Asterisks (*) indicate required fields

Policy

All research work involving recombinant DNA; microbiological agents infectious to humans, animals or plants; select agents and biological toxins; materials from humans and non-human primates, transgenic animals, human gene clinical transfer; xenotransplant clinical studies and field studies involving animals must be reviewed and approved by Boston University's Institutional Biosafety Committee (IBC) and other applicable regulatory agencies before work can commence.

Responsibility

The Principal Investigator (PI) must complete, sign and submit the Biological Use Authorization to the IBC via the Research Information Management System (RIMS). The protocol will be reviewed and discussed at the next scheduled monthly committee meeting if it is received by the submission deadline. A PI who is submitting a new protocol for the first time must also provide a copy of the most current Bio-Sketch. The Bio-Sketch should follow the National Institute of Health (NIH) two-page format. The IBC may contact the PI for questions and comments prior to the scheduled monthly meeting. The PI must provide the information requested to avoid any delay in the review of the protocol. The PI should contact the IBC Office at 617-638-4263 or the Biosafety Office, Research Safety Division of the Office of Environmental Health and Safety (OEHS) at 617-638-8842 for assistance in completing the protocol. The PI must be a faculty member. Applicants who are not faculty members may be listed as an Associate Investigator under the supervision of the PI. Sponsored Personnel are individuals that are sponsored by the PI for an individual project or grant. Post Docs and Fellows that apply for grants under their own names can not apply for an IBC protocol. They must have a faculty sponsor.

Renewals and Updates

Once the protocol is approved, it will be active for three years. The PI must resubmit a completed protocol for review by the IBC after three years before it expires. The IBC Office will send the PI a renewal notice to request an annual update before each annual anniversary date of the approval. The form must be promptly completed and submitted back to the IBC Office.

Amendments

Amendments must be submitted (electronic & hard copy) for changes within an approved project. All changes should be detailed in the amendment form which must be reviewed and approved by the IBC.

Compliance

The laboratory facilities must be inspected within the year prior to approval of the protocol. All laboratory personnel must also complete their annually-required Laboratory Safety Training prior to approval of the protocol. PI's should call the Biosafety Office, Research Safety Division of OEHS for questions or assistance in this matter.

Asterisks (*) indicate required fields

Click on the Save Changes button after completing this form.

Section I. Principal Investigator (MUST be BU Faculty member)

PI Full Name*
BU ID*
BU Alias (Email)*
Non BU Email
Department*
School / College*
Division / Section
Highest Degree Obtained and Specialty
Ph.D
Institution
A Good Institution

Office and Lab Information:

PI Office Address
Office Phone* ?
Lab Phone* ?
Fax

Section II. Laboratory Safety Coordinator

Safety Coordinator Responsibilities

Name*
Phone*
Email*

Section III. 24 Hour Contact for Emergencies

24 Hour Contact Responsibilities

Primary:

Name*
Emergency Phone*
Mobile and/or Pager
Email*

Secondary (optional):

Name
Phone
Mobile and/or Pager
Email

Section IV. Research Safety Inspections

Requires Research Safety Inspections?
- Yes
- No
- See Also

for Safety Inspections, see this PI: Test, PI

Safety Specialist
Phone
Email

Section V. Department Administrator
(This is the individual who will be contacted if the PI cannot be reached. Administrative Contact Information Is For Contact Purposes Only)

Name

Is the Department Administrator a Boston University employee?

(•) Yes ( ) No

Address
Phone
Fax
Email

Section VI. Associate Principal Investigator

Name
BU ID
School
Department
Section
Center
Address
Phone
Fax
Email

Section VII. Sponsored Personnel

Name
BU ID
School
Dept
Section
Center
Address
Phone
Fax
Email

Asterisks (*) indicate required fields

PI Name: *Test, PI
PI BU ID: *U55982740
PI BU Alias: *bjgold
Project Titles: *New Annotations Test

Specify if the research project is a *

- (•) New Project
- ( ) 3 Year Re-submittal
- ( ) Annual Renewal
- ( ) Amendment

What is the source of funding*

- [x] Federal
- [ ] Non-Federal
- [ ] Other

Is your grant administered through: *

- [ ] Boston University - Medical Campus (ORA)
- [x] Boston University - Charles River Campus (OSP)
- [x] Boston Medical Center (ORA)
- [ ] Other (Specify)

Other: test

Anticipated Starting Date*: 08/17/2011

PI CV Formatted in the standard NIH 2 page Bio-Sketch format:

Upload

Pre-2010 applications only: Attach IBC Application (PDF format):

1.)

