Creating BUA Protocols with RIMS

A guide to creating online applications for submittal to the Boston University IBC

Last Update: 8-April-2011

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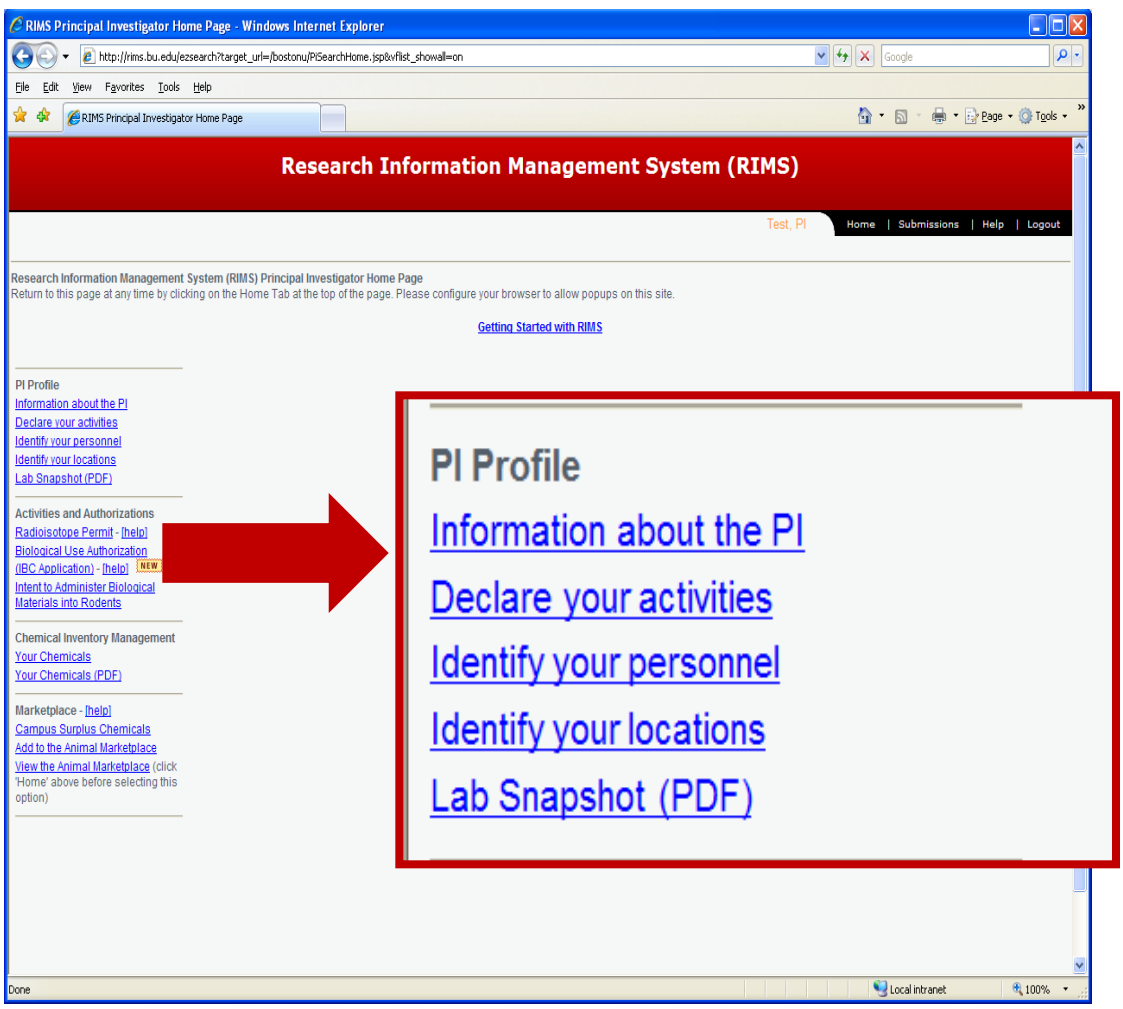
Getting Started

- Log into RIMS
  - http://www.bu.edu/rims
  - Click on “Login” and enter your BU username and Kerberos password
- You will then be directed to your RIMS homepage

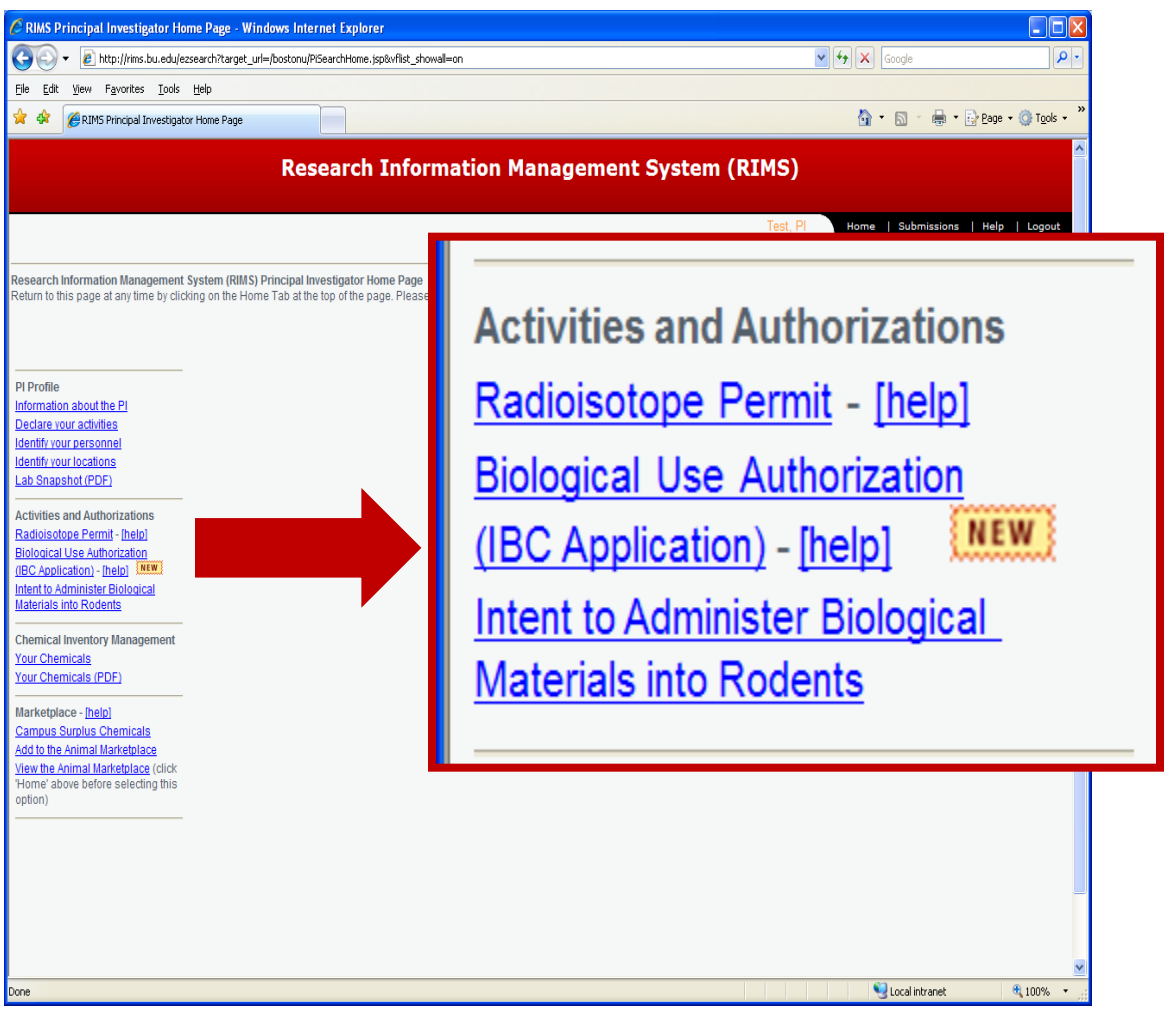
Prerequisites

- The first page you see when you log in will be your personalized RIMS homepage. This will be covered in more detail in another presentation, but for now,
- Ensure that your PI Profile is complete and accurate:
  - Information about the PI
    - Includes office and lab information, and emergency contact information
  - Declare your activities
    - Activities related to your research
  - Identify your personnel
    - List of all personnel in your lab
  - Identify your locations
    - List of your lab locations



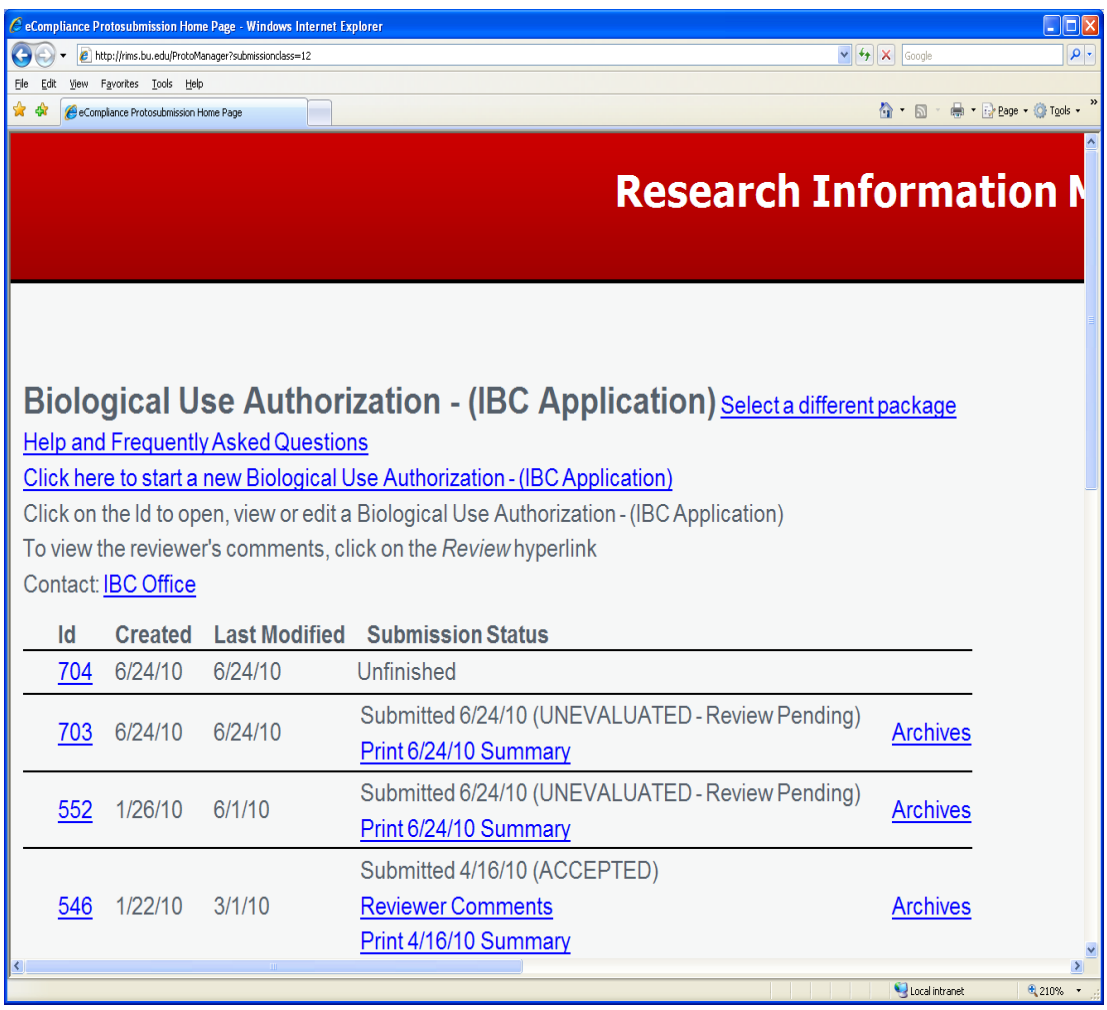
BUA Application

- To start or edit a BUA application, you'll need to go to the BUA Application homepage.
- From the PI homepage, select "Biological Use Authorization (IBC Application)



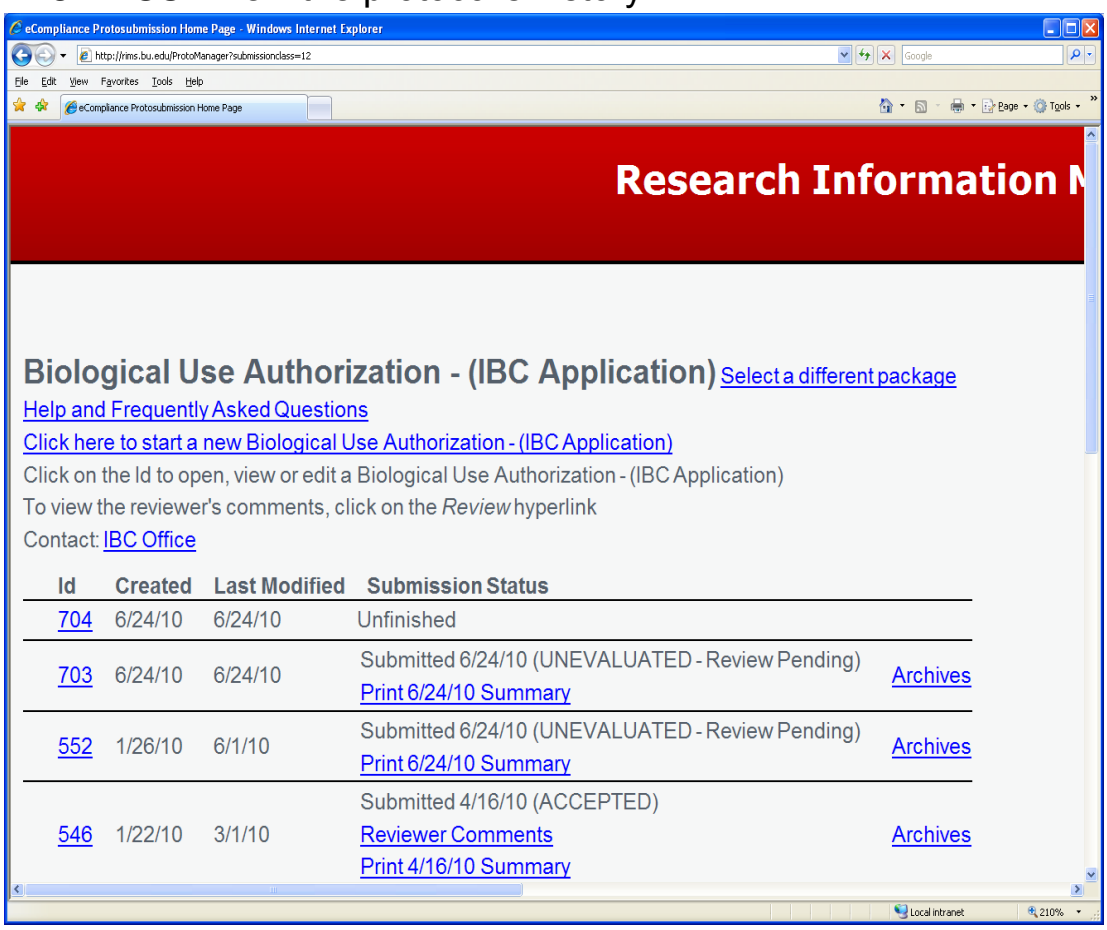
BUA Application

- This page displays all of your BUA applications and the status for each. Older BUA applications (submitted via Word) may not appear.
- Each row in the below table represents a **different** application. Thus, if you have 3 BUAs, you will have 3 entries. In this example, this PI has 6 BUAs in various stages. *Each application (row) is the most recent version of your application, including all amendments and revisions.*



