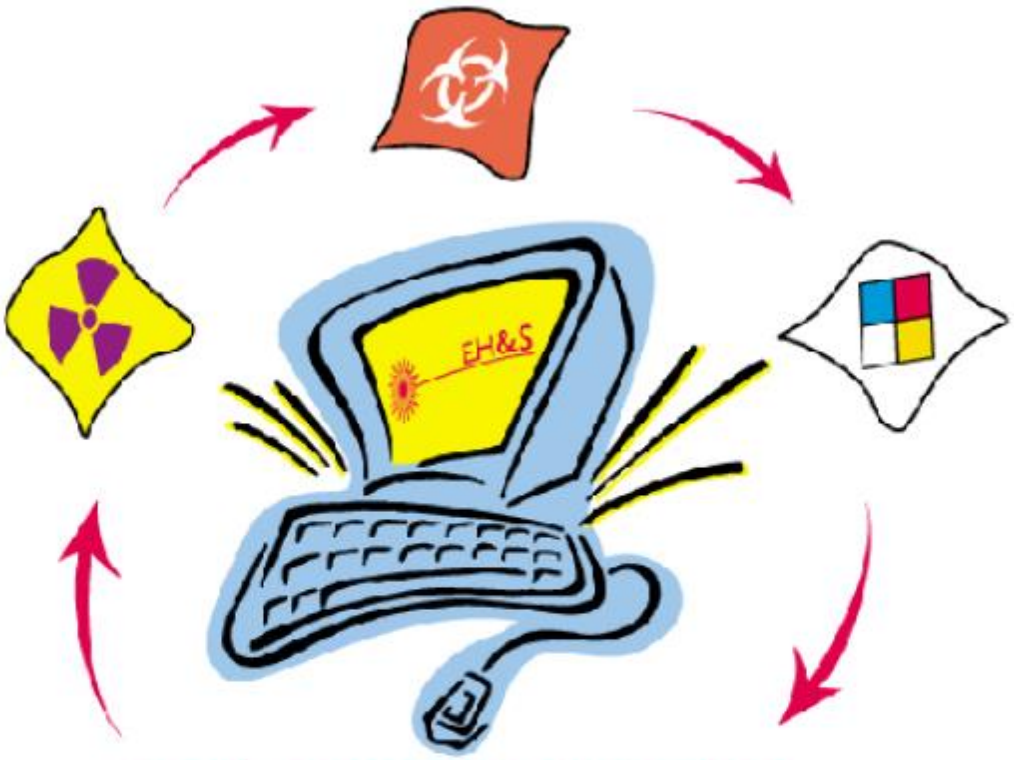


Environmental Health
& Safety Assistant

Principal Investigator's Guide

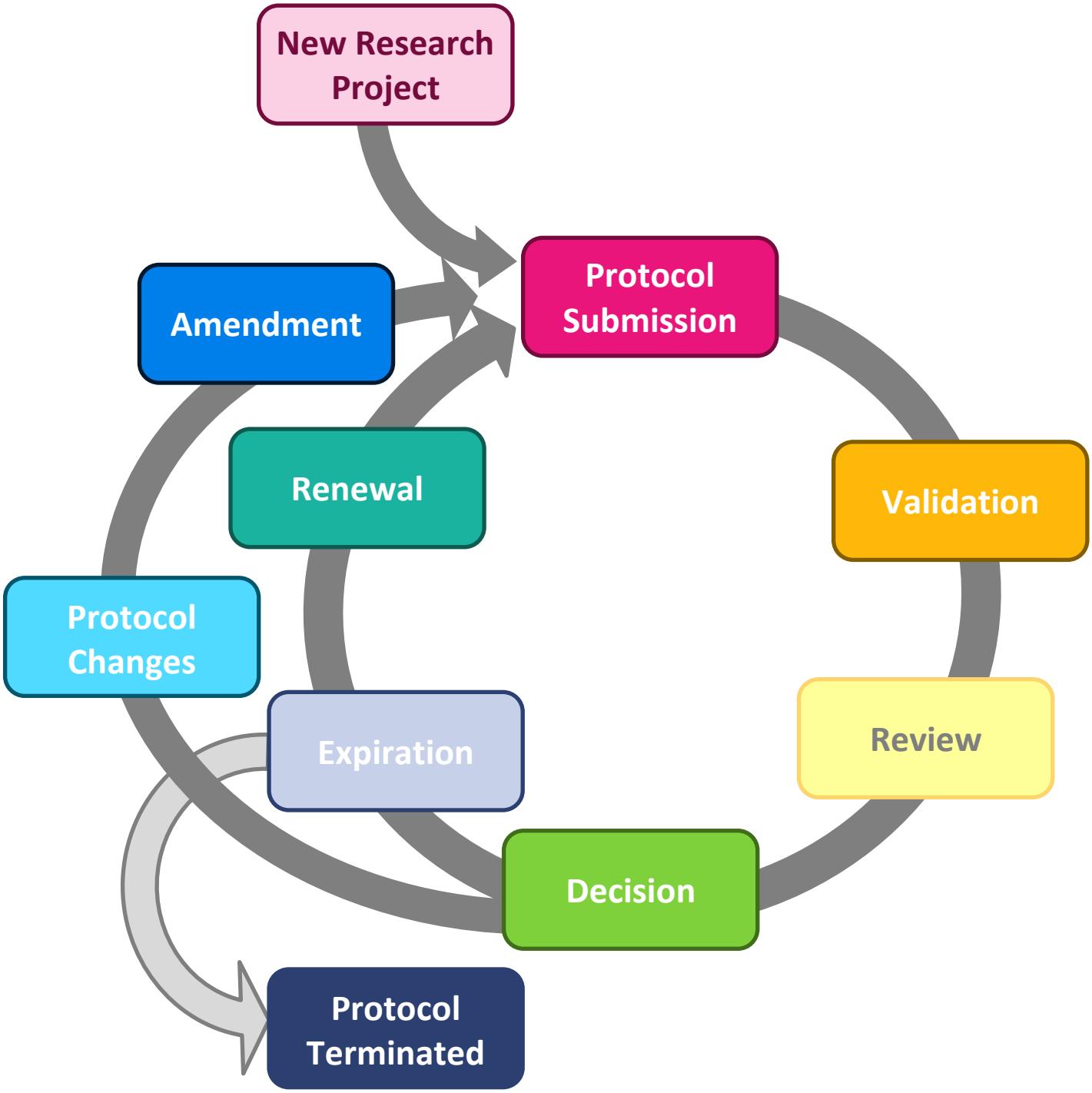
for

Submission of Protocols to the Institutional Biosafety Committee

Updated 6/15/2016

1. Protocol Review