Upload

2.)

Upload

Please upload any supporting documentation:

1.)

Upload

Asterisks (*) indicate required fields

Instructions:

List the names of all personnel involved in the project **including the Principal Investigator.**

- If the person you would like to add has been entered into your PI profile, click the 'Select personnel from your PI list' button to add each individually, making sure you fill out all required information.

To add additional personnel, first click on Save Changes to save the current person, followed by the Add Personnel button.

PI Name* Test, PI
PI BU ID* U55982740
PI BU Alias* bjgold

Select personnel from your PI list

First* Brian

Last* Gold

BU ID* U55982740

BU Email (@bu.edu)* bjgold

Validate against the BU directory

Roles* test

Training Dates BUMC Training Records Self-Check Training Registration

Lab Safety* 08/17/2011

Receive/Ship 08/24/2011

Training Experience and Dates

rDNA: (If not applicable, please put N/A) * test

Infectious Agents: (If not applicable, please put N/A) * test

Select Agents: (If not applicable, please put N/A) * test

Other training (with Dates) test

Is this person experienced with the procedures involved?*

(•) Yes ( ) No

State how many years of experience, when and where it was received

test

All laboratory staff must complete the Initial Health Questionnaire form. Contact the Director of Occupational Health for any research related medical needs at 617-353-6630 (Charles River Campus) or 617-638-8400 (Medical Campus). All staff who works

with human materials including blood, tissue, cells and bodily fluids must be offered the Hepatitis B vaccine and antibody testing.

Has this individual completed and submitted their Initial Health Questionnaire?*

○ Yes ◉ No

Will this individual be working with human materials?*

○ Yes ◉ No

Has the individual submitted and completed an Authorization for Services for Hepatitis B Vaccine Series?*

○ Yes ◉ No ○ N/A

Please explain why this has not been completed:

test

It is the PI's responsibility to ensure that anyone with potential exposure to blood borne pathogens in research studies or in laborato is offered the Hepatitis B Vaccination Series and antibody testing. There are services administered by Research Occupational Heal Program in compliance with the Blood borne Pathogen Exposure Policy for Boston University/Boston University Medical Campus/B Medical Center. Anyone who declines the vaccine must still be offered the Hepatitis B Vaccine by Research Occupational Health P In addition to visible blood, Cerebral, Synovial, Pleural, Peritoneal, Pericardial and Amniotic fluids, unfixed human tissue, human de lines and human cell cultures are also considered potentially infectious.

Note: Hepatitis B virus has been demonstrated to survive in dried blood at room temperature on environmental surfaces for at lea week

Asterisks (*) indicate required fields

Instructions:
List all laboratories and animal containment areas.
To add additional locations, first click on Save Changes to save the current location, followed by the Add Additional Location b

PI* Test, PI
PI BU ID* U55982740
PI Alias* bjgold

Research laboratory facility is: *

(•) On-site ( ) Off-site

On-site Location:

Campus: BUMC
Building: 580 HARRISON AVE
Floor: 2
Room: 200B

Select a Building | Select a Room | OR | Select from PI locations

General Information:

Biological Safety Level

( ) BSL 1 (•) BSL 2 ( ) BSL 2 w/ BSL 3 Practices
( ) BSL 3 ( ) BSL 4

Animal Biological Safety Level

( ) N/A ( ) ABSL 1 ( ) ABSL 2 ( ) ABSL 2 w/ ABSL 3 Practices
(•) ABSL 3 ( ) ABSL 4

Is the research facility shared with another Principal Investigator?*

( ) Yes (•) No

Most recent laboratory inspection date:*

08/18/2011

Were all the findings during the recent inspection corrected?*

( ) Yes (•) No

Please state the finding/s not corrected:

test

Asterisks (*) indicate required fields

The National Science Advisory Board for Biosecurity (NSABB) defined "dual use research of concern" as research that, ba
understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapp
pose a threat to public health, agriculture, plants, animals, the environment, or materiel.

