Creating BUA Protocols with RIMS

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

Last Update: 8-April-2011
Getting Started

- Log into RIMS
  - [http://www.bu.edu/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)"

Activities and Authorizations
- Radioisotope Permit - [help]
- Biological Use Authorization (IBC Application) - [help]
- Intent to Administer Biological Materials into Rodents
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.*

![Table of BUA Applications](image-url)
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

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**Biological Use Authorization - (IBC Application)**

- **Click here to start a new Biological Use Authorization - (IBC Application)**
- **Click on the Id to open, view or edit a Biological Use Authorization - (IBC Application)**
- **To view the reviewer’s comments, click on the Review hyperlink**

<table>
<thead>
<tr>
<th>Id</th>
<th>Created</th>
<th>Last Modified</th>
<th>Submission Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>704</td>
<td>6/24/10</td>
<td>6/24/10</td>
<td>Unfinished</td>
</tr>
<tr>
<td>703</td>
<td>6/24/10</td>
<td>6/24/10</td>
<td>Submitted 8/24/10 (UNEVALUATED - Review Pending)</td>
</tr>
<tr>
<td>552</td>
<td>1/26/10</td>
<td>6/1/10</td>
<td>Submitted 8/24/10 (UNEVALUATED - Review Pending)</td>
</tr>
<tr>
<td>546</td>
<td>1/22/10</td>
<td>3/1/10</td>
<td>Submitted 4/16/10 (ACCEPTED)</td>
</tr>
</tbody>
</table>

**Archives**: View the protocol's history.

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**Research Information Management System**
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
   - Project Title
   - Application Type
   - Funding Source / Grant Administration

3. Grant Funding Information

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
BUA Application Components: Materials Used in Research

- **Materials Used in Research**
  - **Hazardous Biological Agent**
    - Viruses, Bacteria, Fungi, Parasites, Rickettsia, Prion, Human Primary or Cell Lines, Non Human Primate Primary or Cell Lines
  - **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
  - **Human Embryonic Stem Cells**
    - Abrin, Botulinum neurotoxins, Conotoxin, Clostridium perfringens epsilon toxin, Diacetoxyscirpenol (DAS), Ricin, Staphylococcal enterotoxins, Saxitoxin, Shiga-like ribosome inactivating proteins, Shigatoxin, Tetrodotoxin, T-2 toxin
  - **Select Biological Toxins**
    - Environmental or field studies with animals
  - **Field Study with Animals or Insect Vectors**
    - Use of a high hazard chemical
  - **High Hazard Chemical**
    - Use of Radioactively-labeled compounds; Inject animals with radioactive-labeled compounds; X-ray or other imaging of specimens; Use of the irradiator
  - **Radiation and X-ray**
  - **Recombinant DNA**

- **Public Health Commission**
BUA Policy

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

- Application Type
  - New, 3 year resubmission, amendment, annual renewal
- Funding Source and Grant Administration
- PI CV in NIH format
**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.
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.
Dual Use Research of Concern

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

<table>
<thead>
<tr>
<th>Online Form - Dual Use Research of Concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>The National Science Advisory Board for Biosecurity (NSABB)-defined &quot;dual use research of concern&quot; as research that, based on our understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied or otherwise present a threat to public health, agriculture, plants, animals, the environment, or materials.</td>
</tr>
<tr>
<td>Please review the eight categories below and indicate if your research falls into any of the dual use research concern categories.</td>
</tr>
<tr>
<td>Asterisks (*) indicate required fields. Help is available by clicking on the highlighted field label.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI Name*</th>
<th>Test PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BU ID*</td>
<td>U00592764</td>
</tr>
<tr>
<td>BU Alias*</td>
<td>Sg01665</td>
</tr>
</tbody>
</table>

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

- BUA Policy
- Principal Investigator
  - Grant Funding Information
  - Personnel
  - Research Laboratory Facility Information
  - Dual Use Research of Concern
    - Research Project Description
    - 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
    - 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.

<table>
<thead>
<tr>
<th>Laboratory Procedure</th>
<th>Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homogenization, tissue grinding</td>
<td></td>
</tr>
<tr>
<td>Vortexing</td>
<td></td>
</tr>
<tr>
<td>Vagunia mixing, blending</td>
<td></td>
</tr>
<tr>
<td>Freeze drying, lyophilizing</td>
<td></td>
</tr>
<tr>
<td>Sonicator, ultrasonic cleaners</td>
<td></td>
</tr>
<tr>
<td>Animal handling, cage changes</td>
<td></td>
</tr>
<tr>
<td>Petting, necropsy fluid</td>
<td></td>
</tr>
<tr>
<td>Centrifugation, ultra centrifugation</td>
<td></td>
</tr>
<tr>
<td>Opening containers under pressure</td>
<td></td>
</tr>
<tr>
<td>Culture films, shakers</td>
<td></td>
</tr>
<tr>
<td>Plating, colony countings</td>
<td></td>
</tr>
<tr>
<td>Animal inoculations</td>
<td></td>
</tr>
<tr>
<td>Animal aerobiology exposure</td>
<td></td>
</tr>
<tr>
<td>Other (Specify)</td>
<td></td>
</tr>
</tbody>
</table>