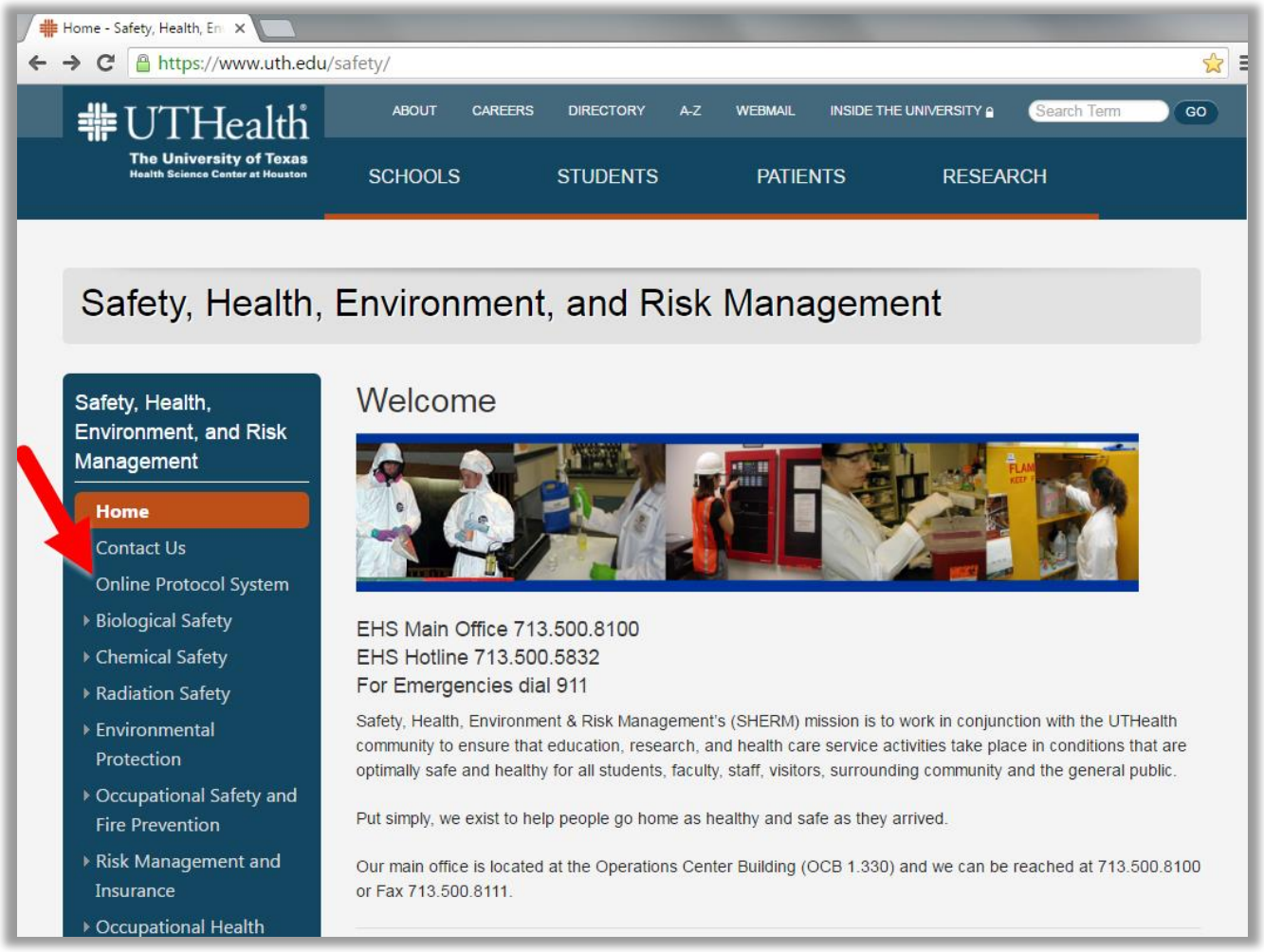
Protocol review by the Institutional Biosafety Committee is similar to protocol review by most other committees. It follows the process of protocol submission, content validation, review, decision, then expiration (and, if desired, renewal) visualized