



Environmental Health & Safety Assistant

Principal Investigator's Guide

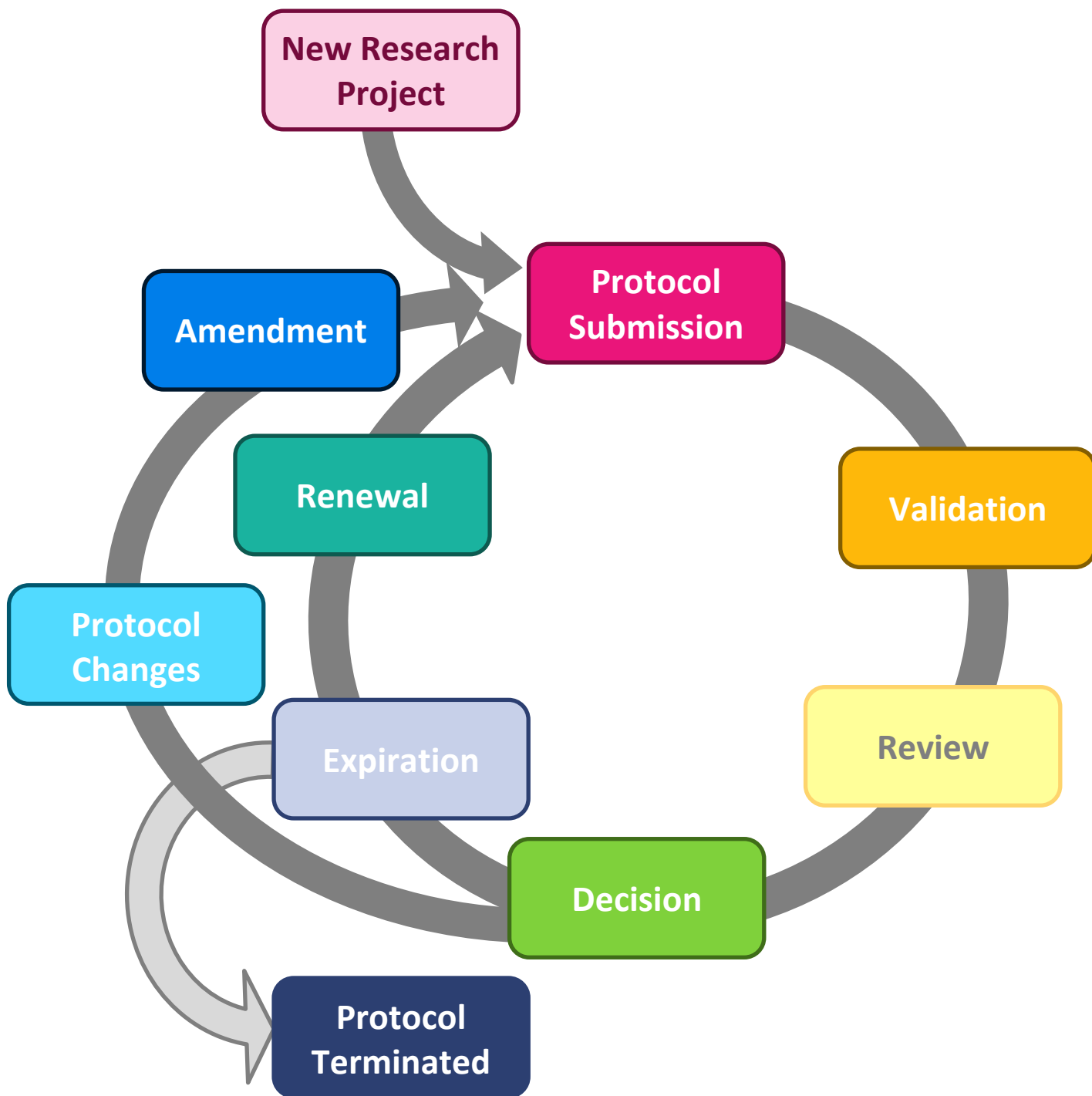
for

Submission of Protocols to the Institutional Biosafety Committee

Updated 6/15/2016

1. Protocol Review


Protocol review by the Institutional Biosafety Committee is similar to protocol review by most other committees. It follows the process of protocol submission, content validation, review, decision, then expiration (and, if desired, renewal) visualized below. Most of this work is managed through the online protocol management system known as Environmental Health & Safety Assistant, or EHSA.



2. EHS Assistant (EHSA)

The online resource for submitting protocols to the Institutional Biosafety Committee can be found at: <http://uth.edu/safety>.

- Click on the link to the Online Protocol System, EHSA (**red arrow**).



The screenshot shows the website <https://www.uth.edu/safety/>. The page features a dark blue header with the UTHealth logo and navigation links: ABOUT, CAREERS, DIRECTORY, A-Z, WEBMAIL, INSIDE THE UNIVERSITY, and a search bar. Below the header, there are links for SCHOOLS, STUDENTS, PATIENTS, and RESEARCH. The main content area is titled "Safety, Health, Environment, and Risk Management" and includes a "Welcome" section with a photograph of laboratory workers. A left-hand navigation menu lists various services, with a red arrow pointing to the "Online Protocol System" link.

Safety, Health, Environment, and Risk Management

Welcome

EHS Main Office 713.500.8100
EHS Hotline 713.500.5832
For Emergencies dial 911

Safety, Health, Environment & Risk Management's (SHERM) mission is to work in conjunction with the UTHealth community to ensure that education, research, and health care service activities take place in conditions that are optimally safe and healthy for all students, faculty, staff, visitors, surrounding community and the general public.

Put simply, we exist to help people go home as healthy and safe as they arrived.

Our main office is located at the Operations Center Building (OCB 1.330) and we can be reached at 713.500.8100 or Fax 713.500.8111.

Please note EHSA works best when accessed using [Chrome](#) or [Firefox](#). It is *NOT* compatible with Internet Explorer



THE UNIVERSITY of TEXAS

HEALTH SCIENCE CENTER AT HOUSTON

Environmental Health & Safety Assistant Login

Note: Internet Explorer 8 (IE8)
is not presently compatible
with the software.

Username
Password

Login


- Log on to the system with your UTHealth user ID and password.
- From the main login page, click the link entitled “Protocol Application for Biological Agents”.

EH&S Assistant

Log Off

Choose PI

PI: X-998: David, Stephen

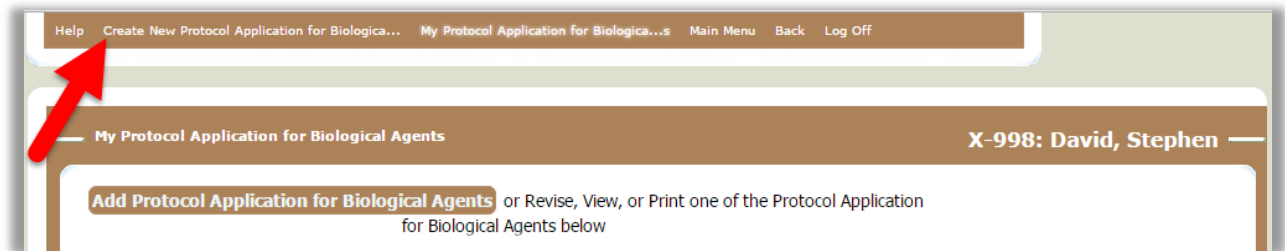
**PROTOCOL SUBMISSION**

- [Protocol Application for Biological Agents](#)
- [Application for Non-Human Use of Radiological Mat](#)
- [Application for the Use of a Highly Toxic Chemical](#)

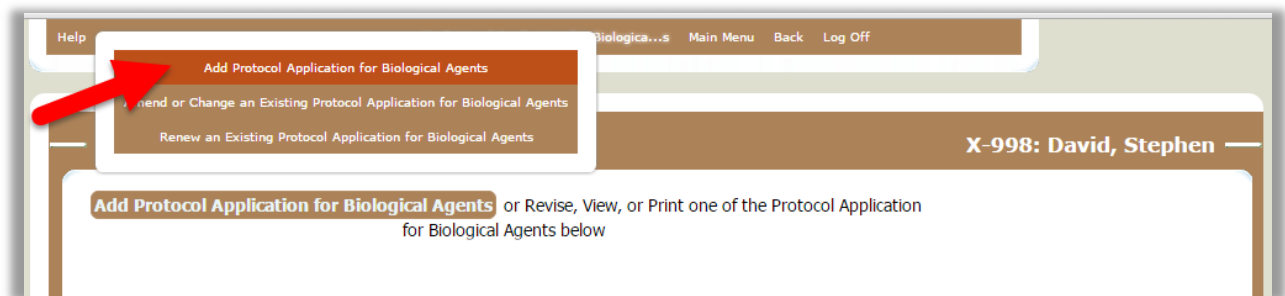


3. New Applications

- Mouse over the option “Create New Protocol Application for Biological...” (red arrow).



- Select “Add Protocol Application for Biological Agents” (red arrow).



3.1. Project Title

- A new protocol is now generated for you. Fill out the “Project Title” field (**blue arrow**) by clicking in the field and typing in your study title.
 - For studies that also require IRB and/or AWC approval, the Office of Sponsored Projects requests that the titles match.
 - The permit number field will be filled out by the Biosafety Office after the protocol is submitted.
 - EHSa supports the Copy and Paste functions, so content can be copied and pasted from another document or application. A basic text editor can also be accessed by clicking on the gray “X” button in the upper right-hand corner of text boxes (**orange arrow**).
- Once your title is entered, click on the “Save & Continue” button (**red arrow**) to progress to the “Permit Instructions” section. To save your work but remain on the same page, click the “Save & Stay” button (**green arrow**).

The screenshot shows a web application interface for 'General Project Information'. At the top, there is a navigation bar with links: Save, Cancel, Email, Help, Answer Questions, Submit for Review, and My Protocol Application for Biological Agents. On the left, a vertical sidebar lists various sections: General Project Information, Permit Instructions, P.I. Information, Protocol Summary, Recombinant DNA, Bioagents Involved, Radiation/Chemical Approvals, Use of Human Subjects, Use of Animals in Research, Biosafety Level/ rDNA Classification, Personnel, Protective Equipment, Location of Work, Biological Waste Disposal and Decontamination, Dual Use Research, Shipping Infectious Substances, Projected Start Date, and Attached Documents. The main content area is titled 'General Project Information' and contains the following fields:

- 'Permit number application is associated with:' with a search box containing 'New9'.
- 'What is the purpose of this application?' with a dropdown menu showing 'Initial'.
- 'Project Title:' with a large text input field. A blue arrow points to this field.
- A small gray 'X' icon in the top right corner of the text input field, with an orange arrow pointing to it.

At the bottom of the form, there are three buttons: '<< Save & Previous', 'Save & Stay' (with a green arrow pointing to it), and 'Save & Continue >>' (with a red arrow pointing to it).

3.2. Permit Instructions section

- Please read the “Permit Instructions” section carefully.
- Once you have read the Permit Instructions, click on the “Save & Continue” button (red arrow) to progress to the “P.I. Information” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

General Project Information

- Permit Instructions
- P.I. Information
- Protocol Summary
- Recombinant DNA
- Bioagents Involved
- Radiation/Chemical Approvals
- Use of Human Subjects
- Use of Animals in Research
- Biosafety Level/ rDNA Classification
- Personnel
- Protective Equipment
- Location of Work
- Biological Waste Disposal and Decontamination
- Dual Use Research
- Shipping Infectious Substances
- Projected Start Date
- Attached Documents

Permit Instructions

INSTITUTIONAL BIOSAFETY COMMITTEE APPLICATION FORM INSTRUCTIONS

Any use of microbiological/infectious agents and/or recombinant DNA molecules in research, must be reviewed and approved or exempted by the Institutional Biosafety Committee (IBC) before the procedure is initiated. The CDC/NIH manual entitled "[Biosafety in Microbiological and Biomedical Laboratories, 5th edition](#)" contains safe practices and laboratory requirements for research using microbiological agents. The NIH "[Guidelines for Research Involving Recombinant DNA Molecules](#)" contains requirements for protocol review and safe practices for work involving rDNA.

The [UTHSC-H Environmental Health & Safety's \(EH&S\) Biological Safety Program](#) is available to help with completion of these forms or to answer any question you may have. You can reach the Environmental Health & Safety Biological Safety Program at 713-500-4193.

Provide as much information as possible where requested. Determine what biosafety level the protocol calls for (BSL-1, 2, or 3). Note that microbiological agents classified as BSL-1 are exempt from committee review. Assistance with determining your biosafety level can be had by contacting EH&S. All levels of Recombinant DNA work require notification and/or approval to the Institutional Biosafety Committee. Complete the necessary information as best you can and contact the Biological Safety Program with any questions, 713-500-4193.

A memorandum of understanding and agreement (MUA) form will be generated by EH&S following submission of this information prior to submission to the IBC.

IBC MEETING DATE: First Thursday of every month. Contact EH&S for time and location.

SUBMISSION DEADLINE: 1st of the month to ensure committee review the following month. For example: Submit by June 1 to ensure review at July meeting.

ONCE APPROVED: Protocols are granted approval for a period of five years, but will be reviewed on an annual basis. An annual protocol renewal form will be distributed to you each August.

CHANGES IN METHODS, MICROBIOLOGICAL AGENT/RDNA, OR PERSONNEL: Protocol changes may be submitted to EH&S at any time. Apply by through this system by referencing the Institutional Biosafety Safety Committee registration number. If changes are extensive, a new application may be required.

IMPORTANT NOTICE TO PRINCIPAL INVESTIGATOR APPLICANTS

The Principal Investigator (PI) is the individual who submits the application to employ biological agents or recombinant DNA in his or her work. This individual is responsible for adherence to all guidelines and regulations. The PI is also fully responsible for the safe use of such agents by themselves and those under his or her direction. Other specific responsibilities of the PI are described in the UTHSC-H Biological Safety Manual and HOOP policies.

Dual use organisms or select agents/toxins will require additional information and review.

REPORTING LABORATORY INCIDENTS INVOLVING rDNA OR NONCOMPLIANCE WITH THE NIH GUIDELINES: Any significant problems, significant research-related accidents or illnesses involving rDNA, or noncompliance with the NIH Guidelines may be brought forward by any person, and should be promptly reported to EHS for investigation and reporting of the incident to the NIH/OBA and the Institutional Biosafety Committee if required.