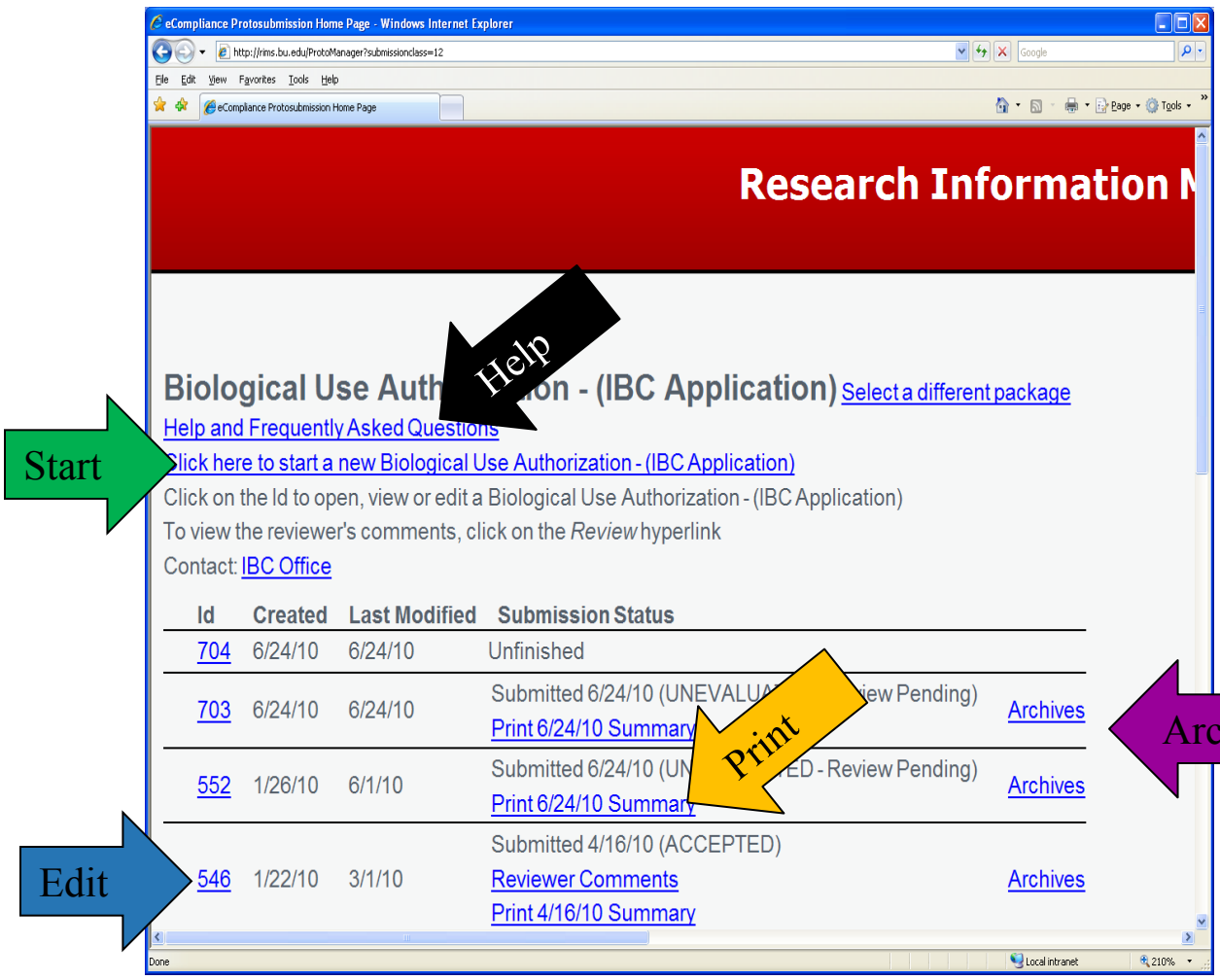
BUA Application

- ID: Identification number for a specific BUA
- Create and Last Modified: Dates referring to when the application was started and last modified by the PI
- Submission Status: Tells you where in the process your application is
  - Unfinished: Not yet submitted to the IBC
  - Unevaluated – Review Pending: Submitted to the IBC, but not reviewed yet
  - Accepted: Accepted by the IBC
  - Declined: Declined by the IBC
  - Deleted: Removed from the system (could be a duplicate protocol, or an expired one, etc.)
- Archives: View the protocol's history



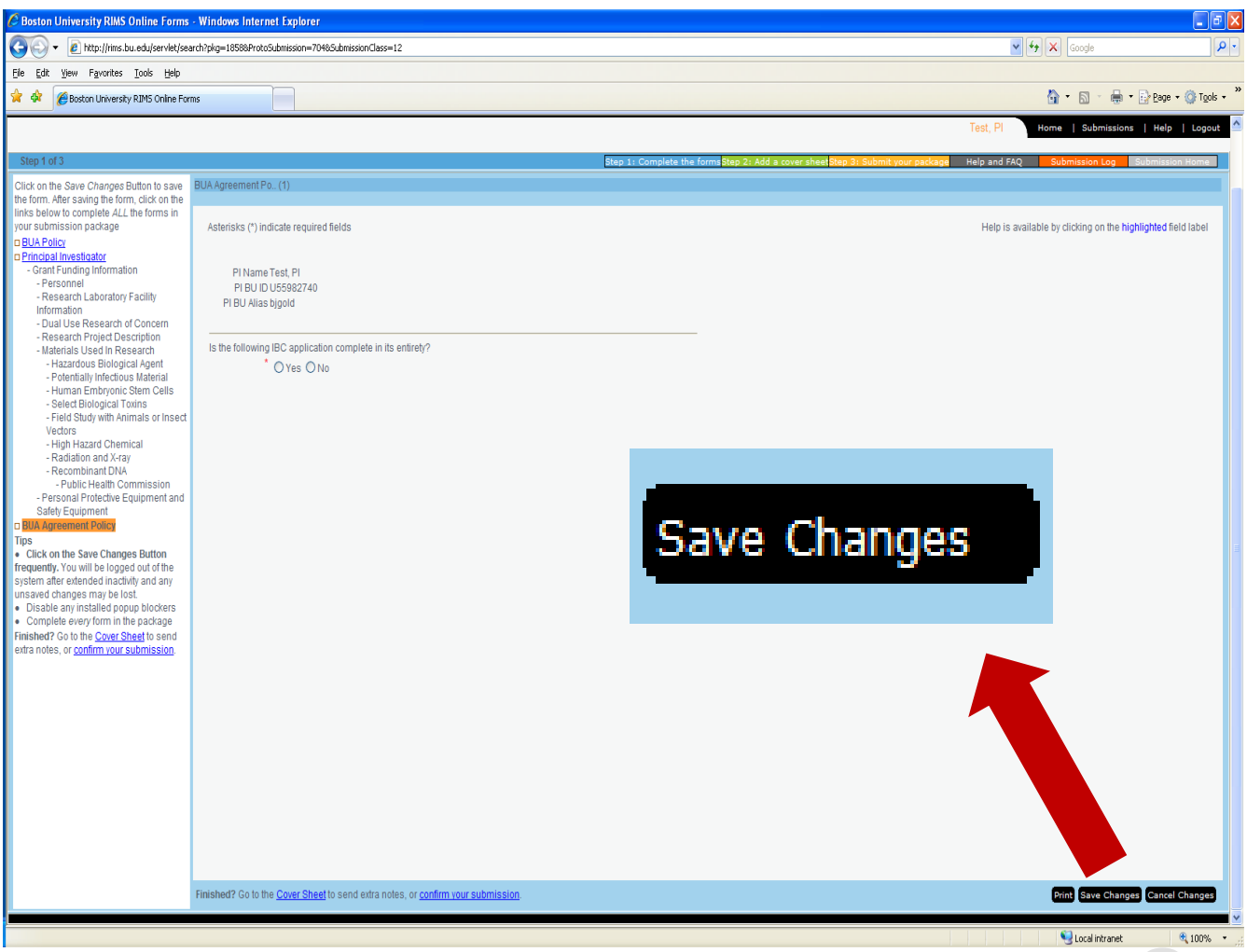
BUA Application

- Start a new BUA application
  - Select “Click here to start a new Biological Use Authorization”
- Edit an existing BUA application (e.g., for an amendment)
  - Click on the ID number of the application you would like to edit
- Print Application Summary
  - Will print a PDF of the most recent submission of your application
- Archives
  - Allows you to view a history of a previously submitted BUA
- Help
  - Help and Frequently Asked Questions



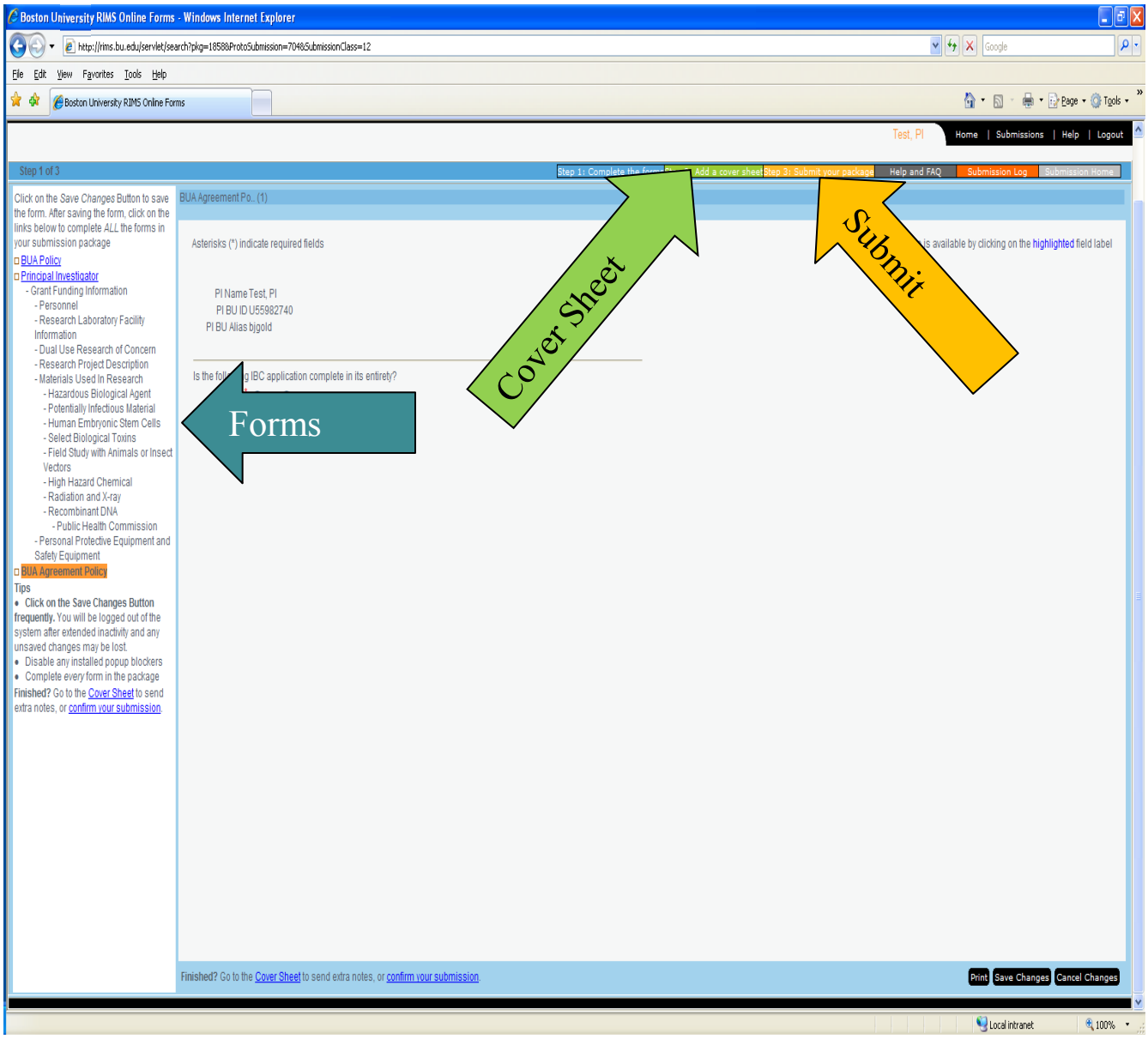
Starting a new BUA Application

- To start a new BUA application, select the appropriate link (see the last slide).
- Editing an existing application? Click the number of the appropriate application
- **Reminder: click "SAVE CHANGES" at the bottom of each page!**
- **Note:** Some yes/no questions may require further information. When you answer a question, it is good practice to click on a blank section of the screen to display any related questions (if there are any).



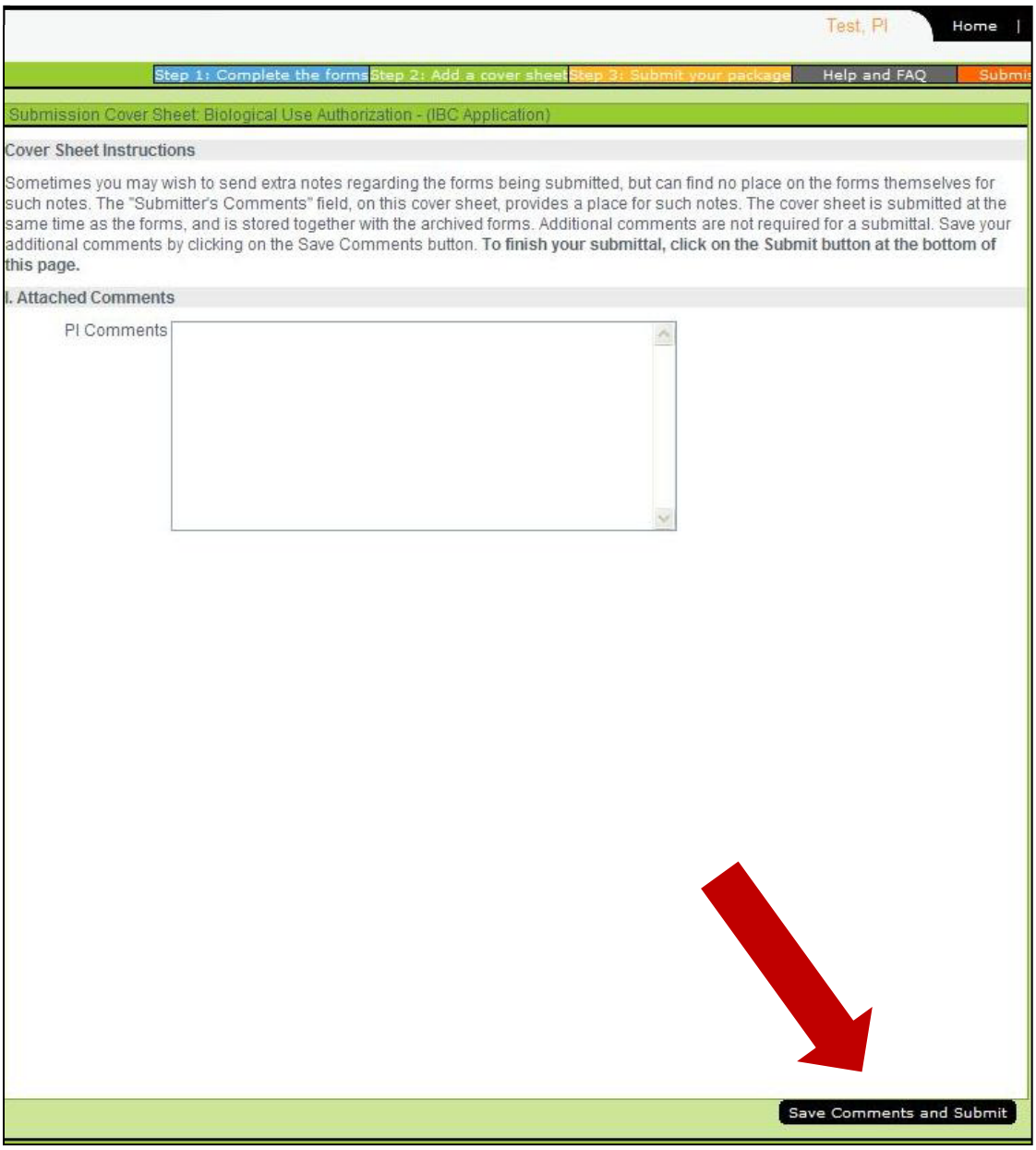
BUA Application in 3 Steps

- 1. Fill out the forms
  - Each form will be covered later in this presentation
- 2. Fill out a cover sheet to send to the IBC (optional, but highly recommended)
- 3. Submit your application