below. Most of this work is managed through the online 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**).

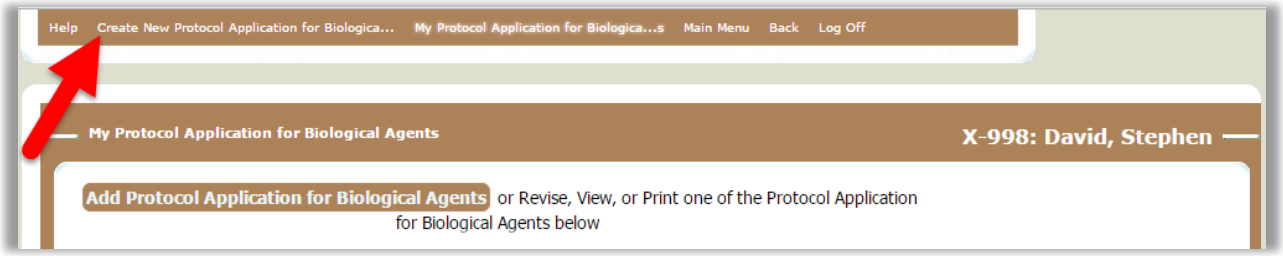


Please note EHSA works best when accessed using Chrome or Firefox. It is *NOT* compatible with Internet Explorer