UTHSC-H must report any significant problems or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and the NIH/OBA within 30 days. Examples include needlesticks containing recombinant DNA, the escape or improper disposal of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet.

Spills and accidents which result in overt exposures to risk group 2 (RG2) organisms or overt or potential exposures to risk group 3 (RG3) organisms containing recombinant DNA molecules must be immediately reported to EHS for investigation and reporting of the incident to the NIH/OBA and the Institutional Biosafety Committee if required. Medical evaluation, surveillance, and treatment will be provided as appropriate and written records will be maintained.

Environmental Health & Safety - Main line, (713) 500-8100; After hours, (713) 500-5832
Biological Safety Program - (713) 500-4193
National Institutes of Health - Office of Biotechnology Activities (<http://www4.od.nih.gov/oba/>)
Institutional Biosafety Committee Chair
Animal Facility Director

« Save & Previous Save & Stay Save & Continue »

3.3. P.I. Information section

- If the person filling out the application is not the PI – such as a postdoctoral fellow, a research coordinator, a study director, or lab manager, make sure that that information is accurate as well.
- After completing the “P.I. Information” section, click “Save & Continue” (red arrow) to progress to the “Protocol Summary” section.

The screenshot displays a web application interface for a protocol application. At the top, a navigation bar includes links for Save, Cancel, Email, Help, Answer Questions, Submit for Review, and My Protocol Application for Biological Agents. On the left, a sidebar lists various sections, with 'General Project Information' and 'Permit Instructions' marked as completed. The main content area is titled 'P.I. Information' and contains the following text and form fields:

PI Information - Click on the "Autofill all" button to pull in the information from the Safety system. If any of the information is inaccurate or missing, please call 713-500-5858.

P.I. Name
Stephen David

Department
Environmental Health & Safety

Position

Phone Number
(713)500-5858

Fax Number

If the person filling out the application is NOT the PI, please provide the following:
Your name:
Your phone number:
Your e-mail address:

At the bottom of the form area, there are three buttons: '< Save & Previous', 'Save & Stay', and 'Save & Continue >'. A red arrow points to the 'Save & Continue >' button.

3.4. Protocol Summary section

- The protocol summary should be a description of the research you plan to perform. It should be written in lay terms as it will be read by community members of the IBC. It should include the project rationale and a brief outline of the experiment(s) to be conducted.
- The IBC is able to perform their Risk Assessment most rapidly when the PI lists all the biological agents to be used, all animal work to be performed, and defines all acronyms.
- Once the “Protocol Summary” section is complete. Click ‘Save & Continue’ (red arrow) to progress to the “Recombinant DNA” section.

The screenshot shows a web application interface for a protocol application. At the top, there is a navigation bar with links: Save, Cancel, Email, Help, Answer Questions, Submit for Review, and My Protocol Application for Biological Agents. On the left side, there is a vertical navigation menu with the following items: General Project Information (checked), Permit Instructions (checked), P.I. Information (checked), Protocol Summary (selected), Recombinant DNA, Bioagents Involved, Radiation/Chemical Approvals, Use of Human Subjects, Use of Animals in Research, Biosafety Level/ rDNA Classification, Personnel, Protective Equipment, Location of Work, Biological Waste Disposal and Decontamination, Dual Use Research, Shipping Infectious Substances, Projected Start Date, and Attached Documents. The main content area is titled "Protocol Summary" and contains the following text: "Protocol Summary: Please include a brief summary including project rationale and a general outline of experiments to be conducted. Please indicate all biological agents and animal work to be performed in the summary, along with defining all acronyms. As an attachment please also provide a copy of your methods, standard operating procedures, and any relevant copies of citations or articles." Below this text is a large empty text input field. At the bottom of the main content area, there is a note: "You will have the opportunity to attach a supplementary information (reference publications, standard operating procedures, lab manuals, etc.) at the end of this application." At the bottom of the interface, there are three buttons: "Save & Previous", "Save & Stay", and "Save & Continue". A red arrow points to the "Save & Continue" button.

3.5. Recombinant DNA section

- If you are using any recombinant or synthetic nucleic acids of any kind, you will need to check the box at the top of the page and fill out the Recombinant DNA table.
 - This includes but is not limited to: DNA or RNA oligos, plasmids, viral vectors, etc.
- Click on the “Add+” button (**blue arrow**) to generate a blank row.
- Fill out the fields according to the instructions. If you have any questions, contact the Biosafety Office at (713) 500-8170.
- If your work will not include the cloning or targeting of oncogenes, click the corresponding box (**orange arrow**).
- If you have other information about your recombinant materials that you believe will impact the IBC’s Risk Assessment, and does not fall into a category in the Recombinant DNA table, please provide it in the “Additional Information” field (**yellow arrow**).
- After information on recombinant and/or synthetic Nucleic Acids is entered, click ‘Save & Continue’ (**red arrow**) to progress to the “Bioagents Involved” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Recombinant DNA

Check here if you are using recombinant or synthetic nucleic acid molecules (If your protocol does NOT involve recombinant or synthetic DNA, press "Save & Continue" to move to the next section.)
IF YES, please fill out the table below describing the recombinant or synthetic nucleic acid molecules to be used. If NO, please proceed to the next section to list the biological agents that you will use in your protocol.

Instructions and definitions for completing the grid:
1. Biological agents - Include agent, strain, concentrations to be used and source info
2. Manipulations - Example: Cloning of protein X into adenoviral vector
3. Agent Characteristics - Antibiotic resistance? Toxin producing? Unique strain characteristics? Bioengineered safety controls?
4. Source of inserted DNA sequence - Please list
5. Nature of inserted DNA sequence - Example: structural gene
6. Host(s) and vector(s) to be used - Example: Host-rat cardiomyocytes and HEK 293; vector - adenovirus serotype V
7. Expression of Foreign Gene
8. BSL - Select the highest appropriate biosafety level

Click "Add" to enter information below:

Add+	Biological Agents	Manipulations	Agent Characteristics	Source of inserted DNA sequence	Nature of inserted DNA sequence	Host(s) and vector(s) to be used	Expression of foreign gene if so protein produced	BSL Level	NIH Guidelines
<input type="checkbox"/>	Check here if NO oncogenes or toxic molecules will be produced in this work.								

Additional information (if necessary):

Save & Previous Save & Stay Save & Continue >>

3.6. Bioagents Involved section

- If you are using any Risk Group II or higher microorganism or any substance that may potentially contain Risk Group II or higher microorganisms (such as blood, bodily fluids, tissues, biopsy samples, or excreta), you must fill this table out. This includes but is not limited to: transformed and primary cell lines, viruses, bacteria, parasites, fungi, blood, bodily fluids, tissues, excreta, etc.
- Risk Group II microorganisms are microbes capable of infecting healthy adult human hosts, cause diseases that are typically non-lethal, and/or can be managed or cured with the appropriate medical treatment. Risk Group III and IV organisms are more dangerous.
- Partial lists of Risk Group II, III, and IV organisms can be found in the [BMBL](#) and also in the [NIH Guidelines](#).
- Transgenic microorganisms may not have the same risk as their wild type parents. If you are working with, or plan to generate transgenic microorganisms, make sure the details of your research are included in the “Recombinant DNA” section of your application. Contact the Biosafety Office (713-500-8170) with any questions regarding transgenic microorganisms.
- To add a Bioagent, click on the “Add+” button (**blue arrow**). This should send you to the Bioagent selection.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Bioagents Involved

Biological agents involved - Please select the biological agents to be used in this protocol from the list below, or manually insert. Click "Add" to enter a biological agent. Click on the "?" to allow you to select information from the tables in the EH&S Safety system. Additional information can be added after the information is pulled from the system.

Add+	Category	Specific Agent	Strain	Concentration and Volume	Bioengineered safety controls	Biological agent source info	Additional Information
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Check below if work involves human blood or human cell lines.

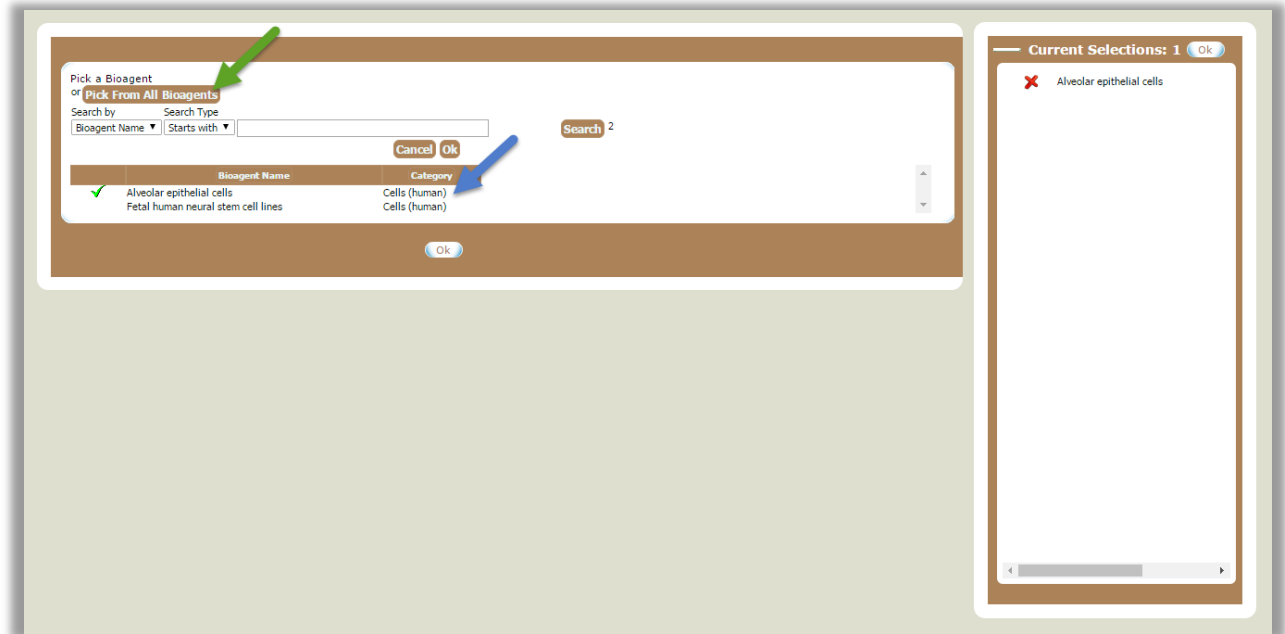
All personnel working on this project will have the Hepatitis B vaccination series or a signed declination form on file with Employee Health. Any exposures will be promptly reported to employee health for post-exposure prophylaxis and baseline/follow up HDV, HCV and HBV testing.

Has Hep B vaccine status been verified with Employee Health?

Additional information (if necessary):

Save & Previous Save & Stay Save & Continue

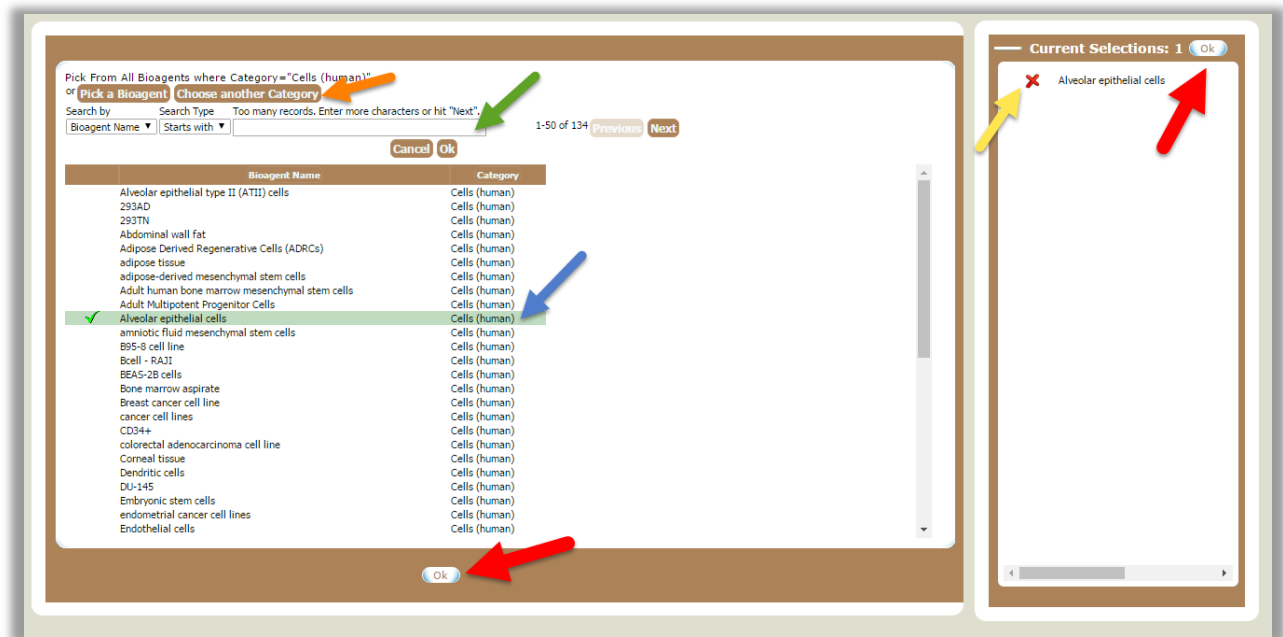
- The Bioagent Selection tool that will be populated with Bioagents you are currently approved for.
 - Select the appropriate Bioagent by clicking on the “Select” link (blue arrow) to the left of the name, or, if the organism you wish to add to your protocol is not on this page, use the “Pick From All Bioagents” button at the top (green arrow).



- This should send you to the All Bioagents selection tool.
- Choose the appropriate category for your new Bioagent (blue arrow).



- Then select the appropriate Bioagent from the category you chose. Or search for it (green arrow) then click on the Bioagent name (blue arrow).
 - If you cannot find the Bioagent you are seeking in the category you have chosen, you can click the “Choose another Category” button (orange arrow) to return to the top level navigation and still retain your previous selections.
 - If you still cannot find your agent after trying other categories and the search function, contact the Biosafety office at (713) 500-8170.
- To un-select a Bioagent that you have previously selected, click on the red “x” to the left of the item name (yellow arrow).
- Once you have selected all the Bioagents you wish to place on this application, click “Ok” to return to the Bioagents table and the “Bioagents Involved” section (red arrows).