Please review the eight categories below and indicate if your research falls into any of the dual use research conc

PI Name* Test, PI
BU ID* U55982740
BU Alias* bjgold

Enhance the harmful consequences of a biological agent or toxin.

Disrupt immunity or effectiveness of an immunization without clinical and or agricultural justification

Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against agent or toxin.

Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitate their ability to evade detection methodologies.

Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin

Alter the host range or tropism of a biological agent or toxin.

Enhance the susceptibility of a host population.

Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

Asterisks (*) indicate required fields

PI Name: * Test, PI
PI BU ID: * U55982740
PI Alias: * bjgold

Provide a brief description of the project in 200 words or less

* test

Describe laboratory procedures and manipulations involved in the study. Provide sufficient detail for the reviewer to fully understand the potential health and environmental hazards associated with the project and any steps or procedures in place to limit the potential hazards

* test

Describe the project in Layman's Terms. NIH requirement of 3 to 4 sentences about the goal of the experiment. This should be written in non-technical language (6th grade reading level) and should address foreseeable concerns for non-scientific lay community member. Avoid or fully explain any jargon or abbreviations.
This section will be available to the public as a synopsis of research. Be brief and concise and limit the number of words. Remember that many community members have reservations about the use of biohazards and rDNA in research.

* test

- [ ] Back fastening gowns
- [ ] Other (describe)

Other

Indicate the personal protective equipment to be used in the ***animal containment*** to prevent potential exposure

- [ ] Laboratory coats
- [ ] Disposable gloves
- [ ] Goggles
- [x] Safety glasses
- [x] Face shield
- [ ] Surgical mask
- [ ] Respirator (i.e. N95)
- [x] Shoe cover
- [ ] Head cover
- [x] Powered Air Purifying Respirator (PAPR)
- [x] Disposable scrubs
- [ ] Double gloves
- [ ] Back fastening gowns
- [ ] Other (describe)

Other

Will Biological Safety Cabinets be used for this work?

* ○ Yes ◉ No

Will sharps be used in the studies?

* ○ Yes ◉ No

Describe how you will treat and dispose of the biological or biohazardous wastes: Key points to address

* test

What disinfectant will be used:

* test

Is there a spill kit in the laboratory?*

○ Yes ◉ No

How and where are biohazardous materials stored? Key points to address

* test

Describe how biohazardous materials are transported (indicate nature of primary and secondary containers)? Key points to address

* test

Asterisks (*) indicate required fields

PI Name* Test, PI
PI BU ID* U55982740
PI BU Alias* bjgold

Indicate all laboratory manipulations involved in the research protocol that have the potential to produce aerosols or droplets

- [ ] Homogenizing, tissue grinding
- [ ] Vortexing
- [ ] Vigorous mixing, blending
- [x] Freeze drying, lyophilizing
- [x] Sonicator, ultrasonic cleaners
- [ ] Animal handling, cage changing
- [x] Pipetting infectious liquid
- [ ] Centrifugation, ultra centrifugation
- [x] Opening containers under pressure
- [x] Culture stirrers, shakers
- [x] Plating, colony counting
- [ ] Animal inoculations
- [ ] Animal aerobiology exposure
- [ ] Other (Specify)

Other

Indicate the engineering controls in place to prevent potential exposure from procedures described

- [ ] Work that produce/ or potentially produce aerosols are done in the Biological Safety Cabinet or other containment equipment
- [x] Use centrifuge with sealed rotor or sealed cups
- [x] HEPA and hydrophobic filter protection on the vacuum line
- [x] Gasket blenders/ homogenizers
- [ ] Others (describe)

Other

Indicate the personal protective equipment to be used in the ***laboratory*** to prevent potential exposure

- [ ] Laboratory coats
- [x] Disposable gloves
- [ ] Goggles
- [x] Safety glasses
- [ ] Face shield
- [ ] Surgical mask
- [x] Respirator (i.e. N95)
- [x] Shoe cover
- [ ] Head cover
- [x] Powered Air Purifying Respirator (PAPR)
- [x] Disposable scrubs
- [x] Double Gloves