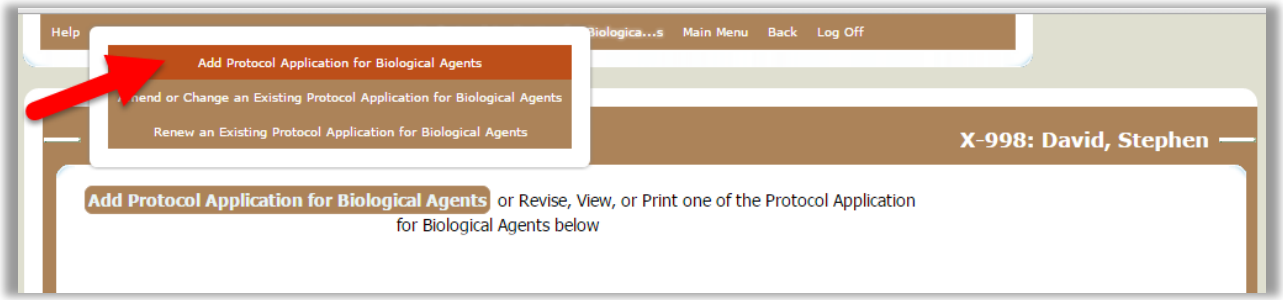
- Log on to the system with your UTHealth user ID and password.
- From the main login page, click the link entitled “Protocol Application for Biological Agents”.

3. New Applications

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

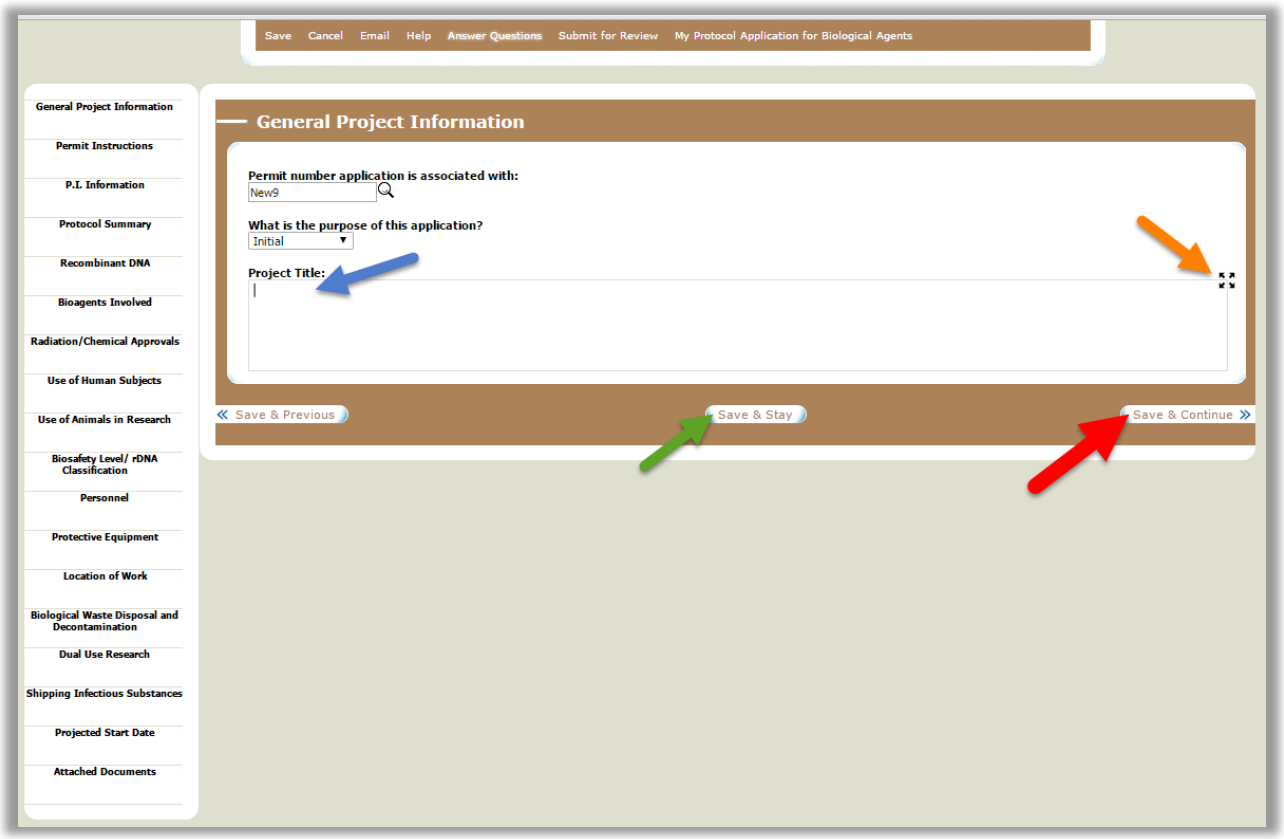


- Select “Add Protocol Application for Biological Agents” (**red arrow**).