- If you choose to 'Cancel' out of the selection process, you can access the selection tool again by clicking on the magnifying glass icon next to the Category field on the "Bioagents Involved" section page (blue arrow).

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Bioagents Involved

Biological agents involved - Please select the biological agents to be used in this protocol from the list below, or manually insert. Click "Add" to enter a biological agent. Click on the "?" to allow you to select information from the tables in the EH&S Safety system. Additional information can be added after the information is pulled from the system.

Add+	Category	Specific Agent	Strain	Concentration and Volume	Bioengineer
unsaved	Cells (human) 	Alveolar epithelial cells	ASD3	1x10 ¹⁶ cells per flask, 10 flasks max	

Check below if work involves human blood or human cell lines.

All personnel working on this project will have the Hepatitis B vaccination series or a signed declination form on file with Employee Health. Any exposures will be promptly reported to employee health for post-exposure prophylaxis and baseline/follow up HIV, HCV and HBV testing.

Has Hep B vaccine status been verified with Employee Health?

Additional information (if necessary):

← Save & Previous Save & Stay Save & Continue →

- Enter the following information as it pertains to your project:
 - Strain of Bioagent (if appropriate) (**blue arrow**).
 - Concentration and Volume – if this is unknown or the quantities will vary, list the maximum volume and concentration generated at any one given point in time (**green arrow**).
 - Bioengineered Safety Controls – examples of Bioengineered Safety Controls include: vaccines available, pre- and post-exposure prophylaxis available, screening of samples for pathogens before handling, deletion of certain genetic elements to limit the virulence of a pathogen or the separation of viral functions from a single genome into multiple plasmids or host genomes. Other examples exist. If your Bioagent has an engineered safety control, please describe it here (**orange arrow**).
 - Biological agent source info – please describe how you are obtaining this Bioagent. If it is from a collaborator, please provide the name and institution of the collaborator. If it is a company, please provide the company’s name. If it is from a field or clinical study, please provide that information.
 - Additional Information – if there is additional information about your Bioagent that you believe would impact the IBC’s Risk Assessment, please provide it in the box provided below the table.
- If you are working with human blood, bodily fluids, tissues, or anything sourced from a human being, personnel who will handle the samples must be enrolled with Occupational Health and either receive the Hepatitis B vaccination series or sign a declination form.
- Once you have completed the “Bioagents Involved” section, click ‘Save & Continue’ (**red arrow**) to proceed to the “Radiation/Chemical Approval” section.

- General Project Information
- Permit Instructions
- P.I. Information
- Protocol Summary
- Recombinant DNA
- Bioagents Involved**
- Radiation/Chemical Approvals
- Use of Human Subjects
- Use of Animals in Research
- Biosafety Level/ rDNA Classification
- Personnel
- Protective Equipment
- Location of Work
- Biological Waste Disposal and Decontamination
- Dual Use Research
- Shipping Infectious Substances
- Projected Start Date
- Attached Documents

Bioagents Involved

Biological agents involved - Please select the biological agents to be used in this protocol from the list below, or manually insert.

Click "Add" to enter a biological agent. Click on the "?" to allow you to select information from the tables in the EH&S Safety system. Additional information can be added after the information is pulled from the system.

Add+	Category	Specific Agent	Strain	Concentration and Volume	Bioengineer
Delete	Cells (human)	Alveolar epithelial cells	A549	1x10 ⁶ cells per flask, 10 flasks max	
	unsaved	Alveolar epithelial cells			

Check below if work involves human blood or human cell lines.

- All personnel working on this project will have the Hepatitis B vaccination series or a signed declination form on file with Employee Health. Any exposures will be promptly reported to employee health for post-exposure prophylaxis and baseline/follow up HIV, HCV and HBV testing.
- Has Hep B vaccine status been verified with Employee Health?

Additional information (if necessary):

Save & Previous

Save & Stay

Save & Continue

3.7. Radiation/Chemical Approval section

- If you are using any of the following types of ionizing or non-ionizing radiation, you must register with the [Radiation Safety Committee \(RSC\)](#) and/or the Radiation Safety Program of EH&S (RSP) for permitting and surveillance:
 - Radionuclides (including PET scanners) – RSC.
 - X-Ray, Fluoroscopy, CT, or MRI - RSP.
 - Lasers (Class 3B and 4) – RSP, Animal or Human Use – RSC.
- If you are using any of the following chemicals, you must register with the [Chemical Safety Committee \(CSC\)](#):
 - Suspected or confirmed carcinogens listed by the International Agency for Research on Cancer (IARC) or National Toxicology Program (NTP).
 - Chemicals with known reproductive hazards.
 - Acutely toxic chemicals.
 - Reactive chemicals.
 - Physically dangerous chemicals (e.g. explosive, pyrophoric, or poisonous).
 - Controlled substances.
 - Antineoplastic agents.
 - Nanomaterials.
 - Select Agent Toxins.
- You are not required to have RSC or CSC approval before submitting your protocol to the IBC, but if you have the approval information, we request that you enter it.
- Once you do receive RSC and/or CSC approval, we request that you inform the IBC via the Biosafety Office.
- If you are not using radiation or hazardous chemicals, choose the ‘No’ response from the drop-down menus and enter “N/A” in the corresponding fields.
- Once you have completed the “Radiation/Chemical Approvals” section, click ‘Save & Continue’ (**red arrow**) to proceed to the “Use of Human Subjects” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Radiation/Chemical Approvals

Are you using radioactive material?
-- No Selection --
No Selection --
Yes
No

Are you using radioactive materials being used.

Radiation safety approval #:

Radiation approval status:
N/A

Are you using chemicals that require approval?
-- No Selection --
No Selection --
Yes
No

Are you using chemicals being used.

Chemical safety approval #:

Chemical approval status:
N/A

Save & Previous Save & Stay Save & Continue

General Project Information
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3.8. Use of Human Subjects section

- If you are performing a clinical trial or otherwise using human subjects in your research, you will need [Institutional Review Board \(IRB\)](#) approval. IRB approval is not required for IBC submission, however changes requested by the IRB frequently impact the Risk Assessment of the IBC and so it may be more straightforward to receive IRB approval before submitting to the IBC.
 - Excepting Human Gene Transfer (HGT) protocols. Since the IRB requires the IBC decision on HGT protocols before making their decisions, HGT protocols must receive IBC approval first.
- Once you have completed the “Use of Human Subjects” section, click “Save & Continue” (**red arrow**) to proceed to the “Use of Animals in Research” section.

The screenshot displays a web application interface for a protocol application. The top navigation bar includes links for Save, Cancel, Email, Help, Answer Questions, Submit for Review, and My Protocol Application for Biological Agents. The left sidebar lists various sections, with 'Use of Human Subjects' currently selected and highlighted. The main content area is titled 'Use of Human Subjects' and contains a form with the following fields:

- Are you using Human Subjects in your research? (Dropdown menu: -- No Selection --)
- CPHS Number: (Text input field)
- CPHS Status: (Dropdown menu: -- No Selection --)

Below the form, there is a note: "You will have the ability to attach a copy of approval letter (if available) at the end of this application." At the bottom of the form, there are three buttons: "Save & Previous", "Save & Stay", and "Save & Continue". A red arrow points to the "Save & Continue" button.

3.9. Use of Animals in Research section

- If you are using animals in your research, including transgenic animals, you will need to fill out this table. You will also require [Animal Welfare Committee \(AWC\)](#) approval.
- AWC approval is not required to submit a protocol to the IBC, however submitting them concurrently can prevent multiple complications. If you don't have AWC approval before submitting to the IBC, please update the IBC via the Biosafety office with the AWC approval number(s) once you receive them.
- If you are not using animals in your research, select 'No' from the drop-down menu and enter "N/A" in the corresponding fields.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Use of Animals in Research

Are you using animals in your research?
Yes
No

AWC Approval Number: _____

AWC Status:
-- No Selection --

Are you breeding transgenic animals?
-- No Selection --

If yes:
 Propagation of colony
 Crossbreeding of transgenics and/or knockouts

Add+	Species	Species (if not in list)	Strain	Animal Housing Location	Manipulation Room Locations	NIH Guidelines	Additional Information
------	---------	--------------------------	--------	-------------------------	-----------------------------	----------------	------------------------

You will have the ability to attach a copy of approval letter (if available) at the end of this application.

<< Save & Previous Save & Stay Save & Continue >>

- If you are using animals, select the appropriate responses from the drop-down menus and fill in the AWC Number field as appropriate.
- To add an animal species to the table, click on the “Add+” button (blue arrow). This will generate a new row for the table.
- Select the appropriate species from the drop-down menu (green arrow) and then fill in strain (orange arrow) and the rest of the table as appropriate.
- Click on the “Save” button or “Save & Continue” button (red arrow) to save your work and proceed to the “Biosafety Level/NIH Guidelines” section.

The screenshot shows the 'Use of Animals in Research' section of a web form. The form includes a sidebar with navigation options and a main content area with various input fields and a table. Annotations include:

- A blue arrow pointing to the 'Add+' button in the table header.
- A green arrow pointing to the 'Species' dropdown menu.
- An orange arrow pointing to the 'Strain' field in the table.
- A red arrow pointing to the 'Save & Continue' button at the bottom right.

The table has the following columns: Add+, Species, Species (if not in list), Strain, Animal Housing Location, and Manipulation Room Locations. The 'Species' dropdown menu is open, showing a list of animal species: Cat, Dog, Fish, Pig, Mice, Monkey, Rabbit, Rat, and Other.

3.10. Biosafety Level/NIH Guidelines section

- Select the highest appropriate Biosafety Level for your work (**blue arrow**).
- Please read this section carefully and choose the classification(s) appropriate to describe your research. If you have questions on which classification to choose, contact the Biosafety office at (713) 500-8170.
- If you are working with infectious material(s) that is/are not recombinant, select the “Not Applicable” box (**green arrow**).
- Once you have selected the appropriate section(s) of the Guidelines for your protocol, click ‘Save & Continue’ to proceed to the “Personnel” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Biosafety Level/ rDNA Classification

Biosafety Level (BSL) - Please use the guidelines below as a reference to accurately assign the proper section of the NIH Guidelines that is applicable to your rDNA work. Based on the risk assessment of the biological agents involved, please select the highest level to be used in this protocol.

-- No Selection --

NIH Recombinant or Synthetic Nucleic Acid Molecules Classification (for recombinant or synthetic nucleic acid molecules only) - Select all that apply:

Not Applicable

Section III-A Experiments that require Institutional Biosafety Committee (IBC) approval and NIH Director approval before initiation of experiments.

III-A-1-a: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V-B, Footnotes and References of Sections I-IV), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC.

Section III-B Experiments that require NIH/OBA and IBC approval before initiation.

III-B-1: Experiments involving the cloning of toxin molecules with LD50 of Less than 100 nanograms per kilogram body weight. Deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight

III-B-2: Experiments that have been Approved (under Section III-A-1-a) as Major Actions under the NIH Guidelines. Upon receipt and review of an application from the investigator, NIH/OBA may determine that a proposed experiment is equivalent to an experiment that has previously been approved by the NIH Director as a Major Action, including experiments approved prior to implementation of these changes. An experiment will only be considered equivalent if, as determined by NIH/OBA, there are no substantive differences and pertinent information has not emerged since submission of the initial III-A-1-a experiment that would change the biosafety and public health considerations for the proposed experiments. If such a determination is made by NIH/OBA, these experiments will not require review and approval under Section III-A.

Section III-C Experiments that require IBC and Institutional Review Board (IRB) approvals, and NIH/OBA registration before initiation.

III-C-1: Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants

Section III-D Experiments that require IBC approval before initiation of experiments.

III-D-1-a: Experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2 agents will usually be conducted at Biosafety Level (BL) 2 containment. Experiments with such agents will usually be conducted with whole animals at BL2 or BL2-N (Animals) containment.

III-D-1-b: Experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 3 agents will usually be conducted at BL3 containment. Experiments with such agents will usually be conducted with whole animals at BL3 or BL3-N containment.

III-D-2-a: Experiments in which DNA from Risk Group 2 or Risk Group 3 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment. Experiments in which DNA from Risk Group 4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment after demonstration that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant. In the absence of such a demonstration, BL4 containment shall be used. The Institutional Biosafety Committee may approve the specific lowering of containment for particular experiments to BL1. Many experiments in this category are exempt from the NIH Guidelines.

III-D-3-a: Experiments involving the use of infectious or defective Risk Group 2 viruses in the presence of helper virus may be conducted at BL2.

III-D-3-b: Experiments involving the use of infectious or defective Risk Group 3 viruses in the presence of helper virus may be conducted at BL2.

III-D-3-c: Experiments involving the use of infectious or defective Risk Group 4 viruses (see Appendix B-IV-D, Risk Group 4 (RG4) - Viral Agents) in the presence of helper virus may be conducted at BL4.

III-D-3-d: Experiments involving the use of infectious or defective restricted poxviruses in the presence of helper virus shall be determined on a case-by-case basis following NIH/OBA review. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens.

III-D-3-e: Experiments involving the use of infectious or defective viruses in the presence of helper virus which are not covered in [Sections III-D-3-a](#) through III-D-3-d may be conducted at BL1.

III-D-4-a: Recombinant or synthetic nucleic acid molecules, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study (see Section V-B, Footnotes and References of Sections I-IV). Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study. Experiments involving the introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III-D-4-b, Experiments Involving Whole Animals. For experiments involving recombinant or synthetic nucleic acid molecule-modified Risk Groups 2, 3, 4, or restricted organisms, see Sections V-4, V-6, and V-1, Footnotes and References of Sections I-IV. It is important that the investigator demonstrate that the fraction of the viral genome being utilized does not lead to productive infection. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens.

III-D-4-b: For experiments involving recombinant or synthetic nucleic acid molecules, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Section III-D-1, Experiments Using Human or Animal Pathogens (Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems), or Section III-D-4-a, the appropriate containment shall be determined by the Institutional Biosafety Committee.

III-D-4-c-1: Experiments involving the generation of transgenic rodents that require BL1 containment are described under [Section III-E-3](#)

III-D-4-c-2: The purchase or transfer of transgenic rodents is exempt from the *NIH Guidelines* under [Section III-F, Exempt Experiments](#)

III-D-5-a: Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules, may be conducted under the containment conditions described in Sections III-D-5-a through III-D-5-e. If experiments involving whole plants are not described in Section III-D-5 and do not fall under Sections III-A, III-B, III-D or III-F, they are included in Section III-E.