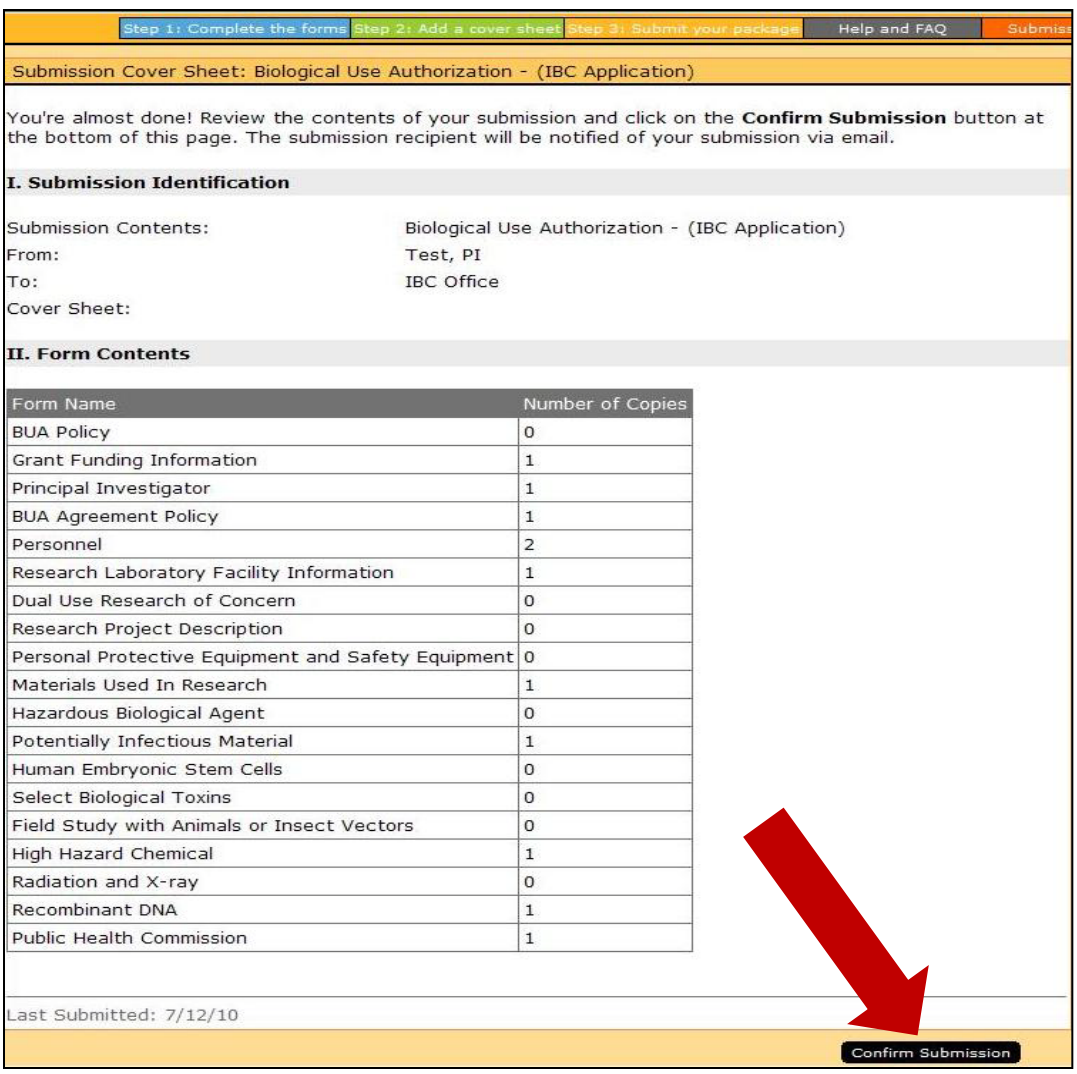
Cover Sheet

- On the cover sheet you may write any comments, questions, etc. to the IBC Office, regarding your application. This is optional, but highly recommended.
- When you have finished with your comments, press the "Save Comments and Submit" button



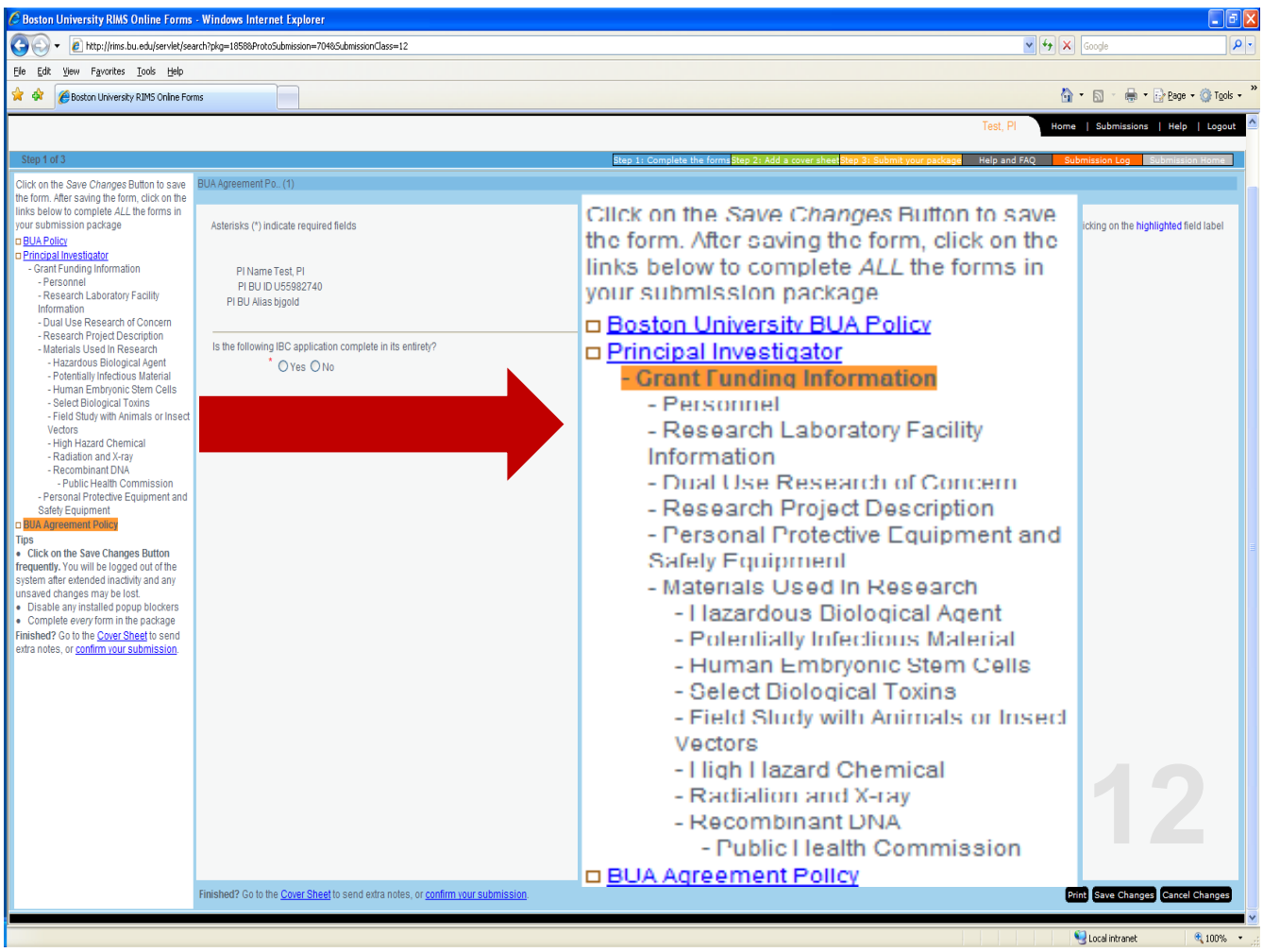
Submittal

- This page contains a summary of your application. You can see from the "number of copies" column how many forms have been filled out.
  - The BUA Policy will always be 0. Other forms that might be 0 would be those forms under Materials Used in Research that you are not using – so if you are not using Stem Cells, then the value of that form will be 0.
  - The number next to the Personnel, Research Laboratory Facility Information, Hazardous Biological Agent, and High Hazard Chemicals refers to the number of these that you have added. So if you have added 4 personnel (including yourself) the value of Personnel will be 4.
- On the submission page, you still need to "Confirm Submission". This will send your application to the IBC Office.



Navigating my BUA Application

- To navigate between different sections in the application, use the left-hand hierarchy.
- The orange highlighted page is the section of the application you are currently viewing.
- You may navigate to any page with a blue hyperlink. To navigate to other (non-hyperlinked) pages in the application, you first need to navigate to the parent page, fill out all required information there, and save changes
  - As shown here, this PI can only navigate to the BUA policy and Principal Investigator sections. If you would like to navigate to the Grant Funding Information page, you must first complete the Principal Investigator section.
- When done, don't forget to **submit your application!**



BUA Application Components

1. BUA Policy
   - Outlines IBC policy
2. Principal Investigator
   - PI Info
   - EHS Safety Specialist
   - Emergency Contact
   - Department Admin/Sponsored Personnel
3. Grant Funding Information
   - Project Title
   - Application Type
   - Funding Source / Grant Administration
4. Personnel
   - Add User
   - Experience and Training Dates
   - Occupational Health
5. Research Laboratory Facility Information
6. Dual Use Research of Concern
7. Research Project Description
   - Brief Project Description (<200 words)
   - Lab Procedures and Manipulations
   - Layman's Project Description
8. Personal Protective Equipment and Safety Equipment
   - Safety Precautions (including PPE)
   - Biosafety Cabinets
   - Biohazardous Waste
9. Materials Used in Research
   - *{various materials}* → See next slide
10. BUA Agreement Policy

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BUA Application Components:

Materials Used in Research

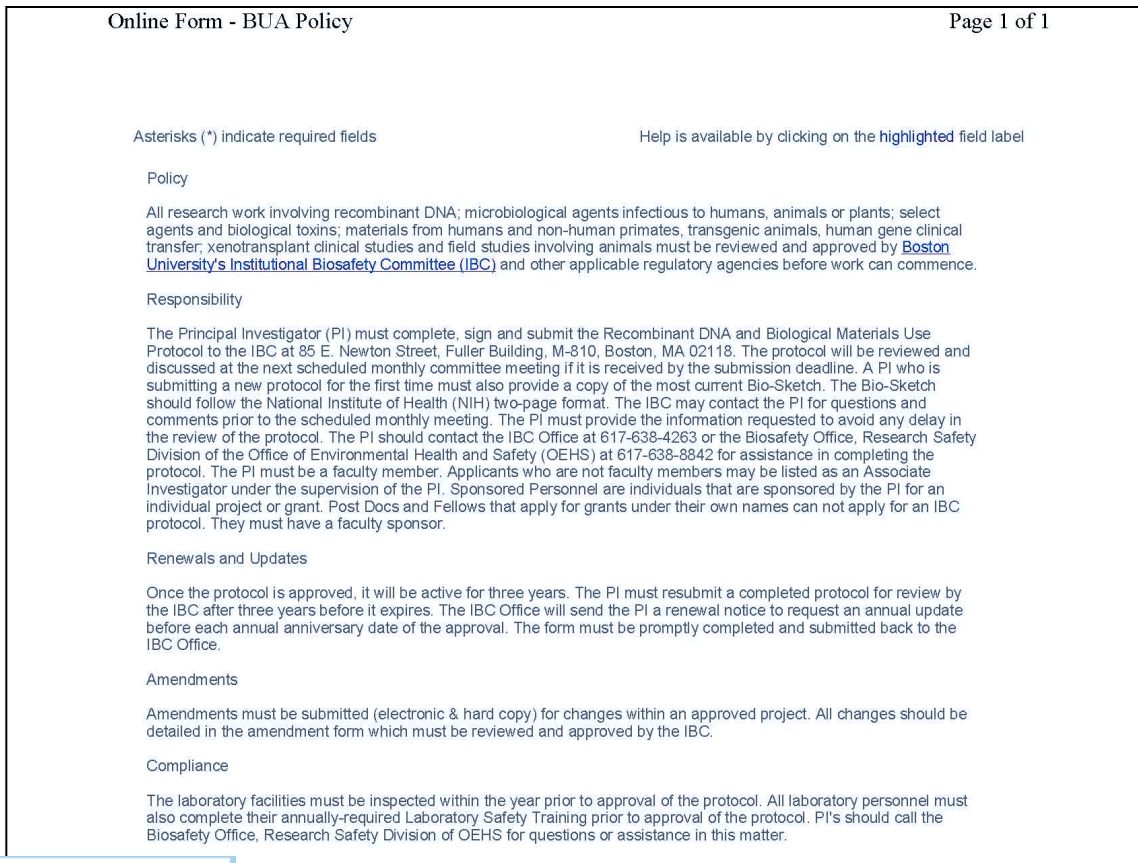
9 Materials Used in Research

- a Hazardous Biological Agent → Viruses, Bacteria, Fungi, Parasites, Rickettsia, Prion, Human Primary or Cell Lines, Non Human Primate Primary or Cell Lines
- b Potentially Infectious Material → 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
- c Human Embryonic Stem Cells
- d 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
- e Field Study with Animals or Insect Vectors → Environmental or field studies with animals
- f High Hazard Chemical → Use of a high hazard chemical
- g 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
- h Recombinant DNA

1 Public Health Commission

BUA Policy

- Details the IBC policy on working with recombinant DNA and other biohazardous materials



Online Form - BUA Policy Page 1 of 1

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

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 Recombinant DNA and Biological Materials Use Protocol to the IBC at 85 E. Newton Street, Fuller Building, M-810, Boston, MA 02118. 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

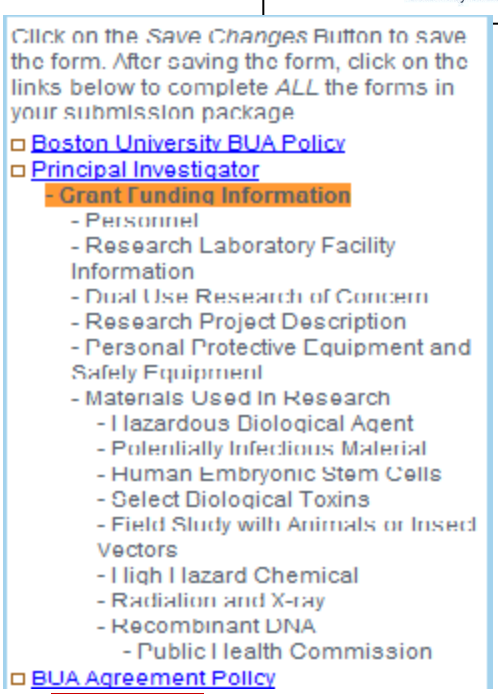
Once the protocol is approved, it will be active for three years. The PI must resubmit a completed protocol for review by the IBC after three years before it expires. The IBC Office will send the PI a renewal notice to request an annual update before each annual anniversary date of the approval. The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

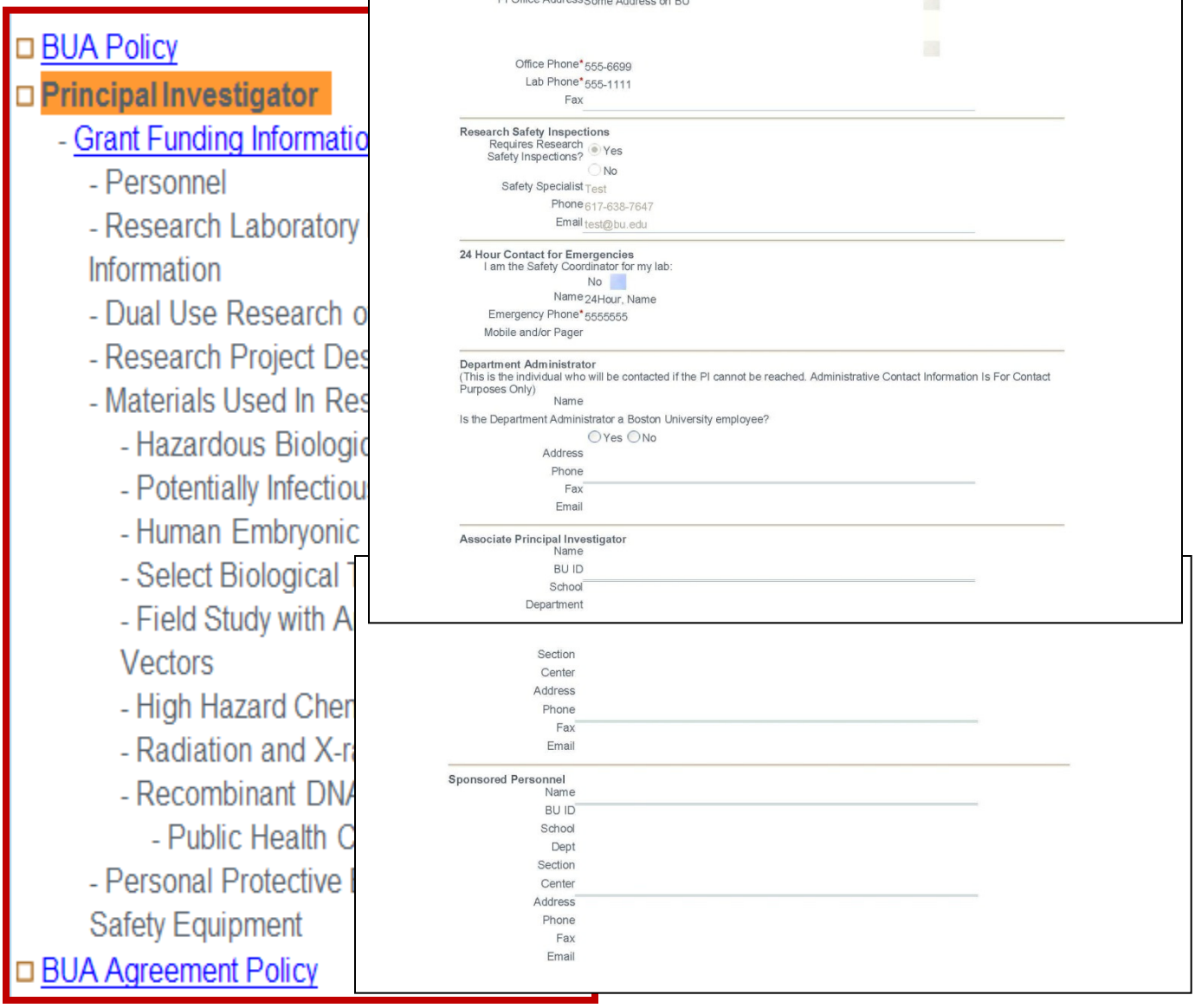


Click on the *Save Changes* Button to save the form. After saving the form, click on the links below to complete *ALL* the forms in your submission package

- Boston University BUA Policy
- Principal Investigator
  - Grant Funding Information
  - Personnel
  - Research Laboratory Facility Information
  - Dual Use Research of Concern
  - Research Project Description
  - Personal Protective Equipment and Safety Equipment
  - Materials Used In Research
    - Hazardous Biological Agent
    - Potentially Infectious Material
    - Human Embryonic Stem Cells
    - Select Biological Toxins
    - Field Study with Animals or Insect Vectors
    - High Hazard Chemical
    - Radiation and X-ray
    - Recombinant DNA
      - Public Health Commission
- BUA Agreement Policy

Principal Investigator

- Most of this is drawn from the “Information about the PI” section of your PI Profile.
- Information about: PI, Emergency Contact, Department Administrator, Associate PIs, and Sponsored Personnel



BUA Policy
Principal Investigator
- Grant Funding Informatio
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- Recombinant DNA
- Public Health C
- Personal Protective E Safety Equipment
BUA Agreement Policy

Online Form - Principal Investigator Page 1 of 2

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

Click on the Save Changes button after completing this form.