Asterisks (*) indicate required fields

PI Name* Test, PI
PI BU ID* U55982740
PI BU Alias* bjgold

If your research involves the following materials or activities (check all that apply)...	Example/Description	Then...
☑ Hazardous Biological Agent including Human Cells and Cell Line	Viruses, Bacteria, Fungi, Parasites, Rickettsia, Prion, Human Primary or Cell Lines, Non Human Primate Primary or Cell Lines	Complete a *Hazardous Biological Agent* form for each Agent
☑ Other Potentially Infectious Materials	Other Human Material: Blood, Plasma, Serum, Unfixed Tissue, Organs, Unfixed Cells, Other; Other Non-Human Primate Material: Blood, Plasma, Serum, Unfixed Tissue, Organs, Unfixed Cells, Other; Sheep Material: Unfixed Tissue, Other	Complete a *Potentially Infectious Material* form for each Material
☑ Human Embryonic Stem Cell	Human Embryonic Stem Cell	Complete a *Human Embryonic Stem Cell* form
☑ Select Biological Toxins	Abrin, Botulinum neurotoxins, Conotoxin, Clostridium perfringens epsilon toxin, Diacetoxyscirpenol (DAS), Ricin, Staphylococcal enterotoxins, Saxitoxin, Shiga-like ribosome inactivating proteins, Shigatoxin, Tetrodotoxin, T-2 toxin	Complete a *Select Biological Toxins* form
☑ Field Study with Animals or Insect Vector	Environmental or field studies with animals	Complete a *Field Study with Animals or Insect Vectors* form
☑ High Hazard Chemical	Use of a high hazard chemical	Complete a *High Hazard Chemical* form for each Chemical
☑ Radiation and X-Ray	Use of Radioactively-labeled compounds; Inject animals with radioactive-labeled compounds; X-ray or other imaging of speciments; Use of the irradiator	Complete a *Radiation and X-ray* form
☑ Recombinant DNA	In the context of this application, recombinant DNA molecules are defined as molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or those resulting from such replication. Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo or is biologically active, polynucleotide or polypeptide product, it is exempt from the NIH Guidelines (NIH Guidelines for Research Work Involving Recombinant DNA Molecules).	Complete a *Recombinant DNA* form and Public Health Commission Form
☑ Synthetically derived nucleic acid	The work involves the creation of synthetically derived nucleic acid molecules	Complete relevant section on the *Recombinant DNA* form

molecules		
☑ Live Animal Use	For work involving the use of biohazardous materials or recombinant DNA in live animals	Complete the relevant sections of the Hazardous Biological Agent form or Recombinant DNA form, respectively

Highest BSL necessary for this project:

○ BSL-1 ◉ BSL-2 ○ BSL-2 with special practices of BSL-3
○ BSL-3 ○ BSL-4

Is this a hospital-based project?

○ Yes ◉ No

Asterisks (*) indicate required fields

Instructions:
List all hazardous biological agents.
To add additional agents, first click on Save Changes to save the current agent, followed by the Add Agent button.

PI Name: Test, PI
PI BU ID: U55982740

To filter your lookup results by agent class select one before hitting lookup

Specific Name: * Absidia corymbifera, AP
Strain: test
Agent Class: * Fungi
Obtained From: (i.e. ATCC, BU researcher, etc.)* test
BSL: * BSL-2

Lookup

Does the Genus and species of biologic agent that you are proposing to conduct experiments with cause human disease?*

○ Yes ○ No

Is the particular strain(s) that you propose to work with attenuated?*

○ Yes ○ No

For pathogenic prokaryotes, is an antibiotic resistance marker being introduced?

○ Yes ○ No ○ N/A

Is the microbiological agent classified a Select Agent by CDC/USDA? List of all Select Agents*

○ Yes ◉ No

Is the agent an attenuated strain of a BSL3 or BSL4 microbiological agent?*

○ Yes ◉ No

The IBC requires that the attenuated strain is verified prior to being used in the laboratory. Please provide the name and contact number of the laboratory that will verify your sample. You must also submit a copy of the verification result.