III-D-5-b: BL3-P or BL2-P + biological containment is recommended for experiments involving plants containing cloned genomes of readily transmissible exotic (see Section V-M, Footnotes and References of Sections I-IV) infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation in plants.

3.11. Personnel section

- Any personnel performing work described in the protocol must be listed on the protocol to ensure adequate training and enrollment with Occupational Health.
- To add personnel to the protocol, click on the “Add+” button (**blue arrow**).

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Personnel

Personnel: Please list each person who will be participating on the project along with a summary of education, experience and training as it relates to the use of the proposed biological units. UTHSC-H personnel may be selected from the drop-down list below. Please indicate when applicable all persons not employed through UTHSC-H by manually inserting them in the table at the bottom of this page.

A list of people associated with your labs will appear. Click the "Delete" key to remove any names. Click "Add" and then click on the "?" to select the names from the master lists in the EH&S Safety system. If the name is in the list, the individuals' training information will be pulled from the system. Additional information can be added after the information is pulled from the system.

UTHSC-H Personnel Listing

Add+	Last Name	First Name	Education Summary	Experience (years)	Training (with date)
------	-----------	------------	-------------------	--------------------	----------------------

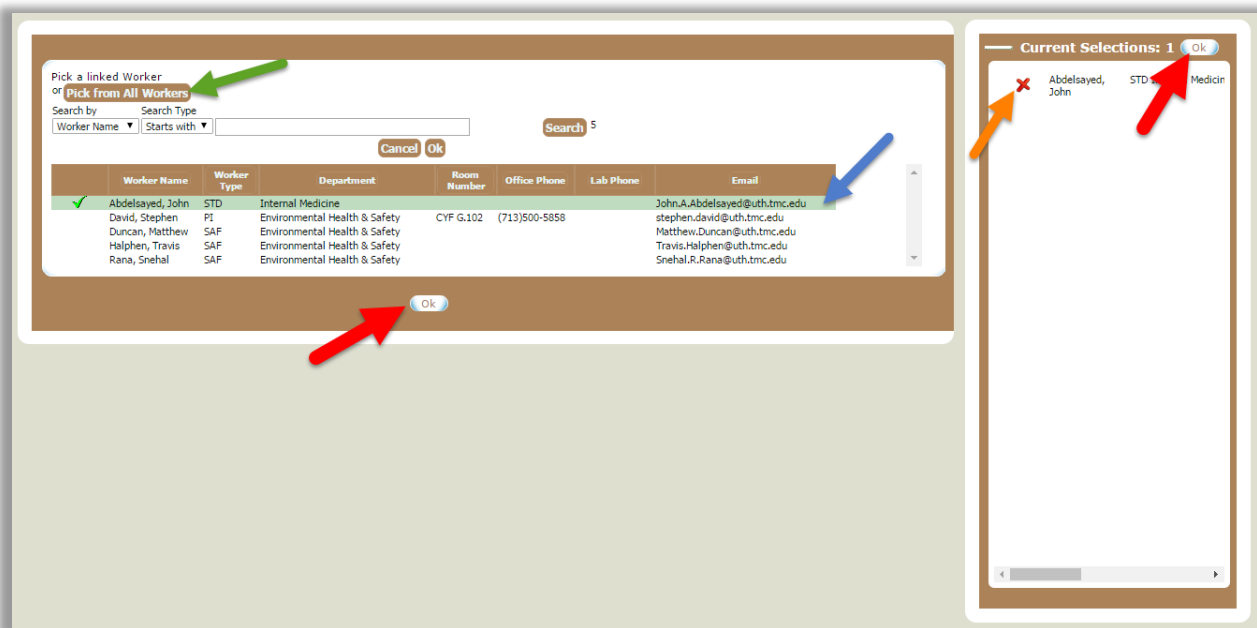
Other lab workers (non UTHSC-H):

Add+	Last Name	First Name	Education Summary	Experience	Training	Where employed
------	-----------	------------	-------------------	------------	----------	----------------

Additional information (if necessary):

<< Save & Previous Save & Stay Save & Continue >>

- You should be sent to the Worker selection tool. Persons already associated with other protocols you may have will appear here. Click on the “Select” link next to the appropriate person’s name to add them to the protocol (**blue arrow**).
- If you do not see the person you wish to add, click on the “Pick from All Workers” button (**green arrow**) to access all the personnel currently registered in EHSA.
- If you still cannot find the person you are looking for, contact EHS at (713) 500-5858 or the Biosafety office at (713) 500-8170.
- You may select more than one person in the Worker selection tool. To remove individuals from the current selection, click on the red ‘x’ (**orange arrow**).
- Once you have the correct personnel selected, click “Ok” (**red arrow**) to return to the “Personnel” table and protocol section.



- If you cancel out of the worker selection and need to re-enter it again, click on the magnifying glass icon in the Personnel table on the Personnel section page (**blue arrow**).
- Enter the education and experience of each person as it is relevant to the work being described (e.g. Ph.D. in Molecular Biology and 12 years' experience in Molecular Biology) (**green arrows**).
- Training information should be auto-populated by EHSA (**orange arrow**), however please double-check it for accuracy before submitting the protocol.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Personnel

Personnel: Please list each person who will be participating on the project along with a summary of education, experience and training as it relates to the use of the proposed biological units. UTHSC-H personnel may be selected from the drop-down list below. Please indicate when applicable all persons not employed through UTHSC-H by manually inserting them in the table at the bottom of this page.

A list of people associated with your labs will appear. Click the "Delete" key to remove any names. Click "Add" and then click on the "?" to select the names from the master lists in the EH&S Safety system. If the name is in the list, the individuals' training information will be pulled from the system. Additional information can be added after the information is pulled from the system.

UTHSC-H Personnel Listing					
Add+	Last Name	First Name	Education Summary	Experience (years)	Training (with date)
unsaved	Abdelsayed	John			BSP: Bloodborne Pathogen Only on 06/28/2012

Other lab workers (non UTHSC-H):						
Add+	Last Name	First Name	Education Summary	Experience	Training	Where employed
Additional information (if necessary):						

[Save & Previous](#)
[Save & Stay](#)
[Save & Continue >>](#)

- To delete personnel, select the “Delete” button (blue arrow) which will appear after the content has been saved.
- For personnel on the protocol who are not UTHSC-H employees, students, or trainees, use the “Other lab workers” table and manually enter the necessary information (yellow arrow).
- Once you have completed the “Personnel” section, click on ‘Save & Continue’ (red arrow) to progress to the “Protective Equipment” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Personnel

Personnel: Please list each person who will be participating on the project along with a summary of education, experience and training as it relates to the use of the proposed biological units. UTHSC-H personnel may be selected from the drop-down list below. Please indicate when applicable all persons not employed through UTHSC-H by manually inserting them in the table at the bottom of this page.

A list of people associated with your labs will appear. Click the "Delete" key to remove any names. Click "Add" and then click on the "?" to select the names from the master lists in the EH&S Safety system. If the name is in the list, the individuals' training information will be pulled from the system. Additional information can be added after the information is pulled from the system.

UTHSC-H Personnel Listing						
Add+	Last Name	First Name	Education Summary	Experience (years)	Training (with date)	
Delete	Abdelsayed	John			BBP: Bloodborne Pathogen Only on 06/28/2012	

Other lab workers (non UTHSC-H):						
Add+	Last Name	First Name	Education Summary	Experience	Training	Where employed
Additional information (if necessary):						

<< Save & Previous Save & Stay Save & Continue >>

3.12. Protective Equipment section

- Please fill out the Protective Equipment section according to what you believe is appropriate for the work you are proposing to perform.
- If you have questions about what protective equipment is appropriate for your work, contact the Biosafety Office at (713) 500-8170.
 - Please note that the BSC must be certified annually and should be currently certified before any work is performed in it.
- Once you have completed the “Protective Equipment” section, click on ‘Save & Continue’ (red arrow) to progress to the “Location of Work” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Protective Equipment

Protective Equipment: The following standard personal protective equipment will be used **IN ALL UT-H LABORATORIES**: full length lab coats, disposable gloves, long pants, closed-toe shoes, protective eyewear or face shields and disposable pipette tips. Please select all other applicable items from the following list and include locations and certification dates for biological safety cabinets

- Safety centrifuge cups
- Sealed centrifuge rotor
- Biosafety cabinet

Number of biosafety cabinets and date of cabinet certification:

Respiratory protection
Please specify type:

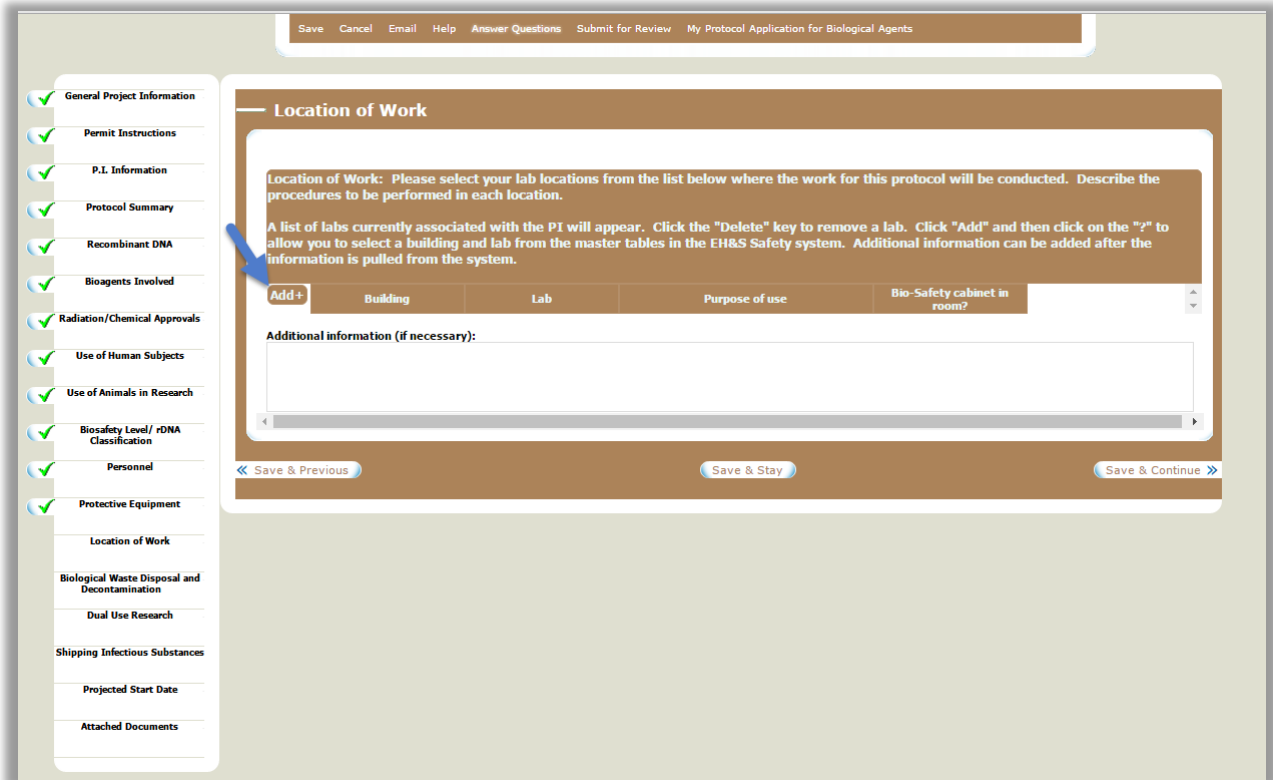
- In-line vacuum filter
- Chemical fume hood

Additional comments/specific details:

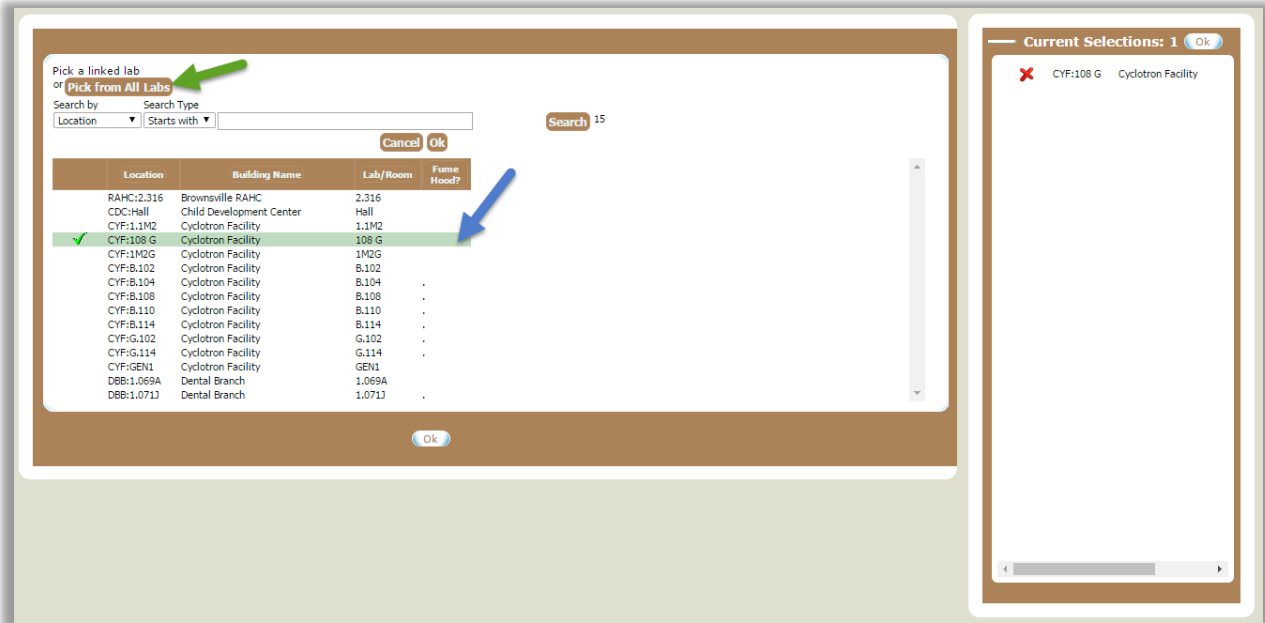
« Save & Previous Save & Stay Save & Continue »