Principal Investigator (MUST be BU Faculty member)

PI Full Name*Test, PI
BU ID*U55982740
BU Alias (Email)*bjgold
Non BU Email
Department*Accounting Department Lookup
School / College*College of Communication Lookup
Division / Section bumv
Highest Degree Obtained and Specialty
Institution

Office and Lab Information
PI Office Address Some Address on BU
Office Phone*555-6699
Lab Phone*555-1111
Fax

Research Safety Inspections
Requires Research Safety Inspections? Yes No
Safety Specialist Test
Phone 617-638-7647
Email test@bu.edu

24 Hour Contact for Emergencies
I am the Safety Coordinator for my lab: No
Name 24Hour, Name
Emergency Phone*5555555
Mobile and/or Pager

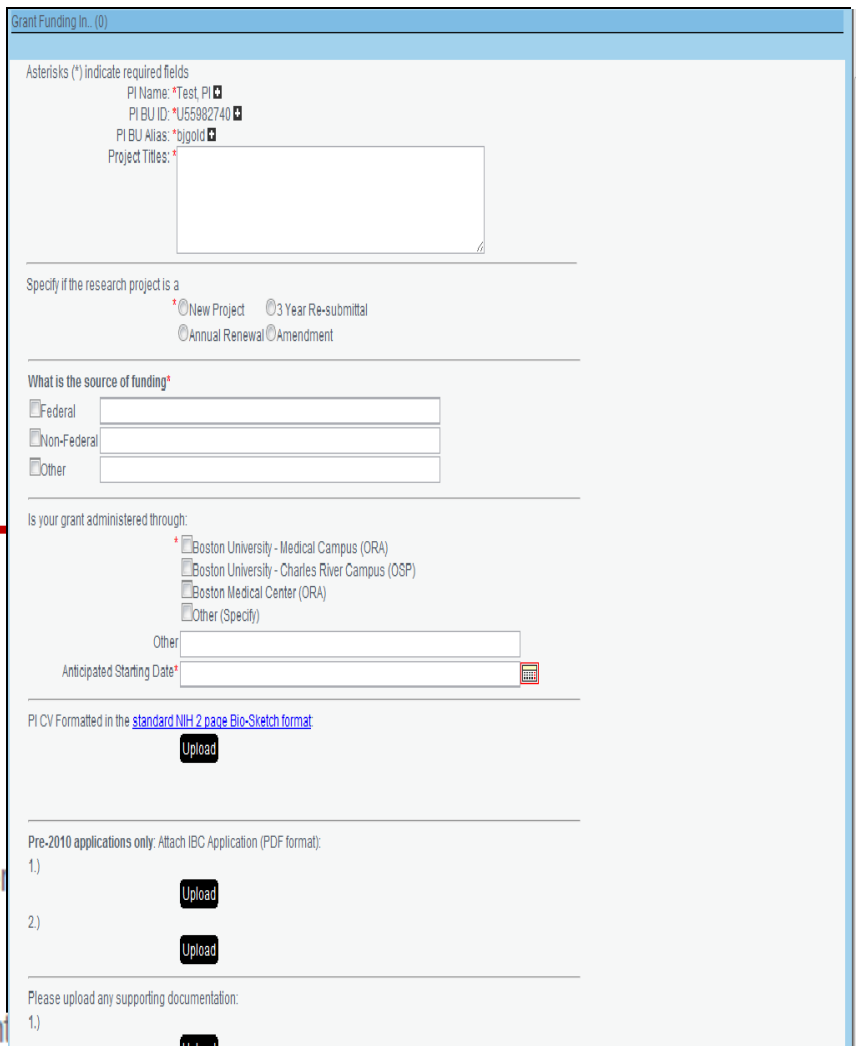
Department Administrator
(This is the individual who will be contacted if the PI cannot be reached. Administrative Contact Information Is For Contact Purposes Only)
Name
Is the Department Administrator a Boston University employee? Yes No
Address
Phone
Fax
Email

Associate Principal Investigator
Name
BU ID
School
Department
Section
Center
Address
Phone
Fax
Email

Sponsored Personnel
Name
BU ID
School
Dept
Section
Center
Address
Phone
Fax
Email

Grant Funding Information

- Application Type
  - New, 3 year resubmission, amendment, annual renewal
- Funding Source and Grant Administration
- PI CV in NIH format



- BUA Policy
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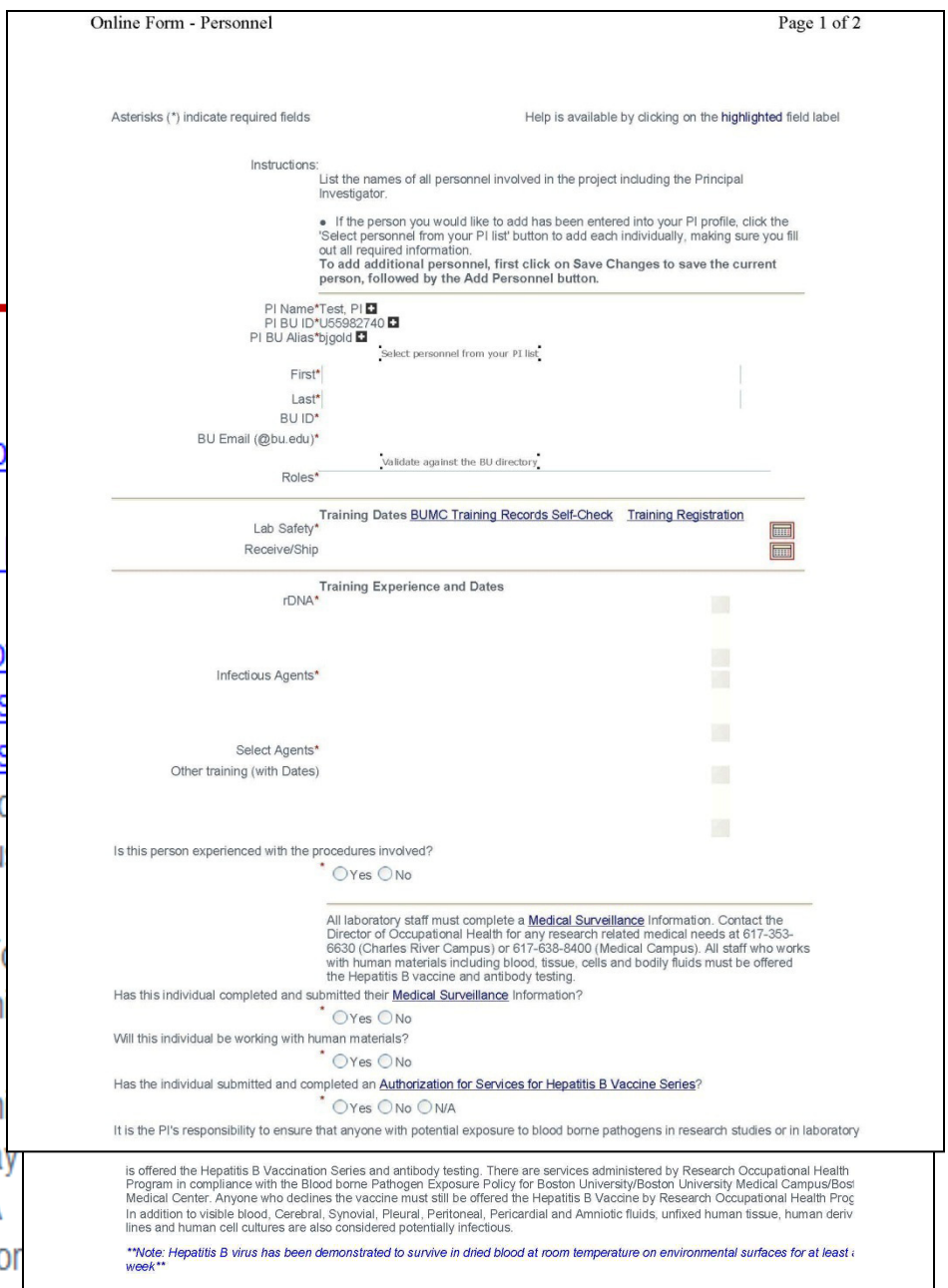
Personnel

- List each person on the permit individually, including the PI.
  - To add a person, you may select from your “Identify your Personnel” list, or type in a person’s BU email address and click the black “Validate” button to populate other information.
  - To add a second person, fill out all the required information for the first person, press “Save Changes” at the bottom of the form, and then press “Add Additional Personnel”.
  - Each person added to your permit will be shown at the top of the screen - to switch between them, click the + button by that person’s name.
- Input each person’s roles in the IBC application (Shipping, Receiving, etc), as well as training dates and experience with the procedures and Medical Surveillance information.


Online Form - Personnel Page 1 of 2

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

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*
Last*
BU ID*
BU Email (@bu.edu)*
Validate against the BU directory
Roles*

Training Dates BUMC Training Records Self-Check Training Registration
Lab Safety*
Receive/Ship

Training Experience and Dates
rDNA*
Infectious Agents*
Select Agents*
Other training (with Dates)

Is this person experienced with the procedures involved? * Yes No

All laboratory staff must complete a Medical Surveillance Information. 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 Medical Surveillance Information? * 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

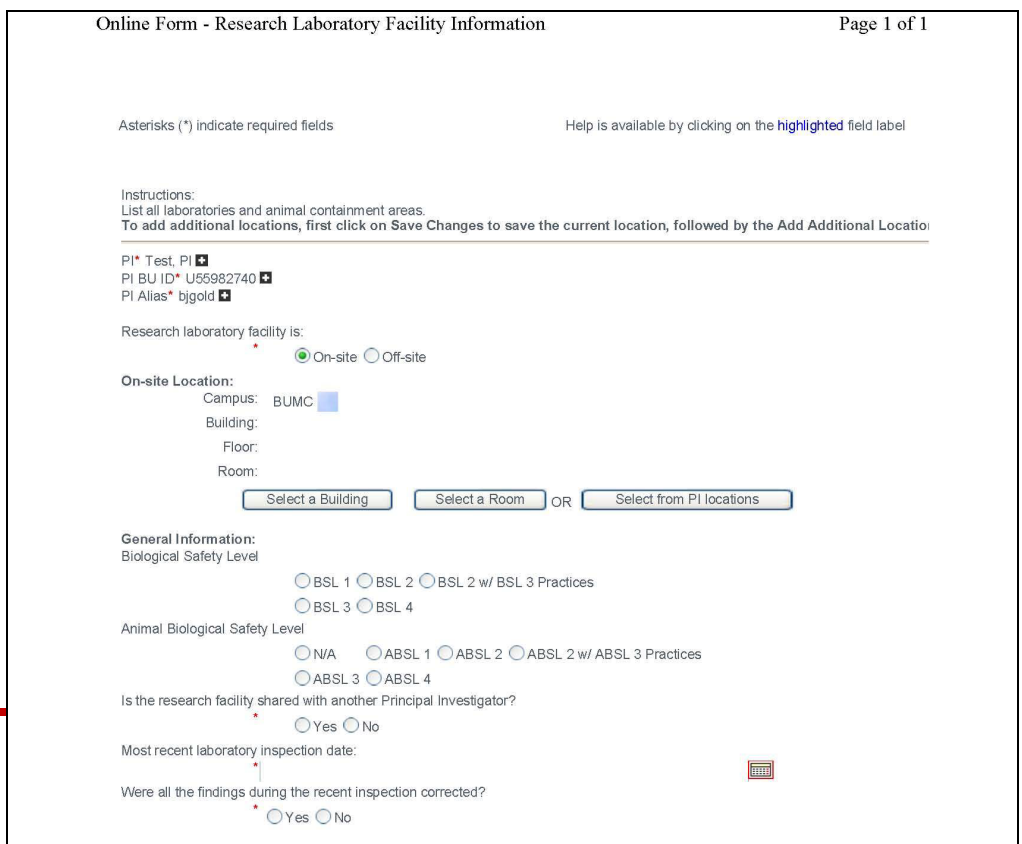
It is the PI's responsibility to ensure that anyone with potential exposure to blood borne pathogens in research studies or in laboratory

is offered the Hepatitis B Vaccination Series and antibody testing. There are services administered by Research Occupational Health Program in compliance with the Blood borne Pathogen Exposure Policy for Boston University/Boston University Medical Campus/Bost Medical Center. Anyone who declines the vaccine must still be offered the Hepatitis B Vaccine by Research Occupational Health Prog In addition to visible blood, Cerebral, Synovial, Pleural, Peritoneal, Pericardial and Amniotic fluids, unfixed human tissue, human deriv 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 least a week

Research Laboratory Facility Information

- On-site or off-site lab location
- List each research location on the permit individually.
  - To add a location, you may select from your “Identify your Locations” list, or select by choosing the campus, building, and room.
  - Next, fill in the BSL, ABSL, shared spaces, and recent inspection dates and results.
  - To add a second location, press “Save Changes” at the bottom of the form, and then press “Add Additional Location”.
  - Each location added to your permit will be shown at the top of the screen - to switch between them, click the + button by that location.



Online Form - Research Laboratory Facility Information Page 1 of 1

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

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 Locatio

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

Research laboratory facility is:
* On-site Off-site

On-site Location:
Campus: BUMC
Building:
Floor:
Room:
Select a Building Select a Room OR Select from PI locations

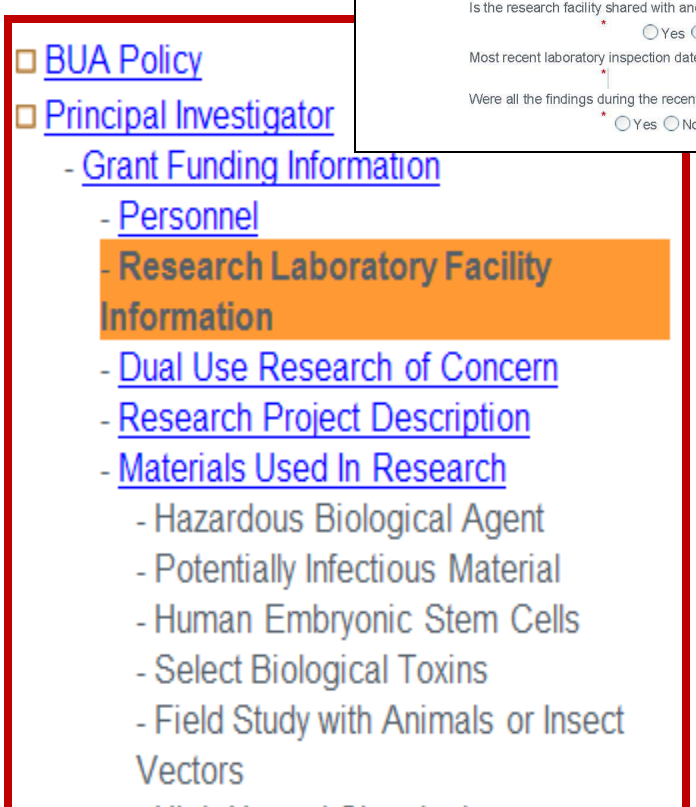
General Information:
Biological Safety Level
BSL 1 BSL 2 BSL 2 w/ BSL 3 Practices
BSL 3 BSL 4

