio-Rad
- ☐ Invitrogen
- ☑ **Other**

If Another Laboratory:

1.2.1 Indicate Institution and PI:

If OTHER:

1.2.2

Please specify:

The vector is produced by Genethon in France- No vector is produced in our lab

1.3 **If available, attach a map of the vector.**

Name	Date Last Modified	Version Number	Owner

There are no items to display

2 * **Please describe the risks associated with the vector briefly here. (e.g. transgene effects, risk of insertional mutagenesis, immunological responses, and potential epigenetic changes?)**

All experiments are in vitro so there are no risks to technologists

3 **Please select the host cells that will be used with the recombinant or synthetic nucleic acid molecules? (e.g. propagation of recombinant or synthetic nucleic acid molecules or plasmid preparations):**

- ☐ E.coli K12 derived strain Indicate type and origin:
- ☐ Other cell line(s) Indicate type and origin:

NOTE: Biological organisms such as E.coli K12 should also be included in the Biological Organisms and Toxins section of the registration form.

4 * **Are packaging cells used? (e.g. HEK 293 cells)**

○ Yes ◉ **No**

If YES:

4.1 Describe the packaging system:

4.2 Could these packaging cells supply deleted genes back to the virus?
○ Yes ○ No

5 * **What are the gene(s) or gene function(s) that will be used in the viral vector system? Include the biological origin of the DNA. (e.g. human, mouse, rat, bacteria, jelly fish etc...)**
human

6 * **What does the inserted genetic material encode?**
- ☐ Allergen
- ☐ Oncogene
- ☐ Proto-oncogene
- ☐ Toxin
- ☐ Tracer Protein
- ☐ Tumor suppressor
- ☑ **Other physiological function**

If Other physiological function:

6.1 Please indicate the physiological function of the genetic material:
the lenti vector express the gp91 phox (CYBB gene) sub-unit of the leukocyte anti-microbial oxidase

7 * **Will the vector have modifications to alter the host range or cell tropism of the virus? (i.e. pseudotyped with VSVg envelope protein)**
◉ **Yes** ○ No

If YES:

7.1 Please specify:
it is pseudotyped with VSVg

8 * **Is the vector replication incompetent?**
◉ **Yes** ○ No

If YES:

8.1 Please describe the features that make the vector replication incompetent. If the vector was validated to be replication incompetent please describe the validation method and procedures.
the lentiviral vector used is a 3rd generation self-inactivating lentiviral vector

9 * **Will the vector be amplified?**
○ Yes ◉ **No**

If YES:

9.1 Please describe how the virus will be amplified:

9.2 Will the amplification of the vector increase its replication deficiency?
○ Yes ○ No

10 * **Will this project require large-scale fermentation (>10 liters in a single container) of organism containing recombinant or synthetic nucleic acid molecules?**
○ Yes ◉ **No**

If YES:

10.1 Identify culture room and type of equipment used for large-scale culture growth and handling.

11 * **Is the vector greater than 1/2 (>1/2) or less than 1/2 (<1/2) of the viral genome?**
◉ **less than (<1/2)**
○ greater than (>1/2)

12 * **Please specify how agent will be inactivated on surface:**
- ☑ **10% Bleach**
- ☐ 70% Ethanol

- ☐ Tuberculocidal disinfectant
- ☑ **Virucidal disinfectant**
- ☐ Other

If OTHER:

12.1 Please specify:

13 * **Please specify how the solid waste will be disposed of:**

- ☐ Autoclave and then dispose of in Red Biohazard Waste Container
- ☑ **Red Biohazard Waste Container**
- ☐ Other

If OTHER:

13.1
Please describe:

14 * **Please specify how the liquid waste will be inactivated and disposed of:**

- ☑ **1:10 bleach, let sit for 20 minutes and sink disposal**
- ☐ Autoclave and then sink disposal
- ☐ Other

If OTHER:

14.1 Please specify:

ID: VIEW4C5DC65A24800
Name: Add Vector

Viral Vectors

1 * **Please select the vector that will be used in this study:**

- ◉ **Adeno-associated virus (AAV)**
- ○ Adenovirus
- ○ Baculovirus
- ○ Epstein-barr virus (EBV)
- ○ Herpes simplex virus type-1 (HSV-1)
- ○ Lentivirus equine infectious anemia virus (EIAV)
- ○ Lentivirus feline immunodeficiency virus (FIV)
- ○ Lentivirus human immunodeficiency virus 1 (HIV 1)
- ○ Lentivirus human immunodeficiency virus 2 (HIV 2)
- ○ Lentivirus simian immunodeficiency virus (SIV)
- ○ Moloney murine leukemia retrovirus (MMLV)
- ○ Murine stem cell virus
- ○ Pseudorabies virus
- ○ Sendai virus
- ○ Sinbus virus
- ○ Vaccinia virus
- ○ Vesicular stomatitis virus (VSV)
- ○ Other

1.1 * **Please describe the selected viral vector. As applicable, for the selected vector please indicate the vector backbone, serotype, generation (e.g. 1st, 2nd, 3rd, 4th), tropism (ecotropic or amphotropic) that you will be using. Include associated plasmids that will be used to prepare the viral vector.**

test

1.2 * **What is the source of the viral vector?**

- ☐ Another Laboratory
- ☑ **ATCC**
- ☐ Bio-Rad
- ☐ Invitrogen
- ☐ Other

If Another Laboratory:

1.2.1 Indicate Institution and PI:

If OTHER:

1.2.2

Please specify:

1.3 If available, attach a map of the vector.

Name	Date Last Modified	Version Number	Owner

There are no items to display

2 * **Please describe the risks associated with the vector briefly here. (e.g. transgene effects, risk of insertional mutagenesis, immunological responses, and potential epigenetic changes?)**

test

3 **Please select the host cells that will be used with the recombinant or synthetic nucleic acid molecules? (e.g. propagation of recombinant or synthetic nucleic acid molecules or plasmid preparations):**

☐ E.coli K12 derived strain Indicate type and origin:

☐ Other cell line(s) Indicate type and origin:

NOTE: Biological organisms such as E.coli K12 should also be included in the Biological Organisms and Toxins section of the registration form.

4 * **Are packaging cells used? (e.g. HEK 293 cells)**

○ Yes ◉ **No**

If YES:

4.1 Describe the packaging system:

4.2 Could these packaging cells supply deleted genes back to the virus?

○ Yes ○ No

5 * **What are the gene(s) or gene function(s) that will be used in the viral vector system? Include the biological origin of the DNA. (e.g. human, mouse, rat, bacteria, jelly fish etc...)**

test

6 * **What does the inserted genetic material encode?**

☐ Allergen

☑ **Oncogene**

☐ Proto-oncogene

☐ Toxin

☐ Tracer Protein

☐ Tumor suppressor

☐ Other physiological function

If Other physiological function:

6.1 Please indicate the physiological function of the genetic material:

7 * **Will the vector have modifications to alter the host range or cell tropism of the virus? (i.e. pseudotyped with VSVg envelope protein)**

○ Yes ◉ **No**

If YES:

7.1 Please specify:

8 * **Is the vector replication incompetent?**

○ Yes ◉ **No**

If YES:

8.1 Please describe the features that make the vector replication incompetent. If the vector was validated to be replication incompetent please describe the validation method and procedures.

9 * **Will the vector be amplified?**

○ Yes ◉ **No**

If YES:

9.1 Please describe how the virus will be amplified:

9.2 Will the amplification of the vector increase its replication deficiency?

○ Yes ○ No

10 * **Will this project require large-scale fermentation (>10 liters in a single container) of organism containing recombinant or synthetic nucleic acid molecules?**

○ Yes ◉ **No**

If YES:

10.1 Identify culture room and type of equipment used for large-scale culture growth and handling.

11 * **Is the vector greater than 1/2 (>1/2) or less than 1/2 (<1/2) of the viral genome?**

◉ **less than (<1/2)**

○ greater than (>1/2)

12

* **Please specify how agent will be inactivated on surface:**

☐ 10% Bleach

☐ 70% Ethanol

☑ **Tuberculocidal disinfectant**

☐ Virucidal disinfectant

☐ Other

If OTHER:

12.1 Please specify:

13 * **Please specify how the solid waste will be disposed of:**

☐ Autoclave and then dispose of in Red Biohazard Waste Container

☑ **Red Biohazard Waste Container**

☐ Other

If OTHER:

13.1

Please describe:

14 * **Please specify how the liquid waste will be inactivated and disposed of:**

☑ **1:10 bleach, let sit for 20 minutes and sink disposal**

☐ Autoclave and then sink disposal

☐ Other

If OTHER:

14.1 Please specify:

ID: VIEW4C5DC65A24800
Name: Add Vector

Non-Viral Systems

1 * **Please describe the bacterial plasmid, bacterial artificial chromosome, yeast artificial chromosome, oligonucleotide, siRNA or other recombinant or synthetic nucleic acid molecule that will be used.**

test

2 * **What is the source of the recombinant or synthetic nucleic acids molecules that will be used?**

☐ Another Laboratory

☑ **ATCC**

☐ Bio-Rad

☐ Invitrogen

☐ Other

If Another Laboratory:

2.1

Indicate Institution and PI:

If OTHER:

2.2

Please specify:

3 * **Please describe the risks associated briefly here. (e.g., transgene effects, risk of insertional mutagenesis, immunological responses, and potential epigenetic changes?)**

test

4 * **Please select the host cells that will be used for replication of the recombinant or synthetic nucleic acid molecules? (e.g., propagation of recombinant or synthetic nucleic acid molecules):**

☑ **E.coli K12 derived strain** **Indicate type and origin:** test

☐ **Other cell line(s)** **Indicate type and origin:**

NOTE: Biological organisms such as E.coli K12 should also be included in the Biological Organisms and Toxins section of the registration form.

5 * **What are the gene(s) or gene function(s) that will be used? Include the biological origin of the DNA or RNA. (e.g. human, mouse, rat, bacteria, jelly fish etc...)**

test

6 * **What does the inserted genetic material encode?**

- ☑ **Allergen**
- ☐ Oncogene
- ☐ Proto-oncogene
- ☐ Toxin
- ☐ Tracer Protein
- ☐ Tumor suppressor
- ☐ Other physiological function

If Other physiological function:

6.1 Please indicate the physiological function of the genetic material:

7 * **Will this project require large -scale fermentation (>10 liters in a single container) of organism containing recombinant or synthetic nucleic acid molecules?**

○ Yes ◉ **No**

If YES:

7.1 Identify culture room and type of equipment used for large-scale culture growth and handling.

8

* **Please specify how agent will be inactivated on surface:**

- ☑ **10% Bleach**
- ☐ 70% Ethanol
- ☐ Tuberculocidal disinfectant
- ☐ Virucidal disinfectant
- ☐ Other

If OTHER:

8.1 Please specify:

9 * **Please specify how the solid waste will be disposed of:**

- ☑ **Autoclave and then dispose of in Red Biohazard Waste Container**
- ☐ Red Biohazard Waste Container
- ☐ Other

If OTHER:

9.1

Please describe:

10 * **Please specify how the liquid waste will be inactivated and disposed of:**

- [x] **1:10 bleach, let sit for 20 minutes and sink disposal**
- [ ] Autoclave and then sink disposal
- [ ] Other

If OTHER:

10.1 Please specify:

ID: VIEW4CD2FACDB2400
Name: Bacterial Vector

Material Infected With Pathogen

1 * **What is the genus/species of the source material?**
test

2 * **What material will be used?**
test

3 * **Where will you be receiving this material from?**
test

4 **What pathogens are present in the material?**

Genus Species	AgentType
Acinetobacter Iwoffii	Bacteria

If OTHER:

4.1 Please enter the name:

5 **Please choose agents that WILL be extracted from material:**

Genus Species	AgentType
Actinobacillus ureae	Bacteria

If OTHER:

5.1 Please enter the name:

6 * **Do any of the above agents noted in questions 4 and 5 require medical surveillance?**
○ Yes ◉ **No**

If YES:

6.1 Please enter details:

7 * **Please specify how the material will be inactivated on surface:**
- [x] **10% Bleach**
- [ ] 70% Ethanol
- [ ] Tuberculocidal disinfectant
- [ ] Virucidal disinfectant
- [ ] Other

If OTHER:

7.1 Please specify:

8 * **Please specify how the solid waste will be disposed of:**
- [x] **Autoclave and then dispose of in Red Biohazard Waste Container**
- [ ] Red Biohazard Waste Container
- [ ] Other

If OTHER:

8.1 Please describe:

9 * **Please specify how the liquid waste will be inactivated and disposed of:**
- [x] **1:10 bleach, let sit for 20 minutes and sink disposal**
- [ ] Autoclave and then sink disposal
- [ ] Other

If OTHER:

9.1 Please specify:

ID: VIEW4C565B2821C00
Name: Add_Genus_Species

Animal Research Study

1 * **Identify the species:**

- (●) **Fish**
- ( ) Frogs
- ( ) Guinea Pigs
- ( ) Mice
- ( ) Swine
- ( ) Rabbits
- ( ) Rats
- ( ) Sheep
- ( ) Hamsters
- ( ) Other

If OTHER:

1.1 Please specify.

2 Please indicate the biological agent(s) that will be used in the animal research model:

Genus Species	AgentType
Actinobacillus	Bacteria

2.1 Please indicate where the inoculations will take place.

- [x] **Biosafety Cabinet (BSC)**
- [ ] Isolator Cage
- [ ] Bench Top
- [ ] Chemical Fume Hood
- [ ] Other

If OTHER:

2.1.1 Please indicate where.

2.2 Please indicate the dose and route of administration.

test

2.3 Please specify how the agent will be inactivated on a working surface(i.e. Sporklenz, Clidox, Other)

test

3 Please indicate the vector(s), plasmids(s) or other rDNA that will be used in the animal research model:

test

3.1 Please indicate where the inoculations will take place.

- [x] **Biosafety Cabinet (BSC)**
- [ ] Isolator Cage
- [ ] Bench Top
- [ ] Chemical Fume Hood
- [ ] Other

If OTHER:

3.1.1 Please indicate where.

3.2 Please indicate the dose and route administration.

test

3.3 Please indicate how the agent will be inactivated on a working surface(i.e. Sporklenz, Clidox, Other).

test

4 Please indicate the human or non human primate materials that will be used in the animal research model:

test

4.1 Please indicate where the inoculations will take place.

- [x] **Biosafety Cabinet (BSC)**
- [ ] Isolator Cage
- [ ] Bench Top
- [ ] Chemical Fume Hood
- [ ] Other

If OTHER:

4.1.1 Please indicate where.

4.2 Please indicate the dose and route of administration.
test

4.3 Please indicate how the agent will be inactivated on a working surface(i.e. Sporklenz, Clidox, Other).
test

5 Please indicate other biological materials that will be used in the animal research model.
test

5.1 Please indicate the dose and route of administration.
test

5.2 Please indicate where the inoculations will take place.

- [x] **Biosafety Cabinet (BSC)**
- [ ] Isolator Cage
- [ ] Bench Top
- [ ] Chemical Fume Hood
- [ ] Other

If OTHER:

5.2.1 Please indicate where.

5.3 Please specify how the material will be disinfected from working surface (i.e. Sporklenz, Clidox, Other)
test

6 * Are the animals used in the experiment immunocompromised or transgenic?
○ Yes ◉ **No**

7 * Please identify what procedures will be performed after agents are administered:

- [x] **Blood Draw**
- [ ] Necropsy
- [ ] Other

If OTHER:

7.1 Please specify:

8 * Please indicate the duration of time between administration of the biological agent and planned euthanasia of the animal.
test

9 * Which of the following present exposure risks to the investigators or animal care personnel after animal has been inoculated with the above agent(s)?

- [x] **Aerosols**
- [ ] Animal Bite
- [ ] Animal Scratch
- [ ] Bedding
- [ ] Blood
- [ ] Contact with lesions on the animals
- [ ] Feces
- [ ] Mucous membrane contact with secretions or excretions
- [ ] Penetrating injury from contaminated caging
- [ ] Saliva
- [ ] Urine
- [ ] Other
- [ ] None of the above

If OTHER:

9.1 Please specify:

10 * **Is shedding likely to occur after the administration of the above agent(s) to the animals?**

○ Yes ◉ **No**

If YES:

10.1 Please describe. In the description please include how long shedding is likely to continue after agent(s) is(are) administered.

11 * **Will animals be transported outside the animal facility (e.g., for imaging, surgeries, lab)?**

○ Yes ◉ **No**

If YES:

11.1 Please specify the purpose and location (e.g. institution, building, room, PI) of the transport:

ID: VIEW4C5B1306F1000
Name: IBC_Animal Species