3.13. Location of Work section

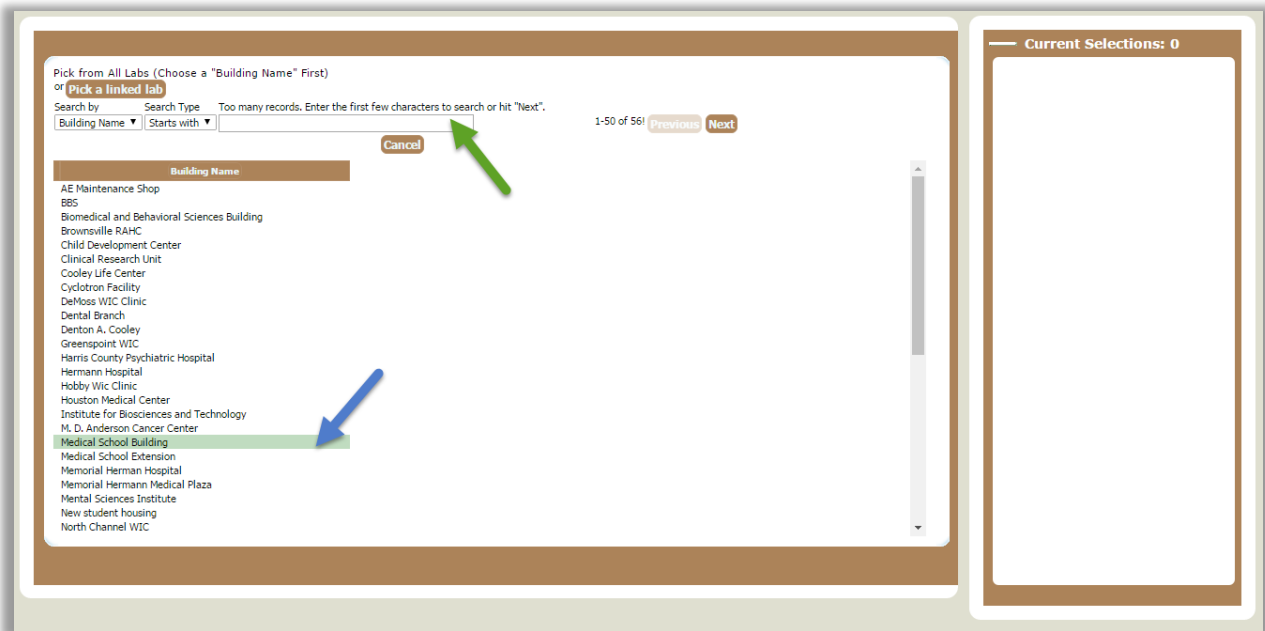
- Enter the location(s) where the work described in the protocol will be performed.
- Click the “Add+” button (**blue arrow**) to enter the Lab Selection Tool. It will be auto-populated with any spaces that you are already registered for.
 - If, after following the steps included in this guide, you still cannot find the laboratory space you are looking for, contact EH&S at (713) 500-5858 or Biosafety at (713) 500-8170



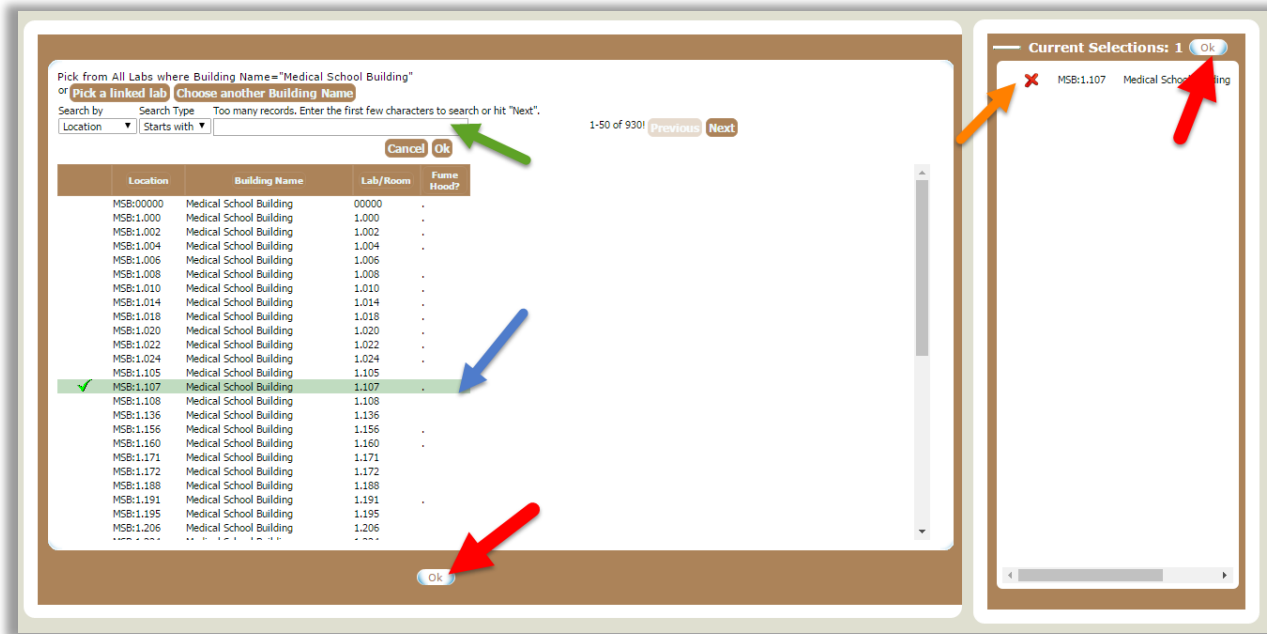
- To select one of your already assigned spaces for the new protocol, click on the “Select” link to the left of the room number (**blue arrow**).
- If you don’t see the space you wish to add, click on the “Pick from All Labs” button (**green arrow**) to pick from all labs.



- Select the building in which your lab is located (blue arrow) or search for it (green arrow).



- Then select the appropriate room (**blue arrow**). You may search for the appropriate room using the search field (**green arrow**).
 - If you still don't see the space you wish to add, contact Biosafety at (713) 500-8170.
- You may add more than one lab in the Lab Selection Tool.
- To remove a selection, click on the red 'x' next to it in the current selection window (**orange arrow**).
- Once you have selected all the labs appropriate for this work, click on the "Ok" button (**red arrow**) to return to the Location of Work section.



- Describe the work to be performed in the listed space (e.g. Tissue Culture, reagent preparation, animal surgery, etc.) (**blue arrow**).
- If there is a Biosafety Cabinet in the room, please check the appropriate box (**orange arrow**).
- If you wish to clarify some aspect of a space listed in this section, please use the “Additional Information” box – for example if you are sharing a space for some portion of the work.
- Once you have completed the “Location of Work” section, click on ‘Save’ (**green arrow**) or ‘Save & Continue’ (**red arrow**) to progress to the “Biological Waste Disposal and Decontamination” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Location of Work

Location of Work: Please select your lab locations from the list below where the work for this protocol will be conducted. Describe the procedures to be performed in each location.

A list of labs currently associated with the PI will appear. Click the "Delete" key to remove a lab. Click "Add" and then click on the "?" to allow you to select a building and lab from the master tables in the EH&S Safety system. Additional information can be added after the information is pulled from the system.

Add+	Building	Lab	Purpose of use	Bio-Safety cabinet in room?
unsaved	Medical School Building	1.107		<input type="checkbox"/>

Additional information (if necessary):

[Save & Previous](#)
[Save & Stay](#)
[Save & Continue](#)

3.14. Biological Waste Disposal and Decontamination section

- To add a type of waste to the table, click on the “Add+” button (**blue arrow**).
- This will add a new line and allow you to select one of the more common waste items from a drop-down menu.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Biological Waste Disposal and Decontamination

Biological waste disposal/Spill & Surface Decontamination: Please select the waste to be generated from the list below and describe the procedures for waste disposal for this project. Include waste disposal/ disinfection practices and methods for transport of waste through the facility for disposal.

Add+	Type of Waste	Method of contamination	Description (if Other) or Autoclave location	Mixed waste?	Method of Disposal
unsaved	-- No Selection --	-- No Selection --		-- No Selection --	

Additional

- Solid Waste
- Liquid Waste
- Animal Cages
- Animal Carcasses
- Spills and surface decontamination
- Sharps
- Other

Contact the Environmental Protection Program at 713-500-8100 for more information regarding proper waste disposal at UTHSC-H. Contact Marshall Lofton at 713-500-7726 for scheduling disposal of animal carcasses.

Save & Previous Save & Stay Save & Continue

- Add as many lines as necessary to cover all the types of waste you will generate during your work and fill out the table as necessary. An example of a completed table is included below. If you have any questions about waste disposal, contact the Environmental Protection Program (EPP) at (713) 500-5835.
- Once you have completed the “Biological Waste Disposal and Decontamination” section, click on ‘Save & Continue’ (red arrow) to progress to the “Dual Use Research” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Biological Waste Disposal and Decontamination

Biological waste disposal/Spill & Surface Decontamination: Please select the waste to be generated from the list below and describe the procedures for waste disposal for this project. Include waste disposal/ disinfection practices and methods for transport of waste through the facility for disposal.

Add+	Type of Waste	Method of Decontamination	Description (if Other) or Autoclave location	Mixed waste?	Method of Disposal	
unsaved	Liquid Waste	10% bleach		-- No Selection --	sink disposal	15 min
unsaved	Solid Waste	Autoclave waste	MSB X.NNN	-- No Selection --	municipal trash	
unsaved	Sharps	-- No Selection --	EPP pick-up	-- No Selection --		
unsaved	Spills and surfs	10% bleach		-- No Selection --	solid waste disposal	15 min

Additional information (if necessary):

Contact the Environmental Protection Program at 713-500-8100 for more information regarding proper waste disposal at UTHSC-H. Contact Marshall Lofton at 713-500-7726 for scheduling disposal of animal carcasses.

Save & Previous Save & Stay **Save & Continue**

3.15. Dual Use Research section

- Read this section carefully and select the appropriate response from the drop-down menu (blue arrow).
- Once you have completed the “Dual Use Research” section, click on ‘Save & Continue’ (red arrow) to progress to the “Shipping Infectious Substances” section.

3.16. Shipping Infectious Substances section

- If you are transporting an infectious substance across a public roadway, whoever assembles the package will need to take the [Infectious Substance Shipper \(ISS\) Training through UTHealth](#).
- If you are transporting an infectious or potentially infectious substance outside of your laboratory, please describe what you will use to contain the substance. Typically the IBC suggests using secondary containment – containment that is shatter-, puncture-, and leak-proof and contains the primary vessel which is also resilient to breakage or release.
- Once you have completed the “Shipping Infectious Substances” section, click on ‘Save & Continue’ (red arrow) to progress to the “Projected Start Date” section.

The screenshot displays a web application interface for the 'Shipping Infectious Substances' section. On the left, a sidebar contains a checklist of sections, with most items marked with a green checkmark. The main content area is titled 'Shipping Infectious Substances' and contains a form with the following elements:

- A checkbox labeled 'Check here if you are shipping infectious substances or patient specimens'.
- A text input area labeled 'If YES, please provide an explanation:'.
- A text input area labeled 'If yes, please provide a description below. Note that crossing any public road is considered shipping (i.e. this includes carrying samples to or from UT-MDACC).'

At the bottom of the form, there are three buttons: 'Save & Previous', 'Save & Stay', and 'Save & Continue'. A red arrow points to the 'Save & Continue' button.

3.17. Projected Start Date section

- Please fill this section out as appropriate.
- Once you have completed the “Projected Start Date” section, click on ‘Save & Continue’ (red arrow) to progress to the “Attached Documents” section.

Save Cancel Email Help Answer Questions Submit for Review My Protocol Application for Biological Agents

Projected Start Date

Projected Start Date:

Upon Approval

Specific Date (if available):

Additional Information:

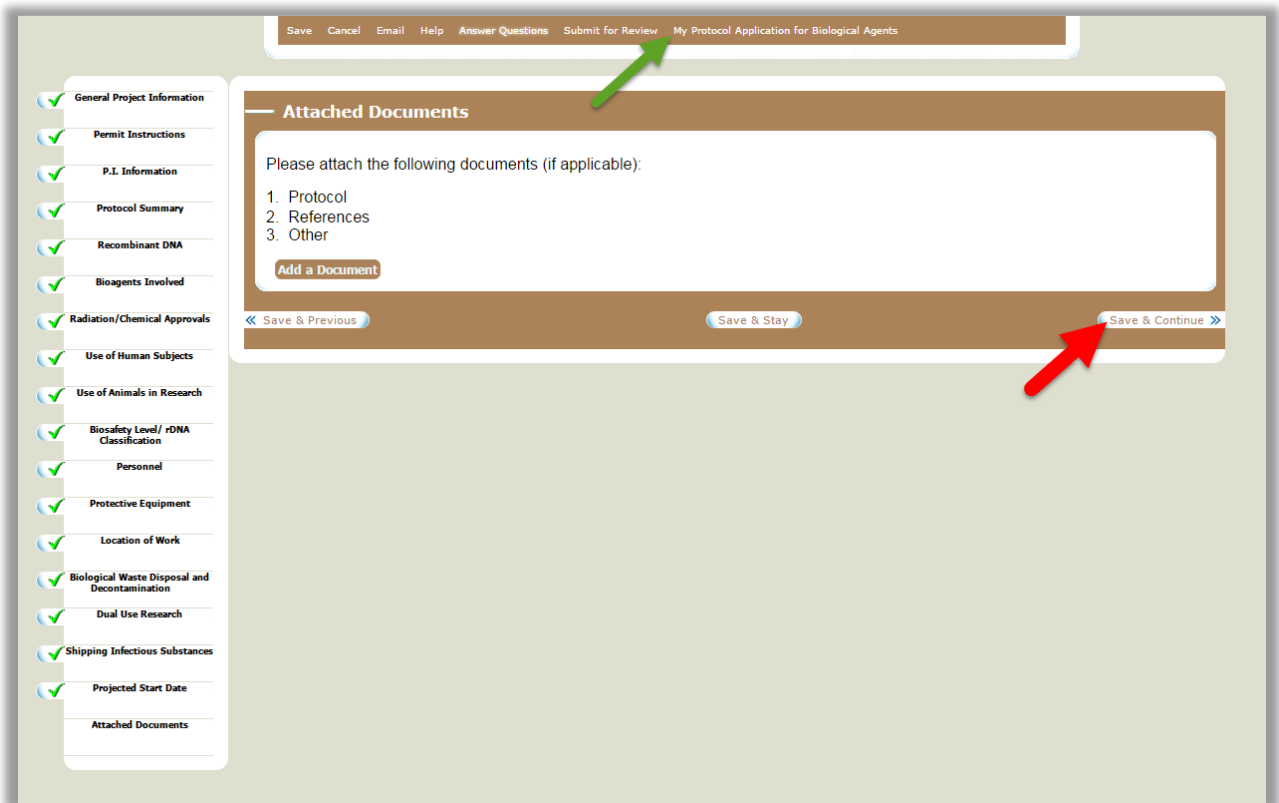
Ongoing (renewal)