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:
*

Were all the findings during the recent inspection corrected?
* Yes No



- BUA Policy
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    - **Research Laboratory Facility Information**
    - Dual Use Research of Concern
    - Research Project Description
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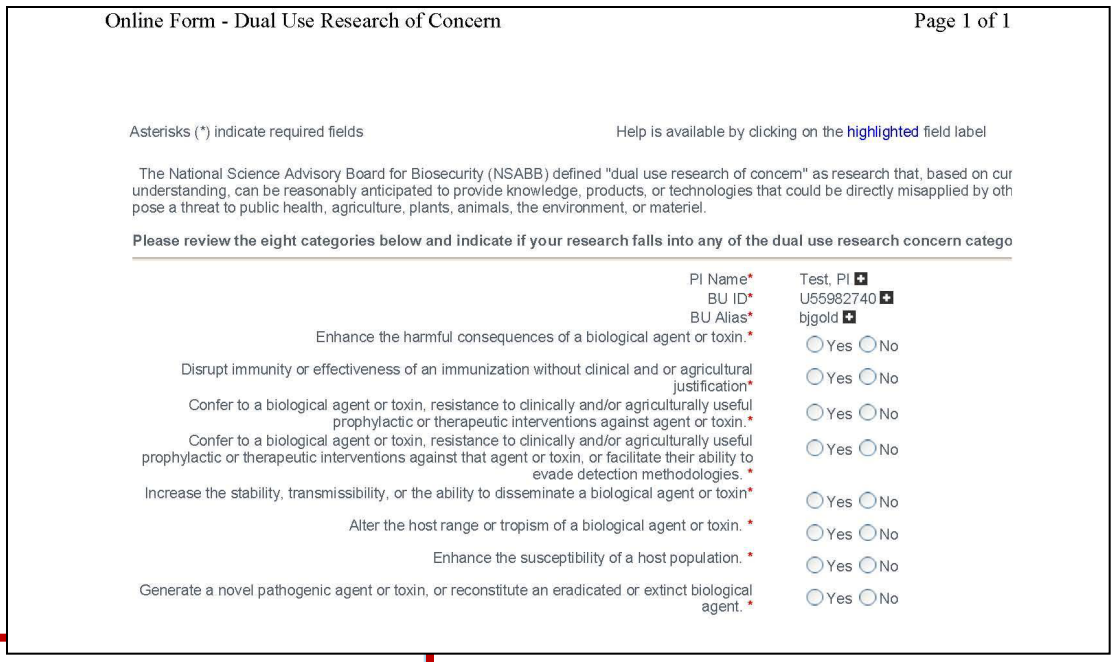
      - Select Biological Toxins
      - Field Study with Animals or Insect Vectors

Dual Use Research of Concern

- Questions asking if your research falls into any of the dual use research concern categories



Online Form - Dual Use Research of Concern Page 1 of 1

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

The National Science Advisory Board for Biosecurity (NSABB) defined "dual use research of concern" as research that, based on cur understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by oth 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 concern catego

PI Name*	Test, PI
BU ID*	U55982740
BU Alias*	bjgold
Enhance the harmful consequences of a biological agent or toxin.*	Yes No
Disrupt immunity or effectiveness of an immunization without clinical and or agricultural justification*	Yes No
Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against agent or toxin.*	Yes No
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. *	Yes No
Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin*	Yes No
Alter the host range or tropism of a biological agent or toxin. *	Yes No
Enhance the susceptibility of a host population. *	Yes No
Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent. *	Yes No

- BUA Policy
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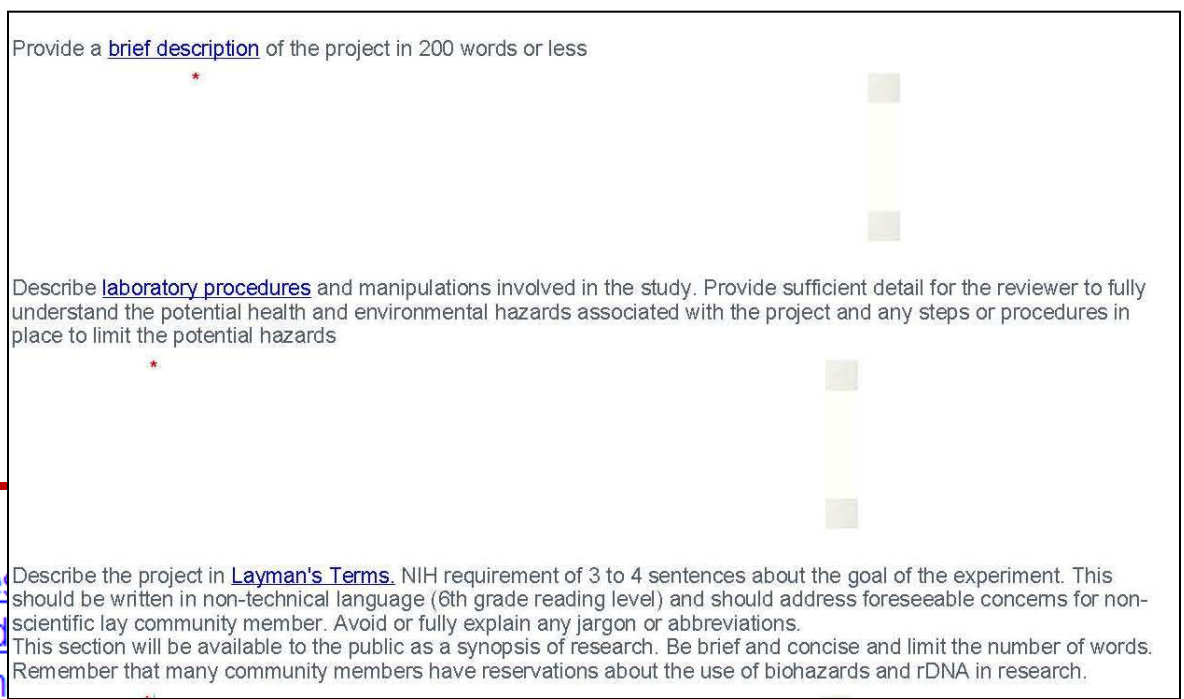
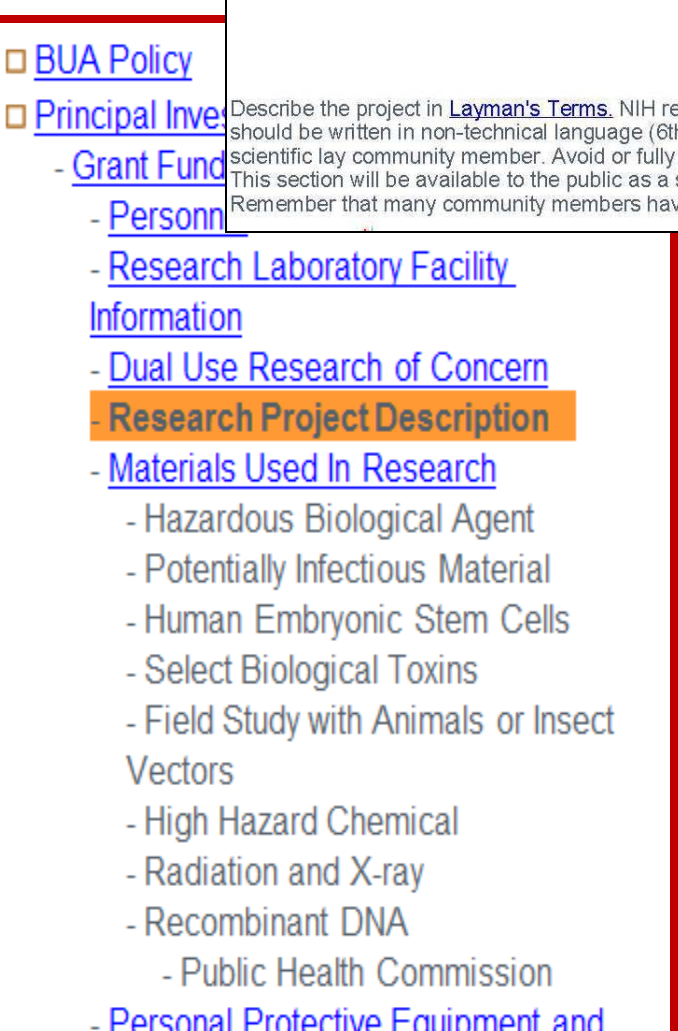
      - Radiation and X-ray
      - Recombinant DNA
        - Public Health Commission
    - Personal Protective Equipment and Safety Equipment
- BUA Agreement Policy

Research Project Description

- The IBC will spend the most time looking at your answers to these three (3) questions, including:
  - Brief Project description (less than 200 words)
  - Detailed description of all laboratory procedures and manipulations, including any potentially or actual hazards and steps to mitigate these hazards
  - NIH Layman's terms description of the project





Personal Protective Equipment (PPE) and Safety Equipment

- If you are working with rDNA, the City of Boston requires that you fill out this ~~registration form for rDNA projects.~~

- BUA Policy
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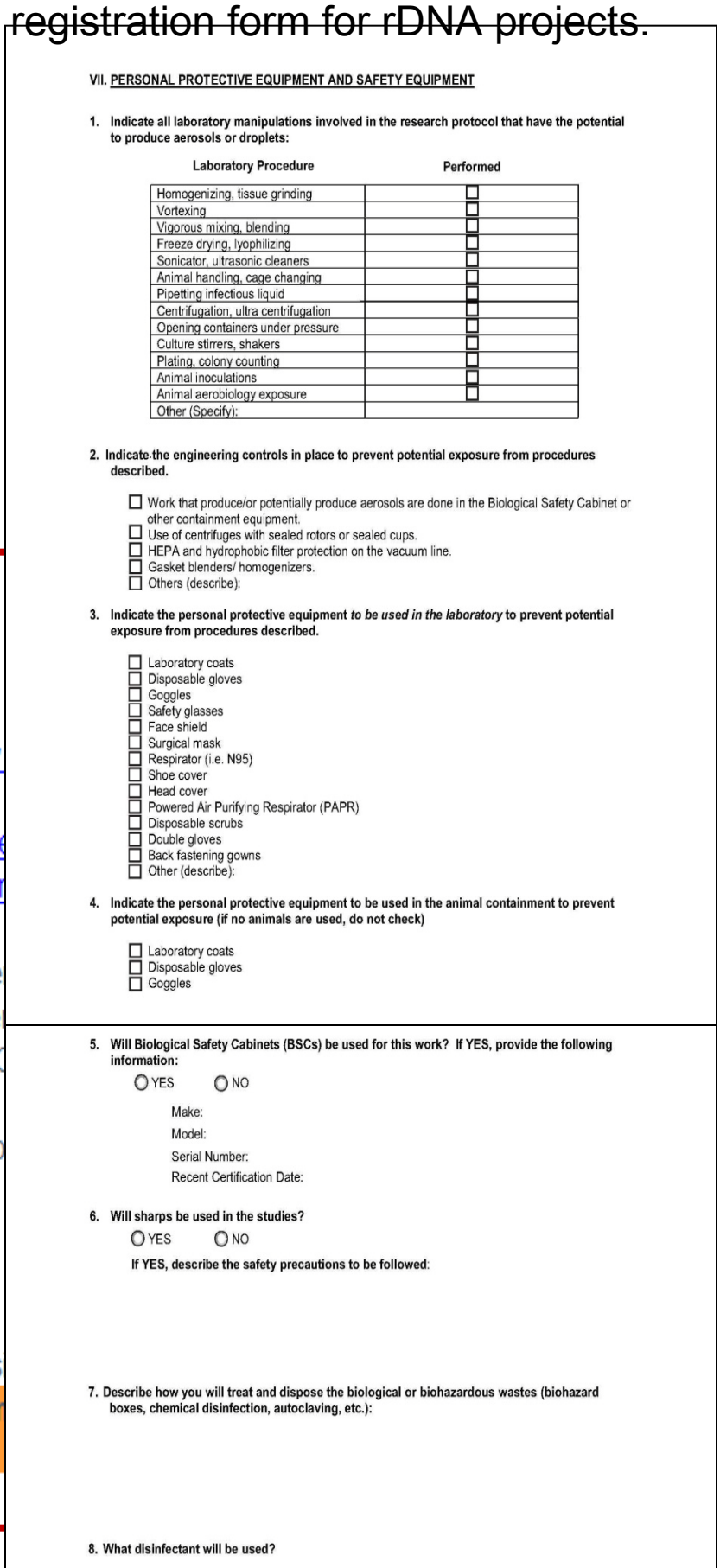
      - Recombinant DNA
        - Public Health Commiss
    - **Personal Protective Equipr and Safety Equipment**
- BUA Agreement Policy



VII. PERSONAL PROTECTIVE EQUIPMENT AND SAFETY EQUIPMENT

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

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

2. **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.
☐ Use of centrifuges with sealed rotors or sealed cups.
☐ HEPA and hydrophobic filter protection on the vacuum line.
☐ Gasket blenders/ homogenizers.
☐ Others (describe):

3. **Indicate the personal protective equipment *to be used in the laboratory* to prevent potential exposure from procedures described.**

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

4. **Indicate the personal protective equipment to be used in the animal containment to prevent potential exposure (if no animals are used, do not check)**

☐ Laboratory coats
☐ Disposable gloves
☐ Goggles

5. **Will Biological Safety Cabinets (BSCs) be used for this work? If YES, provide the following information:**

○ YES ○ NO

Make:
Model:
Serial Number:
Recent Certification Date:

6. **Will sharps be used in the studies?**

○ YES ○ NO

If YES, describe the safety precautions to be followed:

7. **Describe how you will treat and dispose the biological or biohazardous wastes (biohazard boxes, chemical disinfection, autoclaving, etc.):**

8. **What disinfectant will be used?**

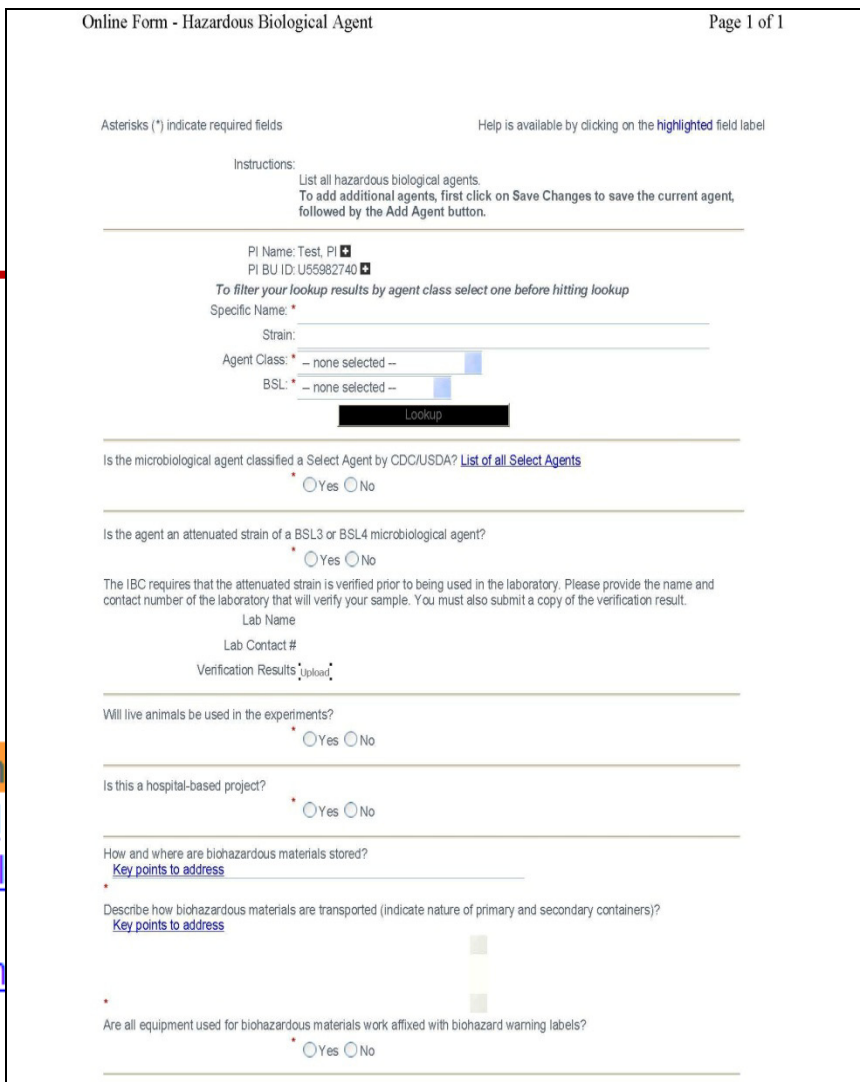
Materials Used in Research

- Check to indicate which activities or materials your research entails, and complete the appropriate forms

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 molecules	The work involves the creation of synthetically derived nucleic acid molecules	Complete relevant section on the *Recombinant DNA* form
What is the highest Biological Safety Containment Level (BSL) required for this project?	BSL-1, BSL-2, BSL-2 with special practices of BSL-3, BSL-3, BSL-4	

Hazardous Biological Agent

- List each agent on the permit individually.
  - To add an agent, we recommend you use the “Lookup” button. If you don’t find the agent in the lookup list, you may type in the required information.
  - To add a second agent, fill out all the required information for the first agent, press “Save Changes” at the bottom of the form, and then press “Add Additional Hazardous Agent”.
  - Each agent added to your permit will be shown at the top of the screen - to switch between them, click the + button by that agent.
- Answer the rest of the questions about the agent, including use, if the project uses animals or is a hospital-based project, and transport and storage information for the agent.