2. Indicate the engineering controls in place to prevent potential exposure from procedures described.
- Work that produces or potentially produces aerosols are done in the Biological Safety Cabinet or other containment equipment.
- Use of centrifuges, sealed flasks, or sealed jars.
- HEPA and high-efficiency filters on the vacuum line.
- Baski, 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.

<table>
<thead>
<tr>
<th>If your research involves the following materials or activities (check all that apply)…</th>
<th>Example/Description</th>
<th>Then…</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hazardous Biological Agent including Human Cells and Cell Line</strong></td>
<td>Viruses, Bacteria, Fungi, Parasites, Rickettsia, Prion, Human Primary or Cell Lines, Non Human Primate Primary or Cell Lines</td>
<td>Complete a Hazardous Biological Agent form for each Agent</td>
</tr>
<tr>
<td><strong>Other Potentially Infectious Materials</strong></td>
<td>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</td>
<td>Complete a Potentially Infectious Material form for each Material</td>
</tr>
<tr>
<td><strong>Human Embryonic Stem Cell</strong></td>
<td>Human Embryonic Stem Cell</td>
<td>Complete a Human Embryonic Stem Cell form</td>
</tr>
<tr>
<td><strong>Select Biological Toxins</strong></td>
<td>Abrin, Botulinum neurotoxins, Conotoxin, Clostridium perfringens epsilon toxin, Diacetoxyscirpenol (DAS), Ricin, Staphylococcal enterotoxins, Saxitoxin, Shiga-like ribosome inactivating proteins, Shigatoxin, Tetrodotoxin, T-2 toxin</td>
<td>Complete a Select Biological Toxins form</td>
</tr>
<tr>
<td><strong>Field Study with Animals or Insect Vector</strong></td>
<td>Environmental or field studies with animals</td>
<td>Complete a Field Study with Animals or Insect Vectors form</td>
</tr>
<tr>
<td><strong>High Hazard Chemical</strong></td>
<td>Use of a high hazard chemical</td>
<td>Complete a High Hazard Chemical form for each Chemical</td>
</tr>
<tr>
<td><strong>Radiation and X-Ray</strong></td>
<td>Use of Radioactively-labeled compounds; Inject animals with radioactive-labeled compounds; X-ray or other imaging of specimens; Use of the irradiator</td>
<td>Complete a Radiation and X-ray form</td>
</tr>
<tr>
<td><strong>Recombinant DNA</strong></td>
<td>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).</td>
<td>Complete a Recombinant DNA form and Public Health Commission Form</td>
</tr>
<tr>
<td><strong>Synthetically derived nucleic acid molecules</strong></td>
<td>The work involves the creation of synthetically derived nucleic acid molecules</td>
<td>Complete relevant section on the Recombinant DNA form</td>
</tr>
</tbody>
</table>

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.
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.
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.
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]

- **BUA Policy**
- **Principal Investigator**
  - Grant Funding Information
  - Personnel
  - Research Laboratory Facility Information
  - Dual Use Research of Concern
  - Research Project Description
- **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
  - Personal Protective Equipment and Safety Equipment
- **BUA Agreement Policy**
Field Study with Animals or Insect Vectors

- Describe any environmental or field studies with animals and supply IACUC information, quarantine and vaccine information
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.
## Radiation and X-ray

Asterisks (*) indicate required fields

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Name* Test PI</td>
<td></td>
</tr>
<tr>
<td>PI BUID* U55092740</td>
<td></td>
</tr>
<tr>
<td>PI Alias* bigold</td>
<td></td>
</tr>
</tbody>
</table>

**Will the study involve the use of Radioactively-labeled compounds?**
- [ ] Yes
- [x] No

**Will you inject animals with Radioactively-labeled compounds?**
- [ ] Yes
- [x] No

**Will you perform X-ray or other Imaging of specimens?**
- [ ] Yes
- [x] No

**Will you use the Irradiator?**
- [ ] Yes
- [x] No

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- **BUA Policy**
- **Principal Investigator**
  - Grant Funding Information
    - Personnel
    - Research Laboratory Facility Information
    - Dual Use Research of Concern
    - Research Project Description
  - Materials Used In Research
    - Hazardous Biological Agent
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    - High Hazard Chemical
    - **Radiation and X-ray**
    - Recombinant DNA
      - Public Health Commission
    - Personal Protective Equipment and Safety Equipment
- **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)
Public Health Commission

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

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