Lab Name

Lab Contact #

Verification Results Upload

Will live animals be used with this agent? *

○ Yes ◉ No

Are all equipment used for biohazardous materials work affixed with biohazard warning labels?*

○ Yes ◉ No

Do you have IRB (Institutional Review Board) approval related to this agent?*

○ Yes ◉ No ○ Pending

Asterisks (*) indicate required fields

Instructions:
List all potentially Infectious Materials.
To add additional potentially infectious material, first click on Save Changes to save the current infectious material, followed by the Add Potentially Infectious Material button.

PI Name* Test, PI
PI BU ID* U55982740
PI Alias* bjgold

Class*
- ○ Other Human Material
- ○ Non-Human Primate Material
- ◉ Sheep Material
- ○ Other

Type of Material*
- ☐ Blood
- ☑ Plasma
- ☐ Serum
- ☐ Unfixed Tissue
- ☑ Organs
- ☐ Cells
- ☐ Other

Other Type test

Source of Material* test

Do you have IRB (Institutional Review Board) approval related to this project?*

○ Yes ◉ No ○ Pending

Asterisks (*) indicate required fields

Name of Cell Line(s)* Test, PI
PI BU ID* U55982740
PI Alias* bjgold

Is the HESC an approved cell line listed in the NIH Human Embryonic Stem Cell Registry?

○ Yes ◉ No

Name of Cell Line(s)* test

Asterisks (*) indicate required fields

PI Name* Test, PI
PI BU ID* U55982740
PI Alias* bjgold

A laboratory that possess a Select Agent Biological Toxin that is less than the maximum excluded amount set by CDC and USDA is exempt from the requirement of the Select Agent regulation. The list of Biological Toxin maximum excluded amount is available at: http://www.cdc.gov/od/sap/sap/toxinamt.htm

If the study involves the use of biological toxins listed by CDC/USDA as Select Agents, provide the total amount to be possessed in the lab for the Biological Toxin/s you will use or possess

Abrin:	test
Botulinum neurotoxins:	
Clostridium perfringens epsilon toxin:	
Conotoxin:	
Diacetoxyscirpenol (DAS):	test
Ricin:	
Staphylococcal enterotoxins:	
Saxitoxin:	test
Shiga-like ribosome inactivating proteins:	
Shigatoxin:	
Tetrodotoxin:	
T-2 toxin:	

Asterisks (*) indicate required fields

PI Name* Test, PI
PI BU ID* U55982740
PI Alias* bjgold

Check all that apply

- [ ] Capture, study and release animals back to the environment or field.
- [ ] Capture and bring back live animals to BU.
- [ ] Capture and bring back animal carcass or tissue to BU

Please provide the IACUC approval number for the study, Species, and ABSL.

Do animals need to be quarantined prior to your use in the study?*

( ) Yes (•) No

If YES, provide the animal containment:

Building | Room | Loc

Is there vaccination recommendation for the activity and type of animals involved in this project?*

( ) Yes (•) No

For Rabies, provide annual titer check

test

Will you bring a first aid kit with you in the field*

( ) Yes (•) No

Why not? test

Asterisks (*) indicate required fields

PI Name* Test, PI
PI BU ID* U55982740
PI BU Alias* bjgold
Instructions:

List all high hazard chemicals.
To add additional chemicals, first click on Save Changes to save the current chemical, followed by the Add High Hazard Chemical button.

Chemical* CHLORO-4-NITROBENZENE, 1- Lookup

CAS Number* 100-00-5

Describe how this chemical will be used in the experiments: * test

How are high hazard chemicals stored?* test

How are they transported (indicate primary and secondary containers)?* test

Asterisks (*) indicate required fields

PI Name* Test, PI
PI BU ID* U55982740
PI Alias* bjgold

Will the study involve the use of Radioactively-labeled compounds?

* ○ Yes ◉ No

Will you inject animals with Radioactively-labeled compounds?

* ○ Yes ◉ No

Will you perform X-ray or other imaging of specimens?

* ○ Yes ◉ No

Will you use the Irradiator?