Online Form - Hazardous Biological Agent Page 1 of 1

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

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: *
Strain:
Agent Class: * -- none selected --
BSL: * -- none selected --
Lookup

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

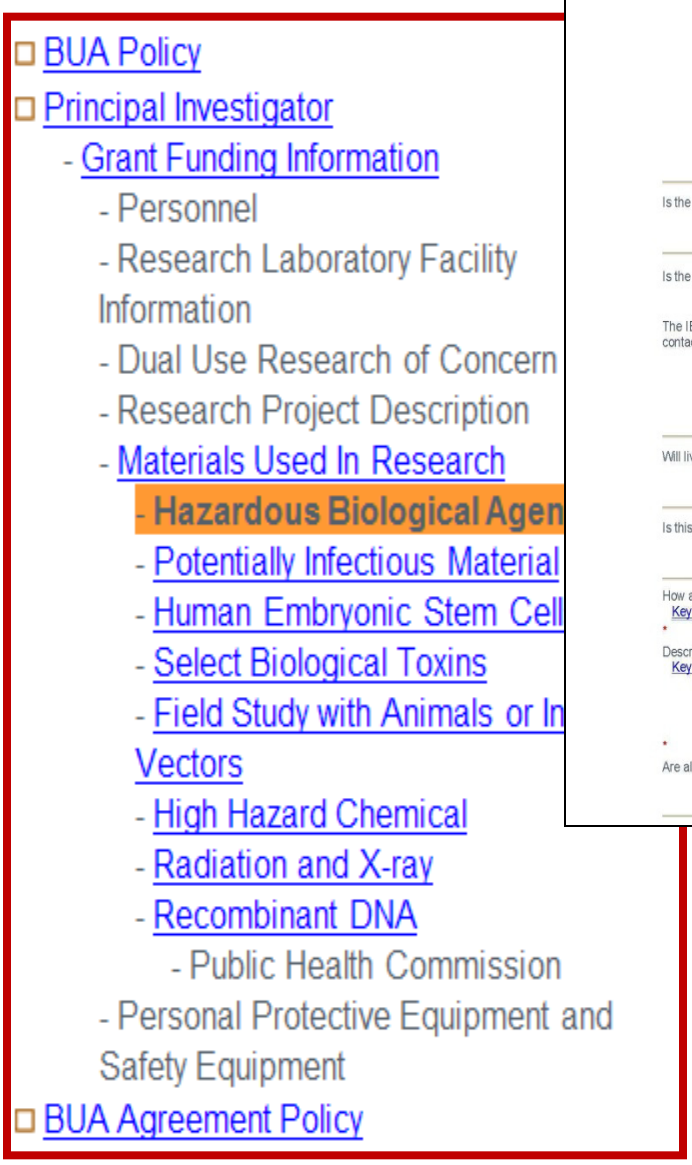
Will live animals be used in the experiments?
* Yes No

Is this a hospital-based project?
* Yes No

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

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

Are all equipment used for biohazardous materials work affixed with biohazard warning labels?
* Yes No



- BUA Policy
- Principal Investigator
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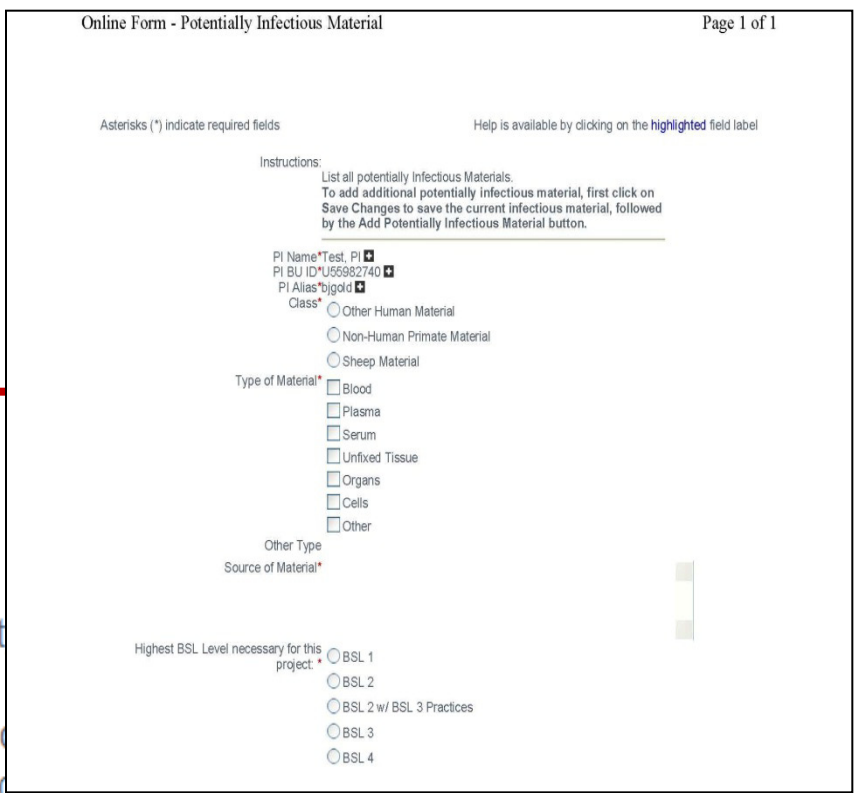
  - Personnel
  - Research Laboratory Facility Information
  - Dual Use Research of Concern
  - Research Project Description
  - Materials Used In Research
    - Hazardous Biological Agen
    - Potentially Infectious Material
    - Human Embryonic Stem Cell
    - Select Biological Toxins
    - Field Study with Animals or In Vectors
    - High Hazard Chemical
    - Radiation and X-ray
    - Recombinant DNA
      - Public Health Commission
  - Personal Protective Equipment and Safety Equipment
- BUA Agreement Policy

Potentially Infectious Material

- Includes other human material, as well as non-human primate material and sheep material. This material is not identified in the previous Hazardous Biological Agent section.
- List the type(s) and source of material.



Online Form - Potentially Infectious Material Page 1 of 1

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

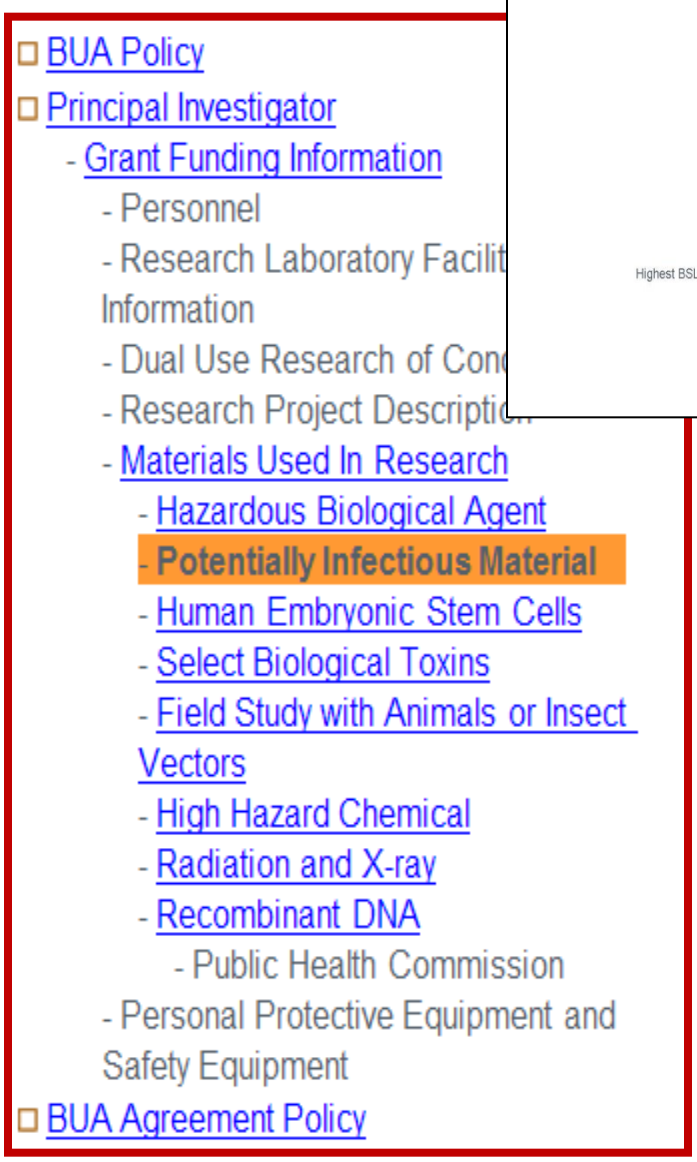
Instructions:
List all potentially Infectious Materials.
To add additional potentially infectious material, first click on Save Changes to save the current infectious material, followed by the Add Potentially Infectious Material button.

PI Name*Test, PI
PI BU ID*U55982740
PI Alias*bjgold
Class*
- Other Human Material
- Non-Human Primate Material
- Sheep Material

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

Other Type
Source of Material*

Highest BSL Level necessary for this project: *
- BSL 1
- BSL 2
- BSL 2 w/ BSL 3 Practices
- BSL 3
- BSL 4



- BUA Policy
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    - Research Project Descriptio
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      - **Potentially Infectious Material**
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      - Select Biological Toxins
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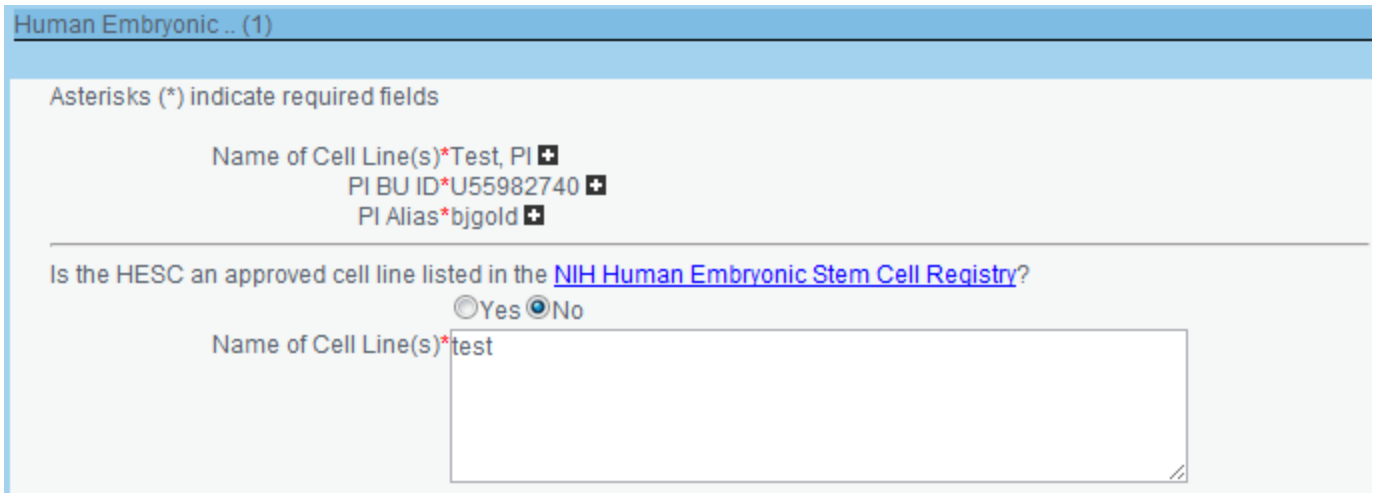
Human Embryonic Stem Cells

- List any human embryonic stem cells you will be using in this protocol – cell lines must be approved and listed on the NIH Registry



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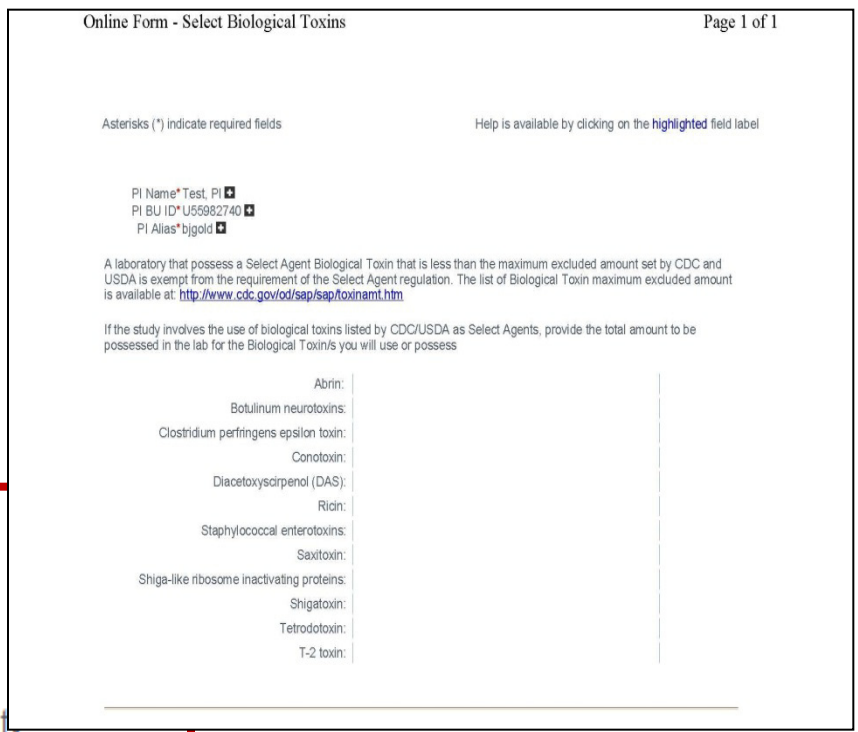
Select Biological Toxins

- List any select agent biological toxins you will be using in your research, as well as the total amount to be used and/or possessed in the lab.



Online Form - Select Biological Toxins Page 1 of 1

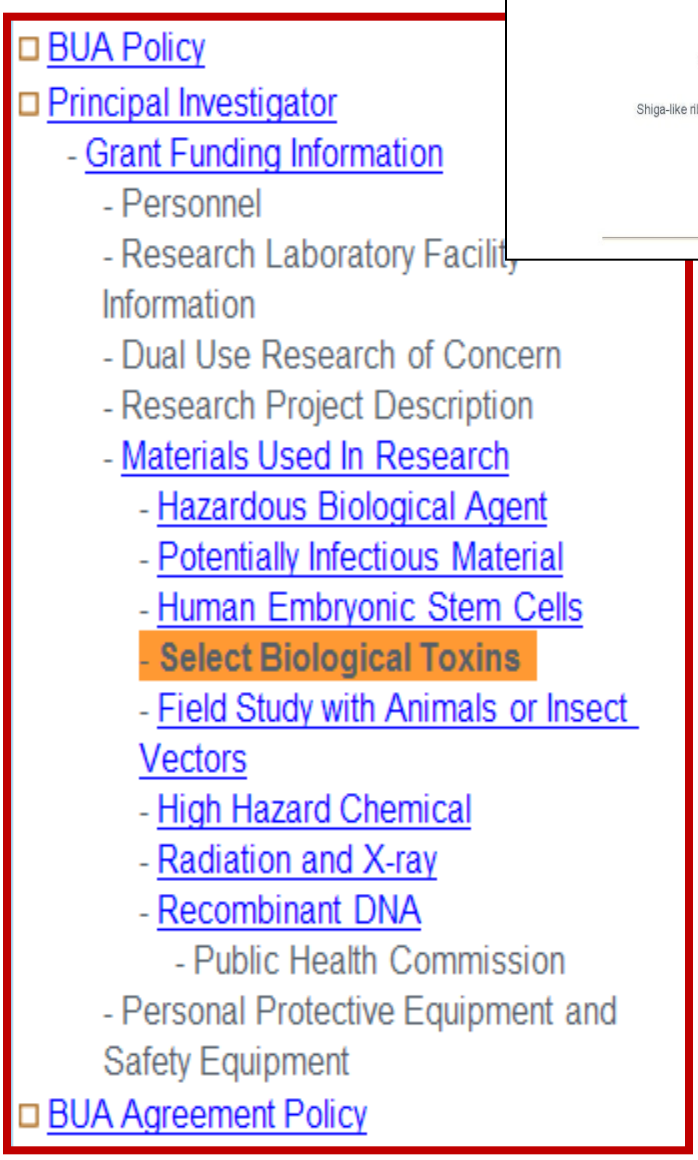
Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

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



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      - High Hazard Chemical
      - Radiation and X-ray
      - Recombinant DNA
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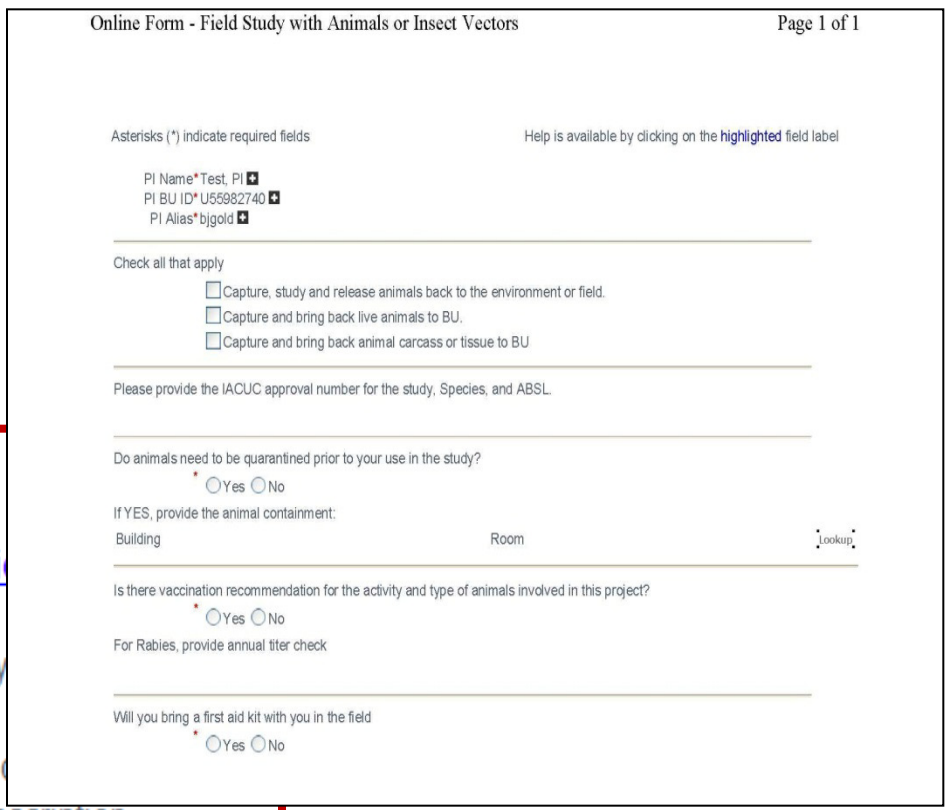
Field Study with Animals or Insect Vectors

- Describe any environmental or field studies with animals and supply IACUC information, quarantine and vaccine information



Online Form - Field Study with Animals or Insect Vectors Page 1 of 1

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

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.