Previous protocol number:

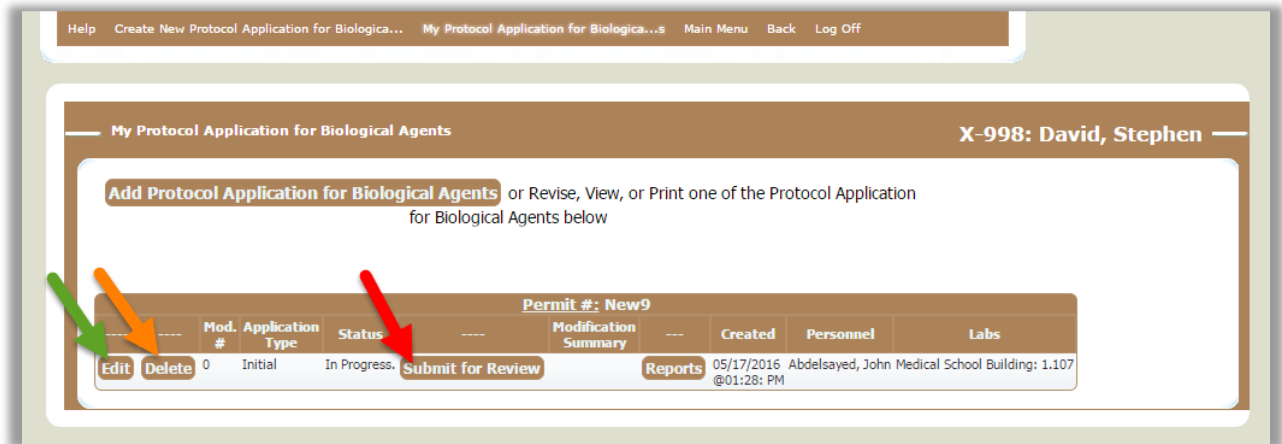
« Save & Previous Save & Stay Save & Continue »

3.18. Attached Documents section

- The IBC requests that you attach Standard Operating Procedures (SOPs) for the work you plan to do as well as vector maps for any viral vectors.
- You may also attach plasmid maps, laboratory manuals, training certificates or study documents that may impact the IBC’s Risk Assessment.
- Once you have completed the “Attached Documents” section, click on ‘Save & Continue’ (**red arrow**) to submit the application and return you to your protocols overview. You may also click on the “My Protocol Application for Biological Agents” link (**green arrow**) to return to the summary screen containing all of your IBC protocols.

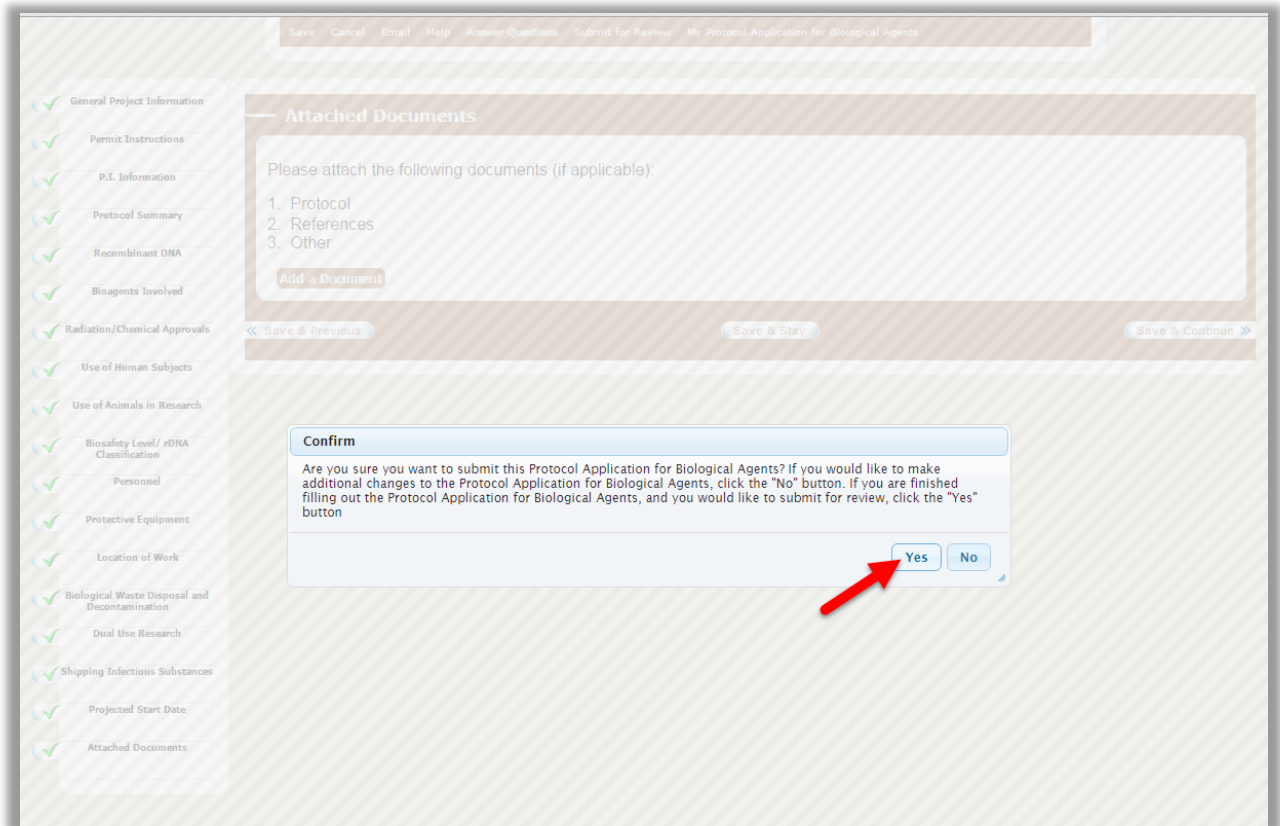


- If you need to return to the protocol to edit, revise, or update information, click on the “Edit” link (green arrow).
- To submit the protocol to the Biosafety Office for review, click on the “Submit for Approval” link (red arrow).
- If you need to delete a protocol that has not yet been submitted, click on the “Delete” link to the left of the Permit # (orange arrow).

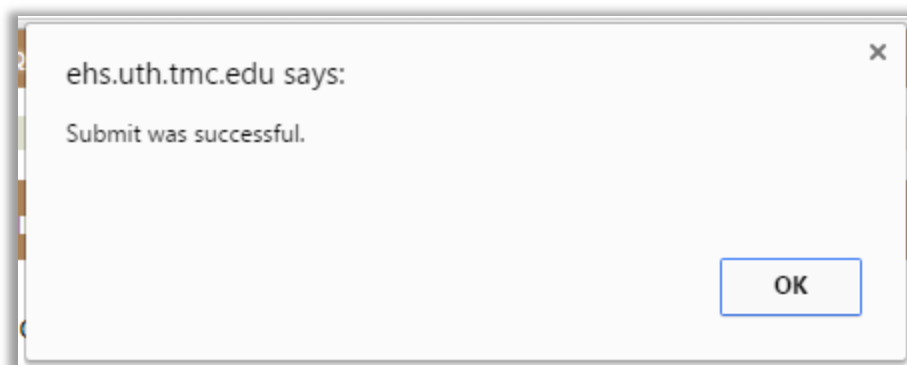


3.19. Submission

- Submitting the protocol from your protocol review page will present you with the following dialogue. If you have no further changes to make, click the “Yes” button (red arrow).



- You should receive the following message that the submission was successful.



- The system should return you to your protocol only now in the status field, it will say “Submitted for Approval” (green arrow).

Help Create New Protocol Application for Biologica... My Protocol Application for Biologica...s Main Menu Back Log Off

My Protocol Application for Biological Agents X-998: David, Stephen

Add Protocol Application for Biological Agents or Revise, View, or Print one of the Protocol Application for Biological Agents below

Permit #: New9

Mod. #	Application Type	Status	Modification Summary	Created	Personnel	Labs
0	Initial	Submitted for Approval.		05/17/2016 @01:28: PM	Abdelsayed, John	Medical School Building: 1.107

View Reports

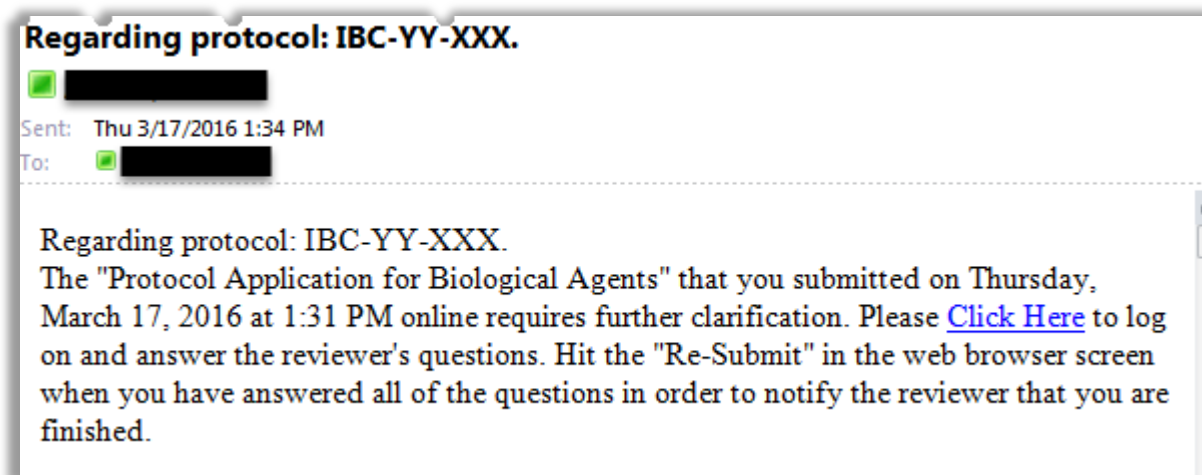
4. Protocol Review and Approval Process

4.1. Protocol Review

- Once the Biosafety office receives the new protocol, they will assign it a number starting with "IBC" with two digits to indicate the fiscal year it was submitted ("YY") and three digits to indicate which protocol it was to be received that year ("XXX") (**green arrow**). This code will be your protocol number.

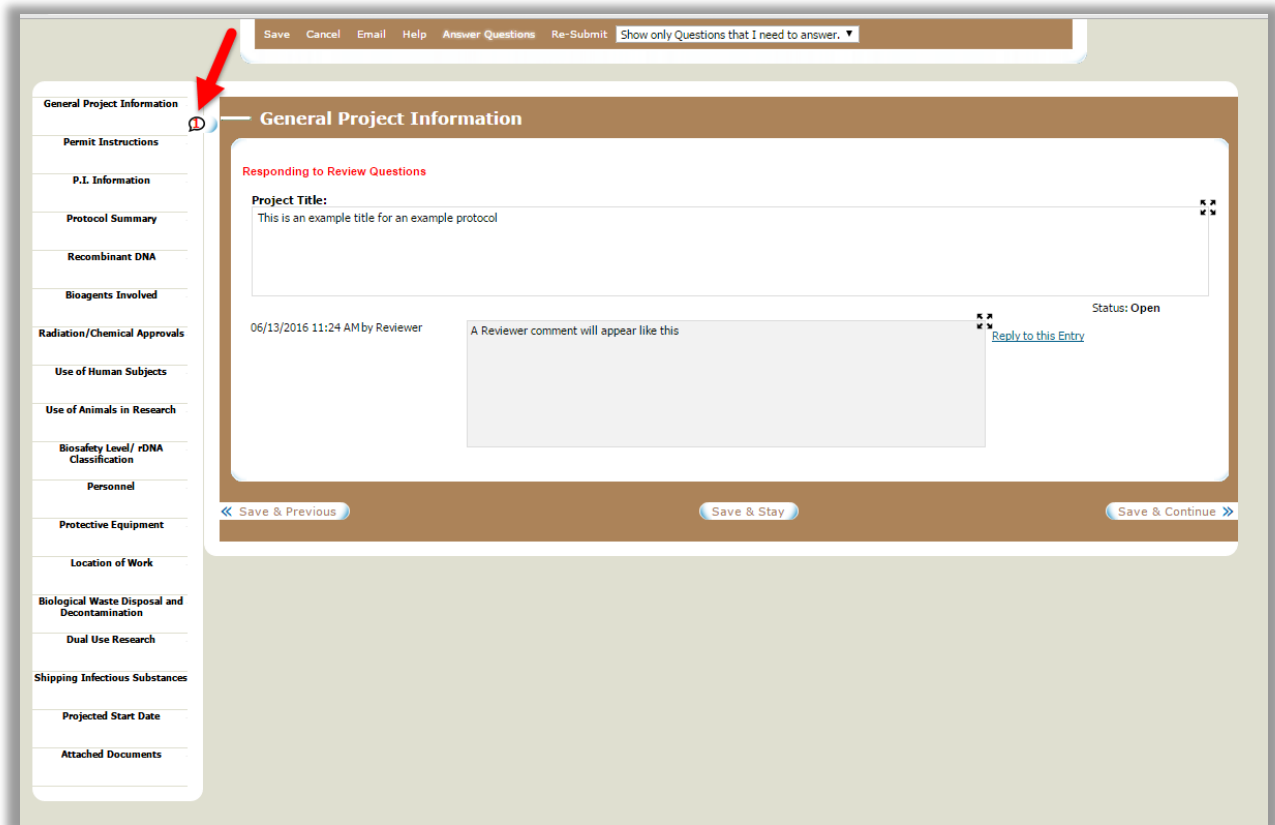


- After the Biosafety office reviews the protocol, it will be determined if the submission also requires review by the IBC. If the protocol requires review by the IBC, it will be reviewed first by a sub-committee of subject-matter experts. They will review the protocol and may have questions about the protocol.
- If there are questions by the sub-committee, you will receive an e-mail notification with a link to log into the system which will direct you to the questions asked.