* ○ Yes ◉ No

Asterisks (*) indicate required fields

PI Name* Test, PI
PI BU ID* U55982740
PI Alias* bjgold

In the context of this application, recombinant DNA molecules are defined as molecules that are constructed outside living
DNA molecules that can replicate in a living cell or those resulting from such replication. Synthetic DNA segments which ar
polypeptide are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed i
polypeptide product, it is exempt from the NIH Guidelines (NIH Guidelines for Research Work Involving Recombinant DNA

***If using rDNA, please complete the Public Health Commission Environmental Health Office Registration Form for Boston Public Health Commission and is a stand-alone document.**

Will rDNA gene be expressed?
*
○ Yes ◉ No

Will the experiments involve rDNA molecules capable of expressing a pathogenic polynucleotide or polypeptide?
*
○ Yes ◉ No

Will the experiments involve the expression of rDNA encoding toxins with LD50 <100 ng/kg body weight?
*
○ Yes ◉ No

Will rDNA construct be provided to another PI for their studies?
○ Yes ◉ No

Will the experiment involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire
*
○ Yes ◉ No

Does the work involve the use or creation of double stranded synthetic nucleic acid that is 200 bps in length or greater?
*
○ Yes ◉ No

Is the viral vector defective?
*
○ Yes ◉ No ○ N/A

Is the viral vector replication competent?
*
○ Yes ◉ No ○ N/A

Will transgenic or knockout animals be used in the experiments?
*
○ Yes ◉ No

Will the experiment involve more than 10 liters of culture (large scale)?
*
○ Yes ◉ No

Specify the relevant section of the NIH Guideline for Research Work Involving Recombinant DNA
*
test

Asterisks (*) indicate required fields

Public Health Commission
Environmental Health Office

Registration Form For rDNA Projects

Principal Investigator:
Test, PI

Project Title:
test

Anticipated Starting Date:
08/17/2011

Brief Description of Project:
test

Institution Name:
Boston University - Charles River Campus (OSP), Boston Medical Center (ORA)

Other:
test

Lab Facility Address(es):
test

Building(s):
580 HARRISON AVE

Room(s):
200B

Are Large Scale Volumes Used (>= 10 liters)?
No

Is an rDNA gene product efficiently expressed?

- ○ Yes
- ○ No

Containment levels:

Highest BSL:

BSL-2

NIH Guideline:

test

Host-Vector Donor System:

test

Lab Personnel to contact in emergency situations requiring immediate remedial action:

24Hour, Name

Emergency Phone:

353-7233

Asterisks (*) indicate required fields

PI Name Test, PI
PI BU ID U55982740
PI BU Alias bjgold

Is the following IBC application complete in its entirety?

* (•) Yes ( ) No

As the Principal Investigator of this project, I certify that the information contained in this application is accurate and complete. I agree to comply with any requirements posed by the Institutional Biosafety Committee (IBC) and pertinent regulatory requirements.

I agree to abide by the following requirements (Check all):

*
- [x] I will not initiate experimentation until this research project has been approve by the IBC.
- [x] I will follow appropriate Biosafety Level laboratory techniques required for this project.
- [x] I will comply with all shipping requirements for materials, as appropriate.
- [x] I will provide to the laboratory staff copies of the approved protocols which describes the potential biohazards and the precautions that must be taken.
- [x] I will train the staff in good microbiological practices and techniques required to ensure safety for this project, and in the procedures for dealing with accidents and waste management.
- [x] I will ensure that all laboratory workers are registered with the IBC.
- [x] I will supervise the staff and correct work errors and conditions that could result in breaches of the Biosafety Manual, Exposure Control Plan, Chemical Hygiene Plan and other plans as appropriate.
- [x] I will submit an amendment for any changes/ additional work to be performed that go beyond the range of the current protocol (before work begins).
- [x] I will obtain required additional approvals if my work involves animals from institutional Animal Care & Use Committee (IACUC) or for the use of primary human tissues or cells from the Institutional Review Board (IRB)
- [x] I will contact Research Occupational Health Program (ROHP) 24/7 at (617) 414-7647 immediately after a potential exposure or accident in my lab.