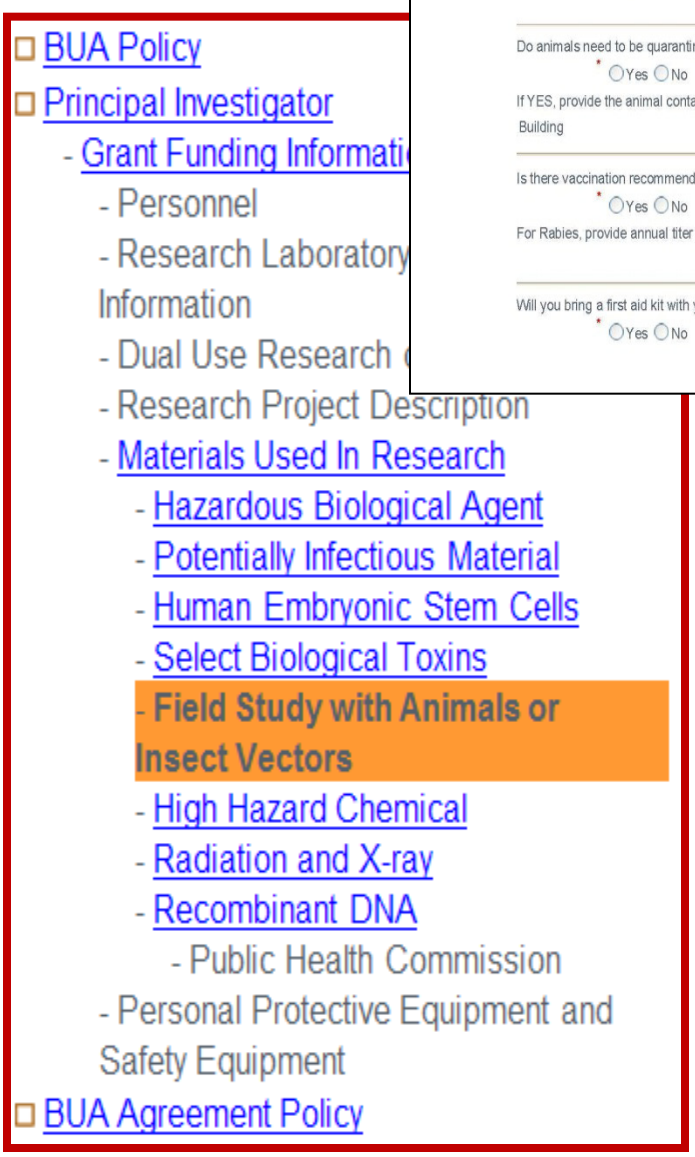
Do animals need to be quarantined prior to your use in the study?
* Yes No

If YES, provide the animal containment:
Building Room Lookup

Is there vaccination recommendation for the activity and type of animals involved in this project?
* Yes No

For Rabies, provide annual titer check

Will you bring a first aid kit with you in the field
* Yes No



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  - Personal Protective Equipment and Safety Equipment
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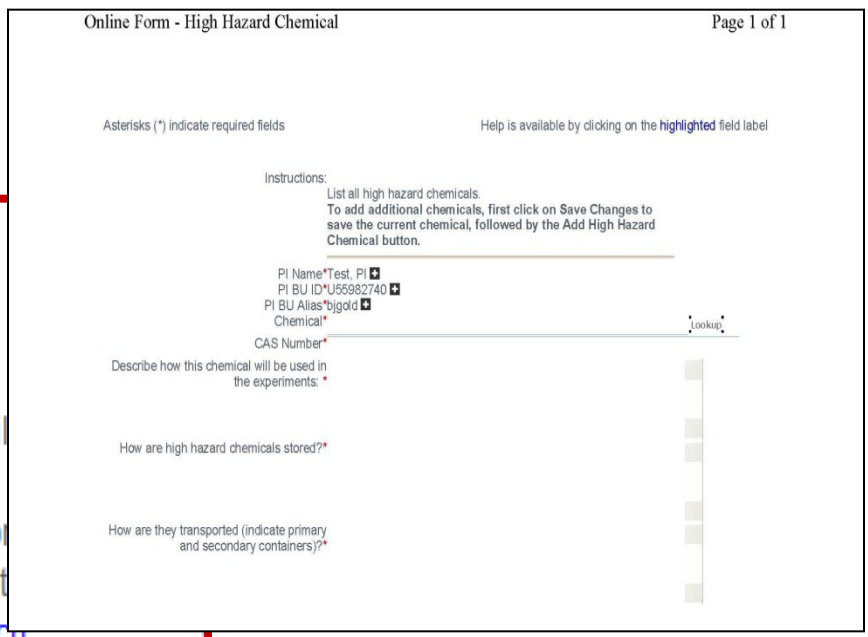
High Hazard Chemical

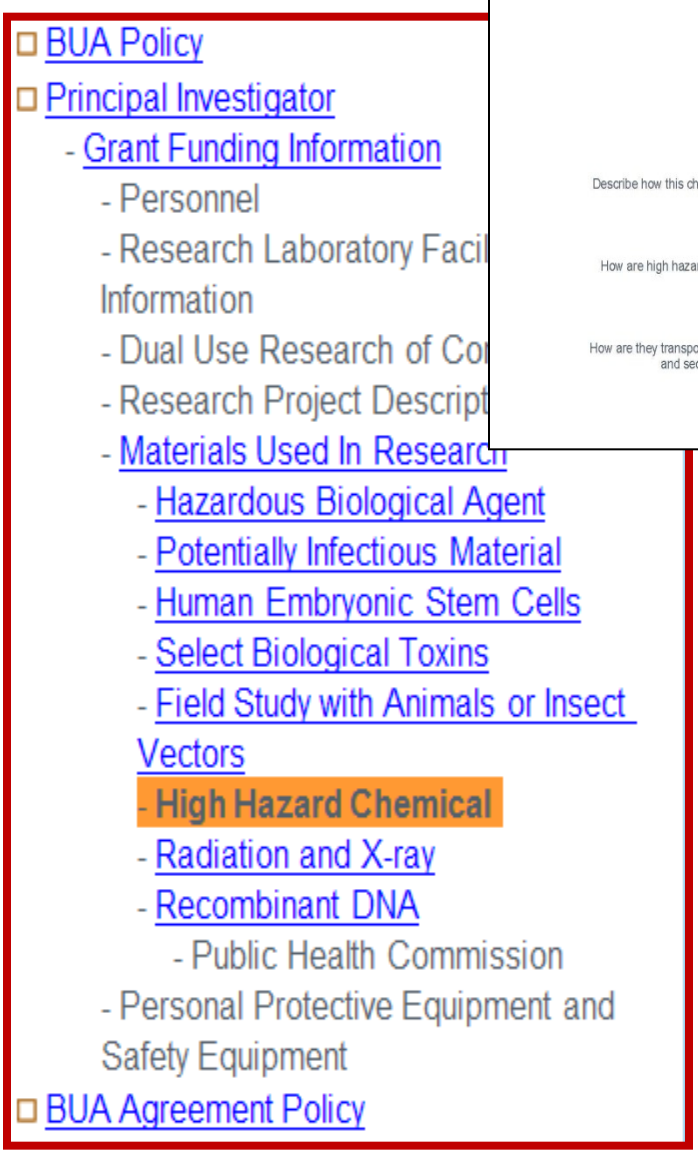
- List each high hazard chemical on the permit individually.
  - To add a chemical, we recommend you use the “Lookup” button. If you don’t find the chemical in the lookup list, you may type in the required information.
  - To add a second chemical , fill out all the required information for the first chemical, press “Save Changes” at the bottom of the form, and then press “Add Additional High Hazard Chemical”.
  - Each chemical added to your permit will be shown at the top of the screen - to switch between them, click the + button by that chemical.
- Answer the rest of the questions about the chemical, including use, storage, and transport.


Online Form - High Hazard Chemical Page 1 of 1

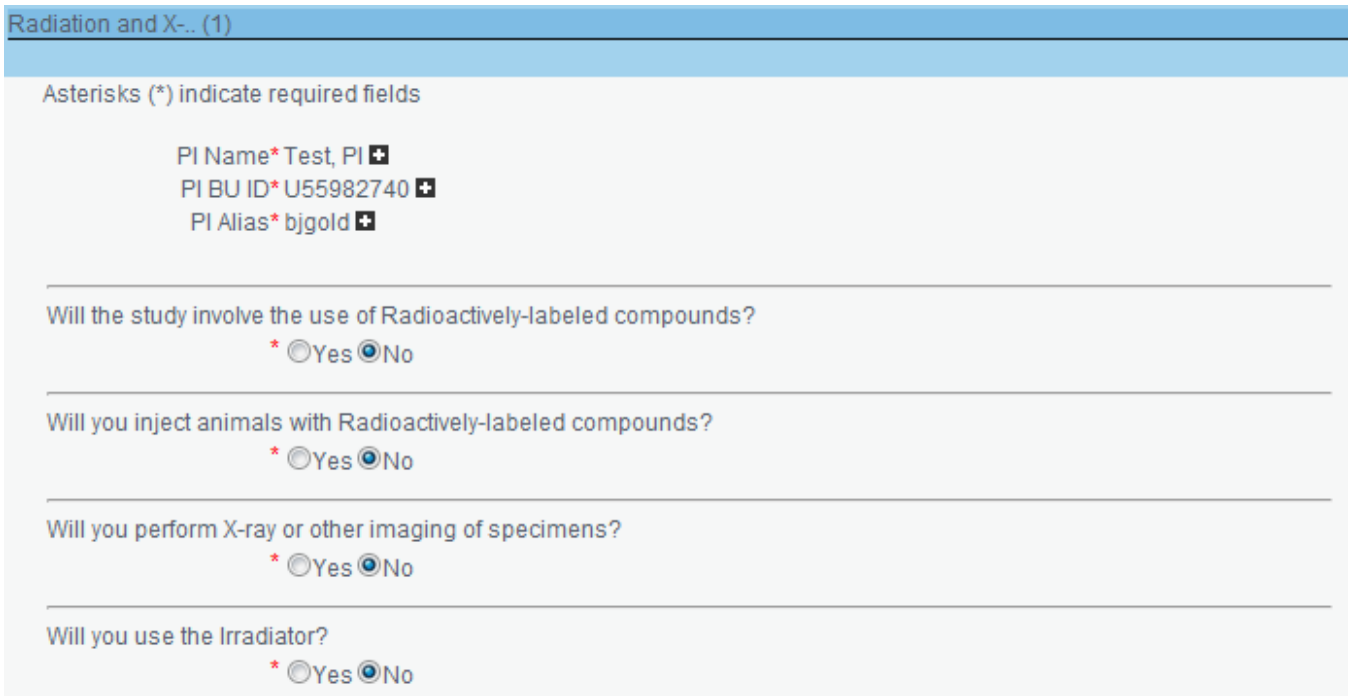
Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

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.

PI Name*Test, PI
PI BU ID*U55982740
PI BU Alias*bjgold
Chemical* Lookup
CAS Number*
Describe how this chemical will be used in the experiments: *
How are high hazard chemicals stored?*
How are they transported (indicate primary and secondary containers)?*



Radiation and X-ray


Radiation and X-.. (1)

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

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      - **Radiation and X-ray**
      - Recombinant DNA
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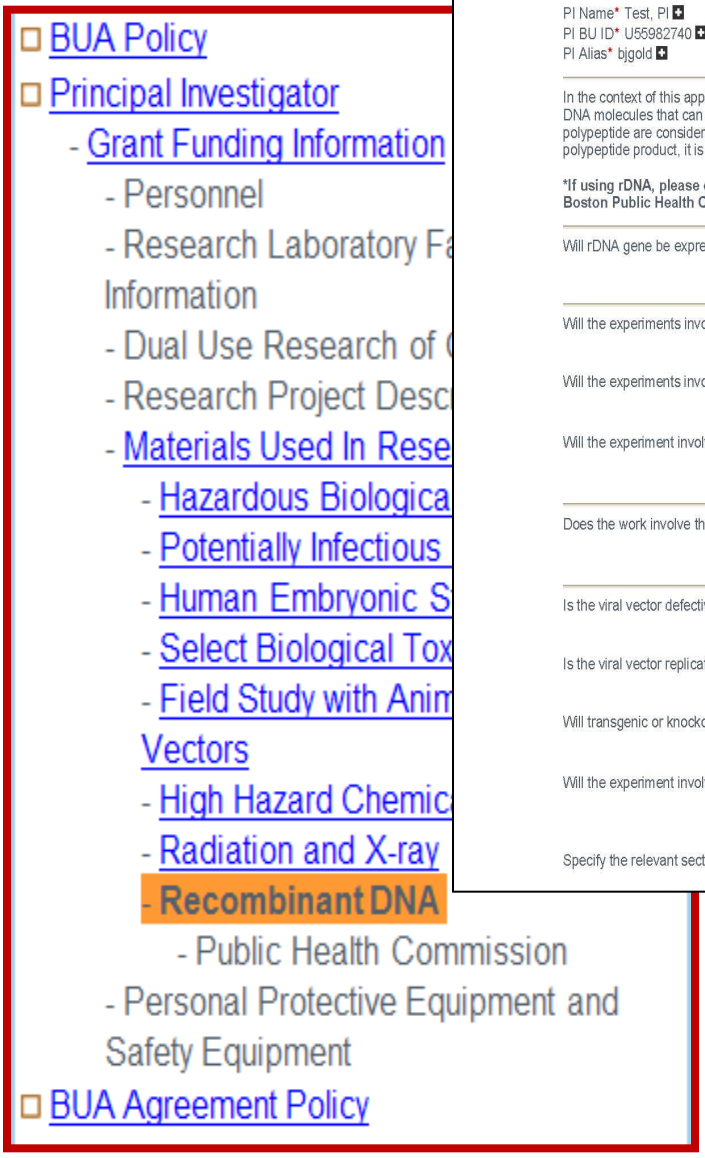
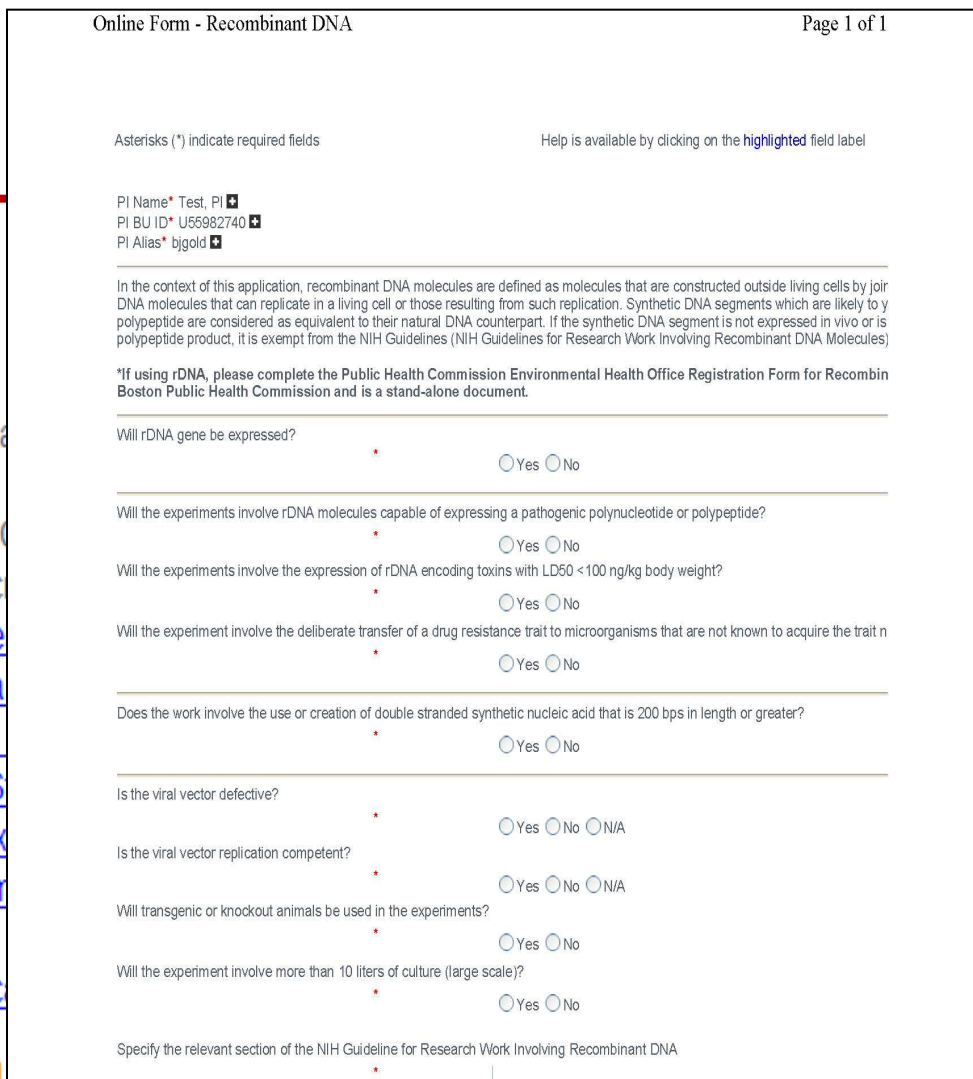
- BUA Agreement Policy