4.2. Responding to Reviewer Questions and Comments

- Click on the link in the email. It should take you to the log-in screen for EHSA. Log in with your university credentials and it should take you to your protocol. There will be call-outs next to each section that has comments for you to address (**red arrow**).



- Make sure that either “Show only Questions that I need to answer” or “Show All Questions” is selected from the Display Options drop-down menu (blue arrow).
- To respond to the question or comment, click on “Reply to this Entry” (green arrow).

Save Cancel Email Help Answer Questions Re-Submit Show only Questions that I need to answer. Hide Review Questions. Show All Questions. Show only Questions that I need to answer.

General Project Information

Responding to Review Questions

Project Title:
This is an example title for an example protocol

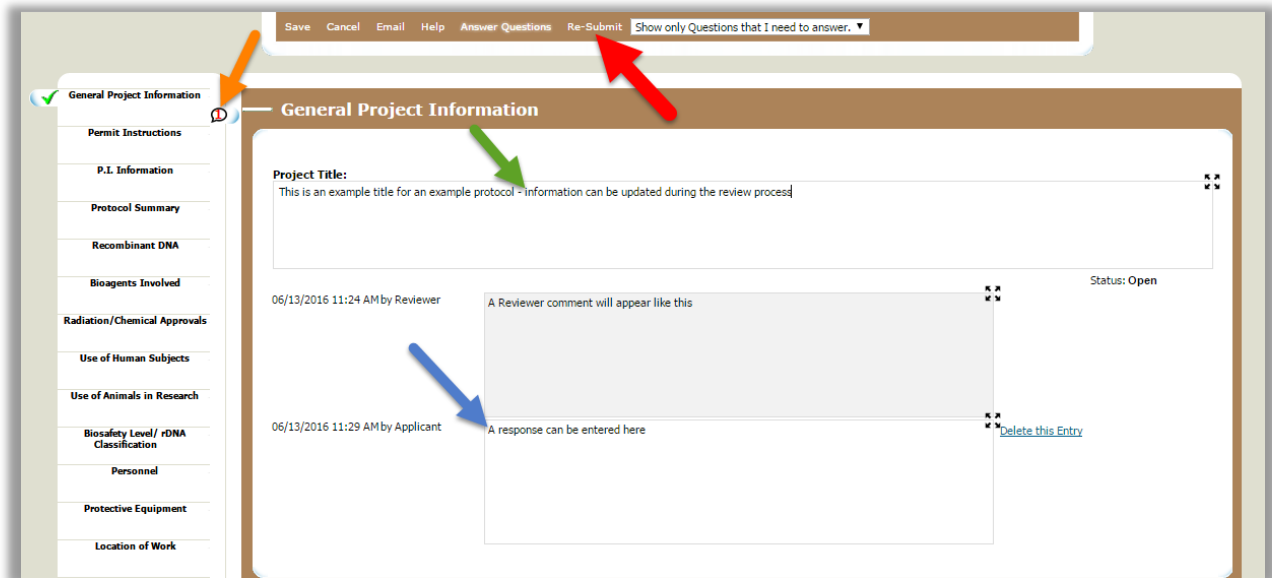
06/13/2016 11:24 AM by Reviewer A Reviewer comment will appear like this

Status: Open
[Reply to this Entry](#)

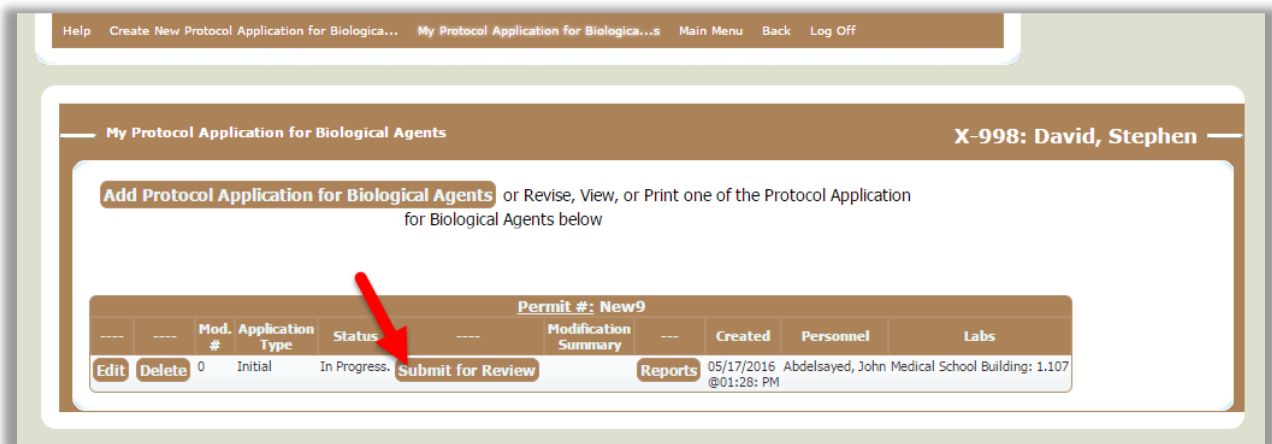
Save & Previous Save & Stay Save & Continue

General Project Information
Permit Instructions
P.I. Information
Protocol Summary
Recombinant DNA
Bioagents Involved
Radiation/Chemical Approvals
Use of Human Subjects
Use of Animals in Research
Biosafety Level/ rDNA Classification
Personnel
Protective Equipment
Location of Work
Biological Waste Disposal and Decontamination
Dual Use Research
Shipping Infectious Substances
Projected Start Date
Attached Documents

- Then enter the text in the response field (**blue arrow**).
- You may also enter text in the corresponding text field of the protocol itself (**green arrow**).
- If you wish to enter text in both the response field and the text field, we recommend saving between each change.
- Please check all sections of the protocol for questions/comments before re-submitting. The call-outs on the left hand panel will show you where in the protocol comments have been made by reviewers (**orange arrow**).
- After addressing all questions/comments in the protocol, select “Re-Submit” from the top of the page or return to your protocol management page and select the “Re-Submit” button (**red arrows**). This will notify the Biosafety Office and the Review sub-committee that their questions and comments have been addressed. If reviewers have remaining or new questions or comments, they will contact you again for further clarification.

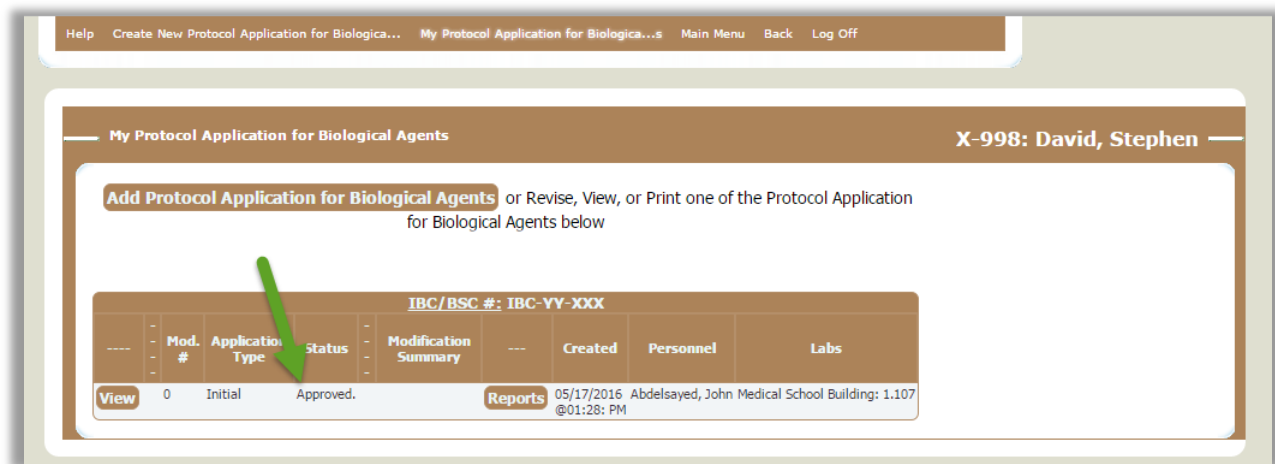


Or



4.3. IBC Review, Risk Assessment, Risk Mitigation, and Approval

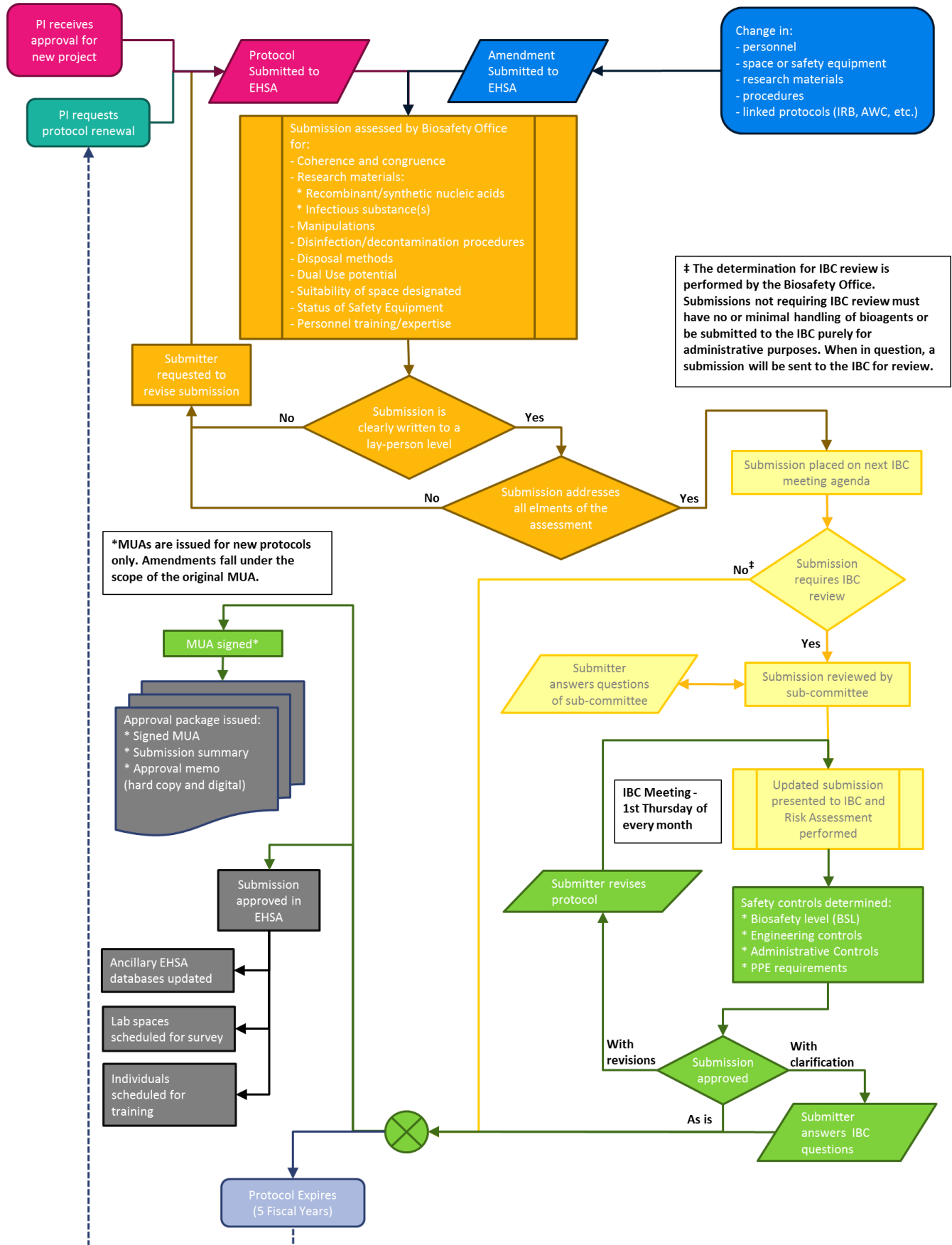
- After submitting your updated protocol, it will be reviewed by the IBC at their monthly meeting (First Thursday of every month).
- The IBC will be presented with your protocol by a Safety Specialist then the IBC will perform a Risk Assessment of the protocol which will:
 - Determine what hazards are present.
 - Determine the likelihood of those hazards occurring.
 - They will then decide what measures will be taken to mitigate the risks they identify as requiring mitigation.
 - These details will be outlined in the Memorandum of Understanding and Agreement (MUA).
- Upon a majority vote of approval, your protocol will be considered approved. The MUA will then be signed by the Chair of the IBC and the Biosafety Manager. Once the MUA contains the signatures of PI as well, the protocol is considered approved and active.
 - If the Biosafety office anticipates the IBC to approve a protocol during the next session, they may ask the PI to sign the MUA beforehand to expedite the paperwork.
- Copies of the signed MUA, the protocol summary, and the approval memo from the Biosafety office will be sent electronically to the PI as well as anyone else who participated in submitting the protocol. Physical copies of the signed MUA, protocol summary and approval memo will be sent to the PI's on-campus address through inter-office mail. Retain these documents for your records.
- EHSa will be updated with the approval information and the protocol listing will change from "In Progress" to "Approved" (green arrow).



4.4. Protocol Expiration

- Protocols have a lifetime of 5 business years meaning a given protocol will expire at the end of the fifth fiscal year from the date of approval – i.e. any protocol approved in FY2016 will expire on August 31st, 2021.
 - Expired protocols are not valid and no work may be performed on them. However, protocols can be resubmitted (see Section 6 – Protocol Renewals).

4.5. Protocol Approval Flow Chart



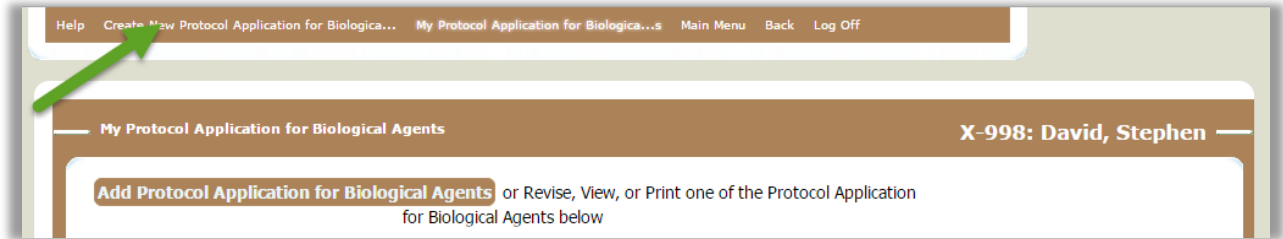
5. Protocol Amendments

5.1. Conditions Requiring an Amendment

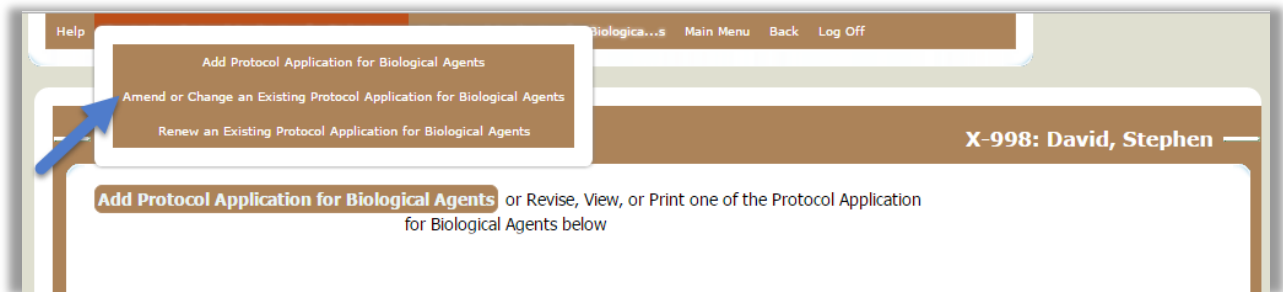
- Since research often changes, amendments to an IBC protocol are frequently necessary. The following changes require submission of an Amendment to the IBC:
 - Personnel changes – addition or removal.
 - Research material changes – for example, addition of new microorganisms, animal models, subject populations, recombinant materials, etc.
 - Research procedure changes – addition of new model systems, exposure methods, manipulations, etc.
 - Laboratory changes – use of new physical spaces or evacuation of old physical spaces.
 - Changes to safety equipment used – for example, use of a new Biosafety Cabinet.
 - Changes to linked protocols – for example, IRB or AWC protocols.

5.2. Generating an Amendment in EHSA

- Enter the EHSA (see section [2](#) of this document).
- Mouse over the “Create New Protocol Application for Biological Agents” option (**green arrow**).



- Select the “Amend or Change an Existing Protocol Application for Biological Agents” option (**blue arrow**).



- Select the appropriate protocol to change (**blue arrow**).



- Provide a brief description of the reason for the Amendment (e.g. personnel change, addition of new recombinant materials, addition of new animal species or bacterial strains, etc.).

The screenshot shows a web application interface for 'General Project Information'. At the top, there is a navigation bar with links: Save, Cancel, Email, Help, Answer Questions, Submit for Review, and My Protocol Application for Biological Agents. On the left side, there is a vertical menu with various sections: General Project Information, Permit Instructions, P.I. Information, Protocol Summary, Recombinant DNA, Bioagents Involved, Radiation/Chemical Approvals, Use of Human Subjects, Use of Animals in Research, Biosafety Level/ rDNA Classification, Personnel, Protective Equipment, Location of Work, Biological Waste Disposal and Decontamination, Dual Use Research, Shipping Infectious Substances, Projected Start Date, and Attached Documents. The main content area is titled 'General Project Information' and contains several fields: 'Permit number application is associated with:' with a text input field containing 'B-10002' and a search icon; 'What is the purpose of this application?' with a dropdown menu showing 'Amendment'; 'Project Title:' with a text area containing 'This is an example title for an example protocol'; and 'For modifications, please briefly summarize the changes below:' with a text area containing 'This is an example amendment'. At the bottom of the main content area, there are three buttons: '<< Save & Previous', 'Save & Stay', and 'Save & Continue >>'. The interface has a clean, professional design with a light beige background and brown accents.

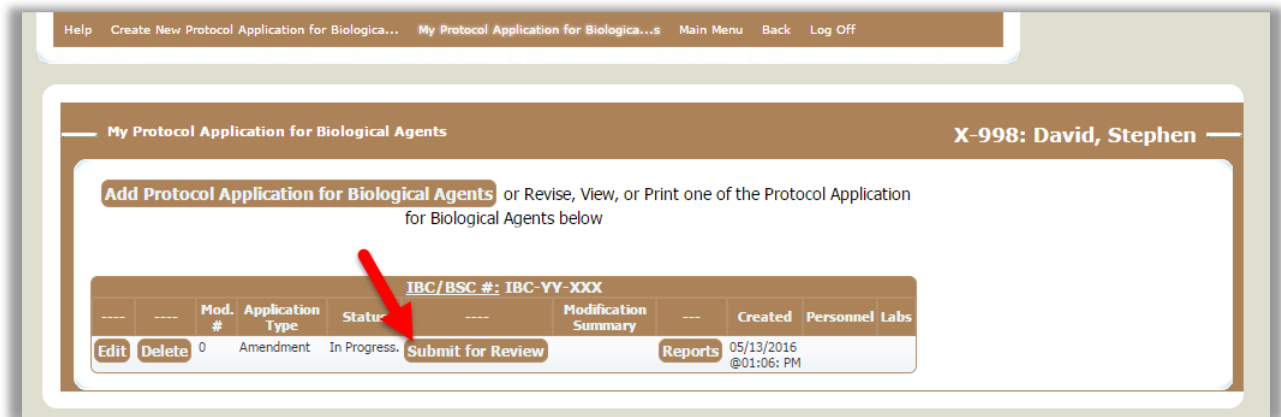
- Although the system attempts to put the appropriate information in the correct place, double-check that all information is correct in each section.

5.3. Information Updates

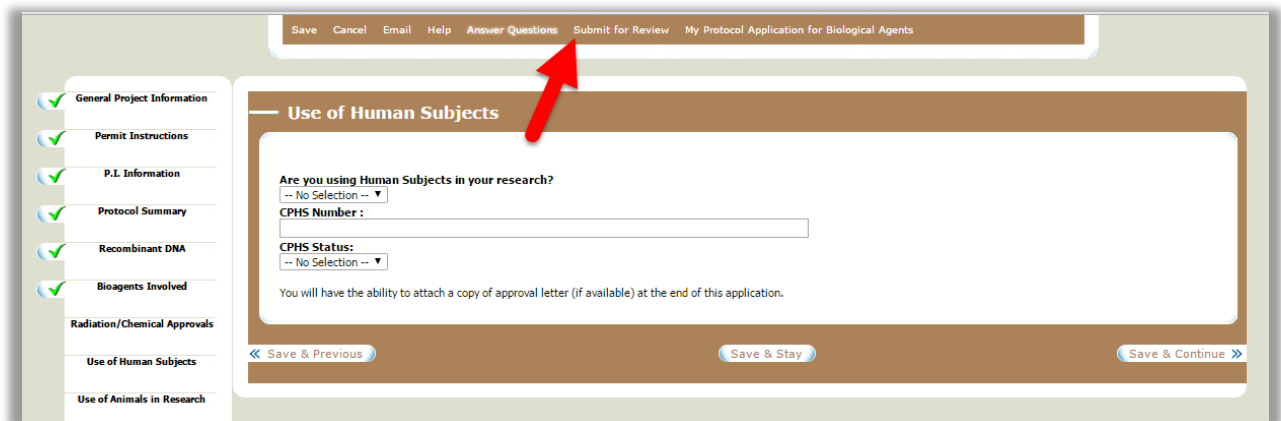
- Navigate to the section(s) that need(s) to be updated.
- Amend the information as necessary to reflect the changes in the research.
 - Now is also a good time to update any committee information such as AWC, or IRB committee approval numbers.
 - We also request that you update information on the Biosafety Cabinet Certification and Personnel Training information as well as update the personnel list to reflect any changes in personnel that have transpired in the lab.

5.4. Submission

- Click on the “Submit for Approval” button.



Or



5.5. Review

- The protocol will proceed through a similar process as the initial protocol submission (see flow-chart 4.5) however, for purely administrative updates, the Biosafety Office may determine that the protocol does not require full committee review.
- If the Biosafety Office or an IBC reviewer has questions about your Amendment, you will receive an e-mail notification similar to the one received during the initial submission process (see Guidance section [4.2](#)). Click on the link in the e-mail and respond to the question(s) as necessary as described in Guidance section [4.2](#).
- If the Biosafety Office or the IBC determines that your Amendment poses significantly different risks from the original protocol, they may ask you to submit a new Initial Protocol.

5.6. Approval

- Once review of the amendment is complete, you will receive notice that the IBC has approved your Amendment.
- You will be issued an approval memo detailing the changes made to the protocol as well as the amendment summary for your records.
- Approval of Amendments does not change the original protocol expiration date.

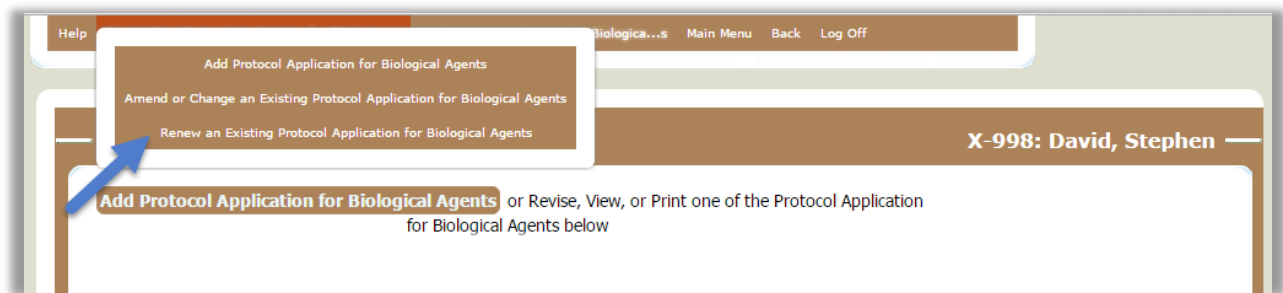
6. Protocol Renewals

6.1. Conditions Requiring Protocol Renewal

- Protocols that are expiring (i.e. have reached the end of their 5 year life span) must be renewed. Work performed on an expired protocol is not sanctioned by the University. We recommend that PI's submit a protocol renewal at least 2 months prior to the expiration date of their protocol (i.e. June of the expiring year).

6.2. Generating a Renewal Request in EHSA

- Log in to the IBC protocols section of EHSA as in Section 2.
- Select the "Renewal" button (**blue arrow**).



- Select the appropriate protocol to renew (**blue arrow**).



6.3. Information Updates

- Since most research projects change over time, make sure that the protocol is current with the most recent information. This includes:
 - The protocol summary.
 - Bioagents.
 - Recombinant or synthetic nucleic acids.
 - Decontamination and disposal techniques.
 - Personnel and their training.
 - The certification on BSCs.
 - Spaces used by the lab.

6.4. Submission

- Click on 'Submit'.

6.5. Review

- The review process for protocol renewals is identical to the initial protocol submission process (See Protocol Approval Flow-Chart, Guidance Section [4.5](#)).

6.6. Approval

- Upon approval, you will be issued a new Approval Package with an updated MUA, Protocol Summary, and Approval Memo. You will receive both a digital copy and a hard copy as you did with the initial submission.

7. Protocol Termination

7.1. Conditions Requiring Protocol Termination

- Protocols may be terminated when the work described in the protocols is no longer occurring and no research materials from the work remain in the laboratory.
- Protocols that have expired without any movement by the PI to renew will be terminated.

7.2. Submitting Termination Requests

- Contact the [Biosafety Office](#) and inform them of your need to terminate a protocol. They will ask you for the protocol number and the reason for termination.

7.3. Review and Notification

- The protocol termination request will be processed by the Biosafety Office.
- You will be notified when the Biosafety Office processes your termination request and will receive a termination letter electronically. Please retain it for your records.

8. Frequently Asked Questions (FAQs)

Q) Can someone other than a PI submit an Initial protocol or an Amendment?

A) Yes! If the PI approves of having someone else submit the protocol on his or her behalf, they can e-mail anyone in the Biosafety office a brief note saying so. Please allow some time for the individual to be added to the system.

Q) How soon can I get my approval?

A) Your application will be processed as soon as possible; however it typically takes at least two weeks to complete the process of internal review and at least two weeks to complete the process of review by IBC subcommittee. For this reason, we estimate that a protocol submitted by the first business day of a given month will be reviewed in the following month's IBC meeting. Promptly answering any questions posed by reviewers will expedite the review process.

Q) Does everything have to go through full committee review?

A) No, conditionally exempt work does not need to be reviewed by the IBC before approval. The Biosafety Office will determine if work is conditionally exempt from both the NIH Guidelines and from the stated purview of the IBC.

Q) Does an Amendment Approval change the protocol's expiration date?

A) No, an Amendment – approved or not approved, does not change the expiration date of a protocol.

Q) Can I transfer a protocol from one PI to another?

A) No, the system does not allow protocols to be transferred between PIs. If you wish to transfer work from one PI to another, you must enter the work as a new Initial Protocol under the new PI and then terminate the old protocol under the previous PI.

Q) Does the IBC allow co-PIs on a protocol?

A) The IBC recognizes only one PI per protocol. That PI is responsible for the safety and training of all personnel performing work described by the protocol. Resources are available from EHS to assist in this; please contact us at (713) 500-8100.

Q) Which other committees does the IBC talk to?

A) The IBC currently has no standing agreement to communicate with any other committee; the PI is currently the primary point of communication with all committees regarding a research project.

Q) What is a Significant Amendment?

A) Amendments are any changes made to a protocol. Significance is determined by the Biosafety Office.

9. Glossary:

AWC – Animal Welfare Committee (Institutional Animal Care and Use Committee - IACUC)

BMBL – Biosafety in Microbiology and Biomedical Laboratories

BSC – Biosafety Cabinet

CDC – Centers for Disease Control and Prevention

CSC – Chemical Safety Committee

EHS – Environmental Health & Safety

EHSA – EHS Assistant

IBC – Institutional Biosafety Committee

IRB – Institutional Review Board

MUA – Memorandum of Understanding and Agreement

NIH – National Institutes of Health

OBA – Office of Biotechnology Activities

OSP – Office of Sponsored Projects

RSC – Radiation Safety Committee