Recombinant DNA (rDNA)

- List all information about your rDNA project, including:
  - Host-vector-donor system if a rDNA gene will be expressed,
  - Copies of all approvals for human gene therapy clinical projects
  - The use or creation of synthetic nucleic acids
  - Defective or replication competent viral vectors
  - Animal use
- Include the relevant section of the NIH Guideline for Research Work involving Recombinant DNA
- Fill out the Public Health Commission form (see next slide)




Online Form - Recombinant DNA Page 1 of 1

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

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 cells by joir DNA molecules that can replicate in a living cell or those resulting from such replication. Synthetic DNA segments which are likely to y polypeptide are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo or is polypeptide product, it is exempt from the NIH Guidelines (NIH Guidelines for Research Work Involving Recombinant DNA Molecules)

***If using rDNA, please complete the Public Health Commission Environmental Health Office Registration Form for Recombin 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 the experiment involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait n * 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

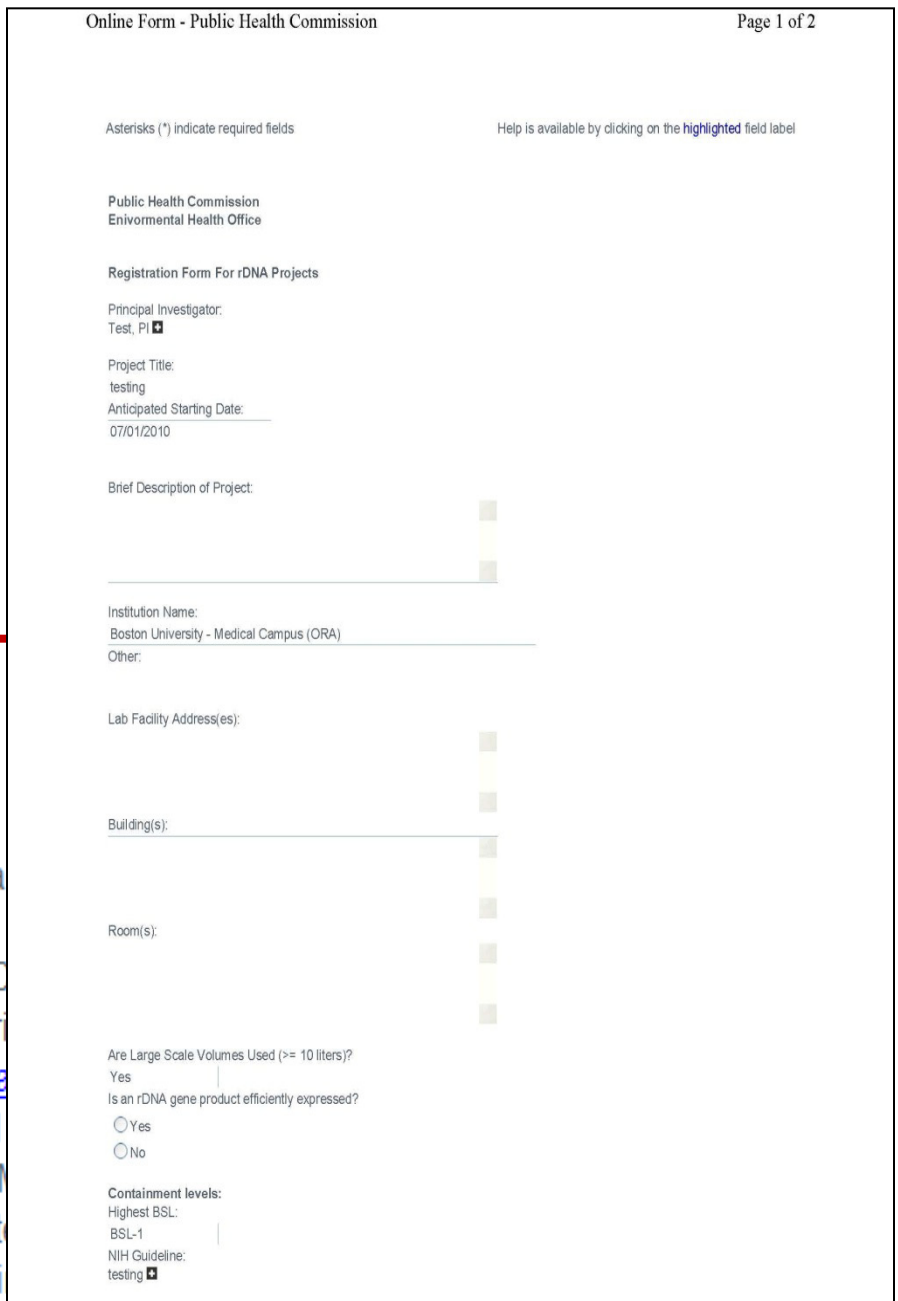
Will transgenic or knockout animals be used in the experiments? * Yes No

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 *

Public Health Commission

- If you are working with rDNA, the City of Boston requires that you fill out this registration form for rDNA projects.



Online Form - Public Health Commission Page 1 of 2

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

Public Health Commission
Enivormental Health Office

Registration Form For rDNA Projects

Principal Investigator:
Test, PI

Project Title:
testing
Anticipated Starting Date:
07/01/2010

Brief Description of Project:

Institution Name:
Boston University - Medical Campus (ORA)
Other:

Lab Facility Address(es):

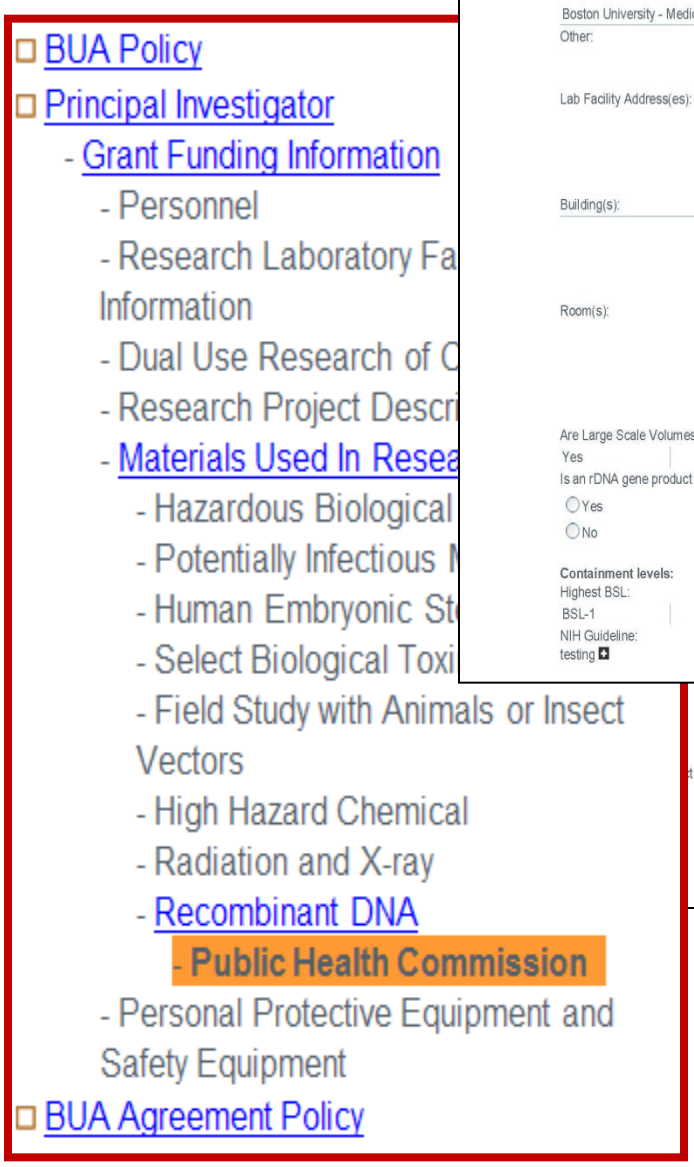
Building(s):

Room(s):

Are Large Scale Volumes Used (>= 10 liters)?
Yes
Is an rDNA gene product efficiently expressed?
Yes
No

Containment levels:
Highest BSL:
BSL-1
NIH Guideline:
testing

t in emergency situations requiring immediate remedial action:



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      - Radiation and X-ray
      - Recombinant DNA
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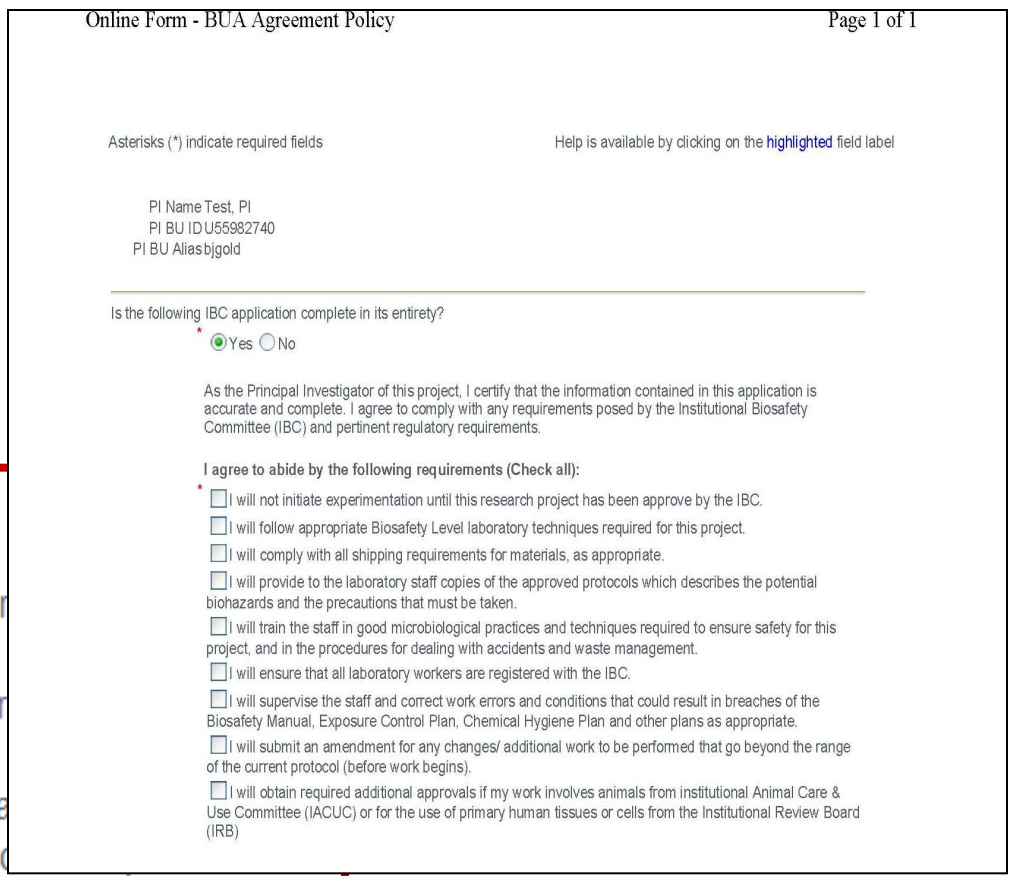
- BUA Agreement Policy

BUA Agreement Policy

- If you are working with rDNA, the City of Boston requires that you fill out this registration form for rDNA projects.



Online Form - BUA Agreement Policy Page 1 of 1

Asterisks (*) indicate required fields Help is available by clicking on the highlighted field label

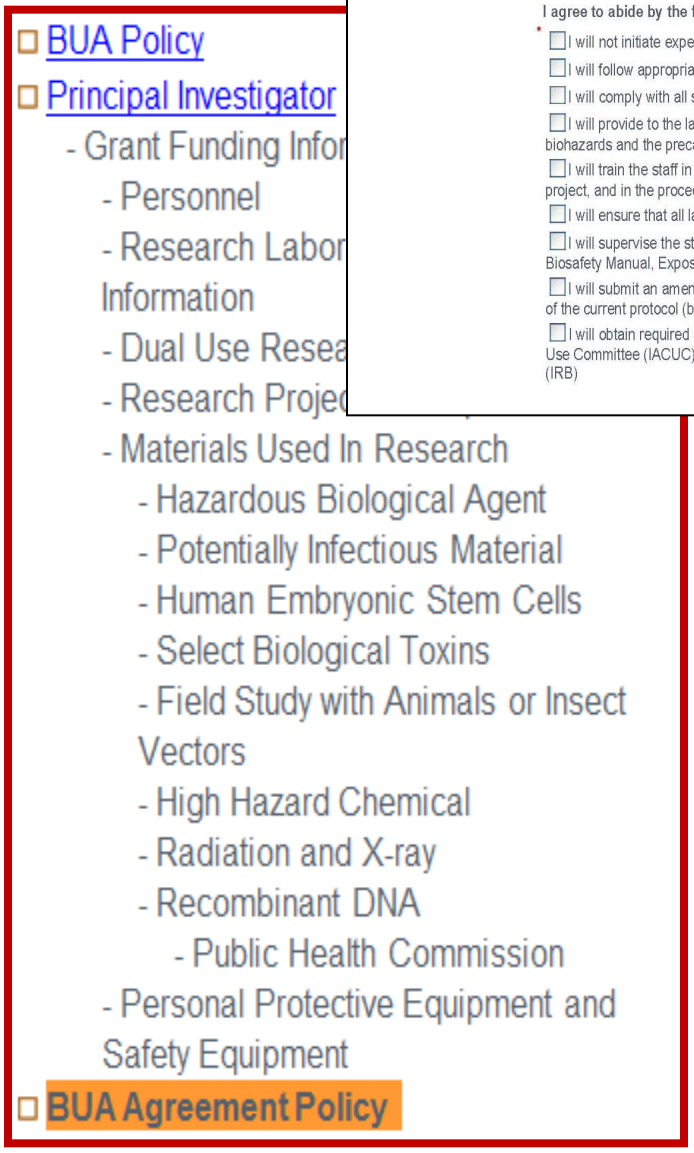
PI Name Test, PI
PI BU ID U55982740
PI BU Alias bjgold

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):

* I will not initiate experimentation until this research project has been approve by the IBC.
I will follow appropriate Biosafety Level laboratory techniques required for this project.
I will comply with all shipping requirements for materials, as appropriate.
I will provide to the laboratory staff copies of the approved protocols which describes the potential biohazards and the precautions that must be taken.
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.
I will ensure that all laboratory workers are registered with the IBC.
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.
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).
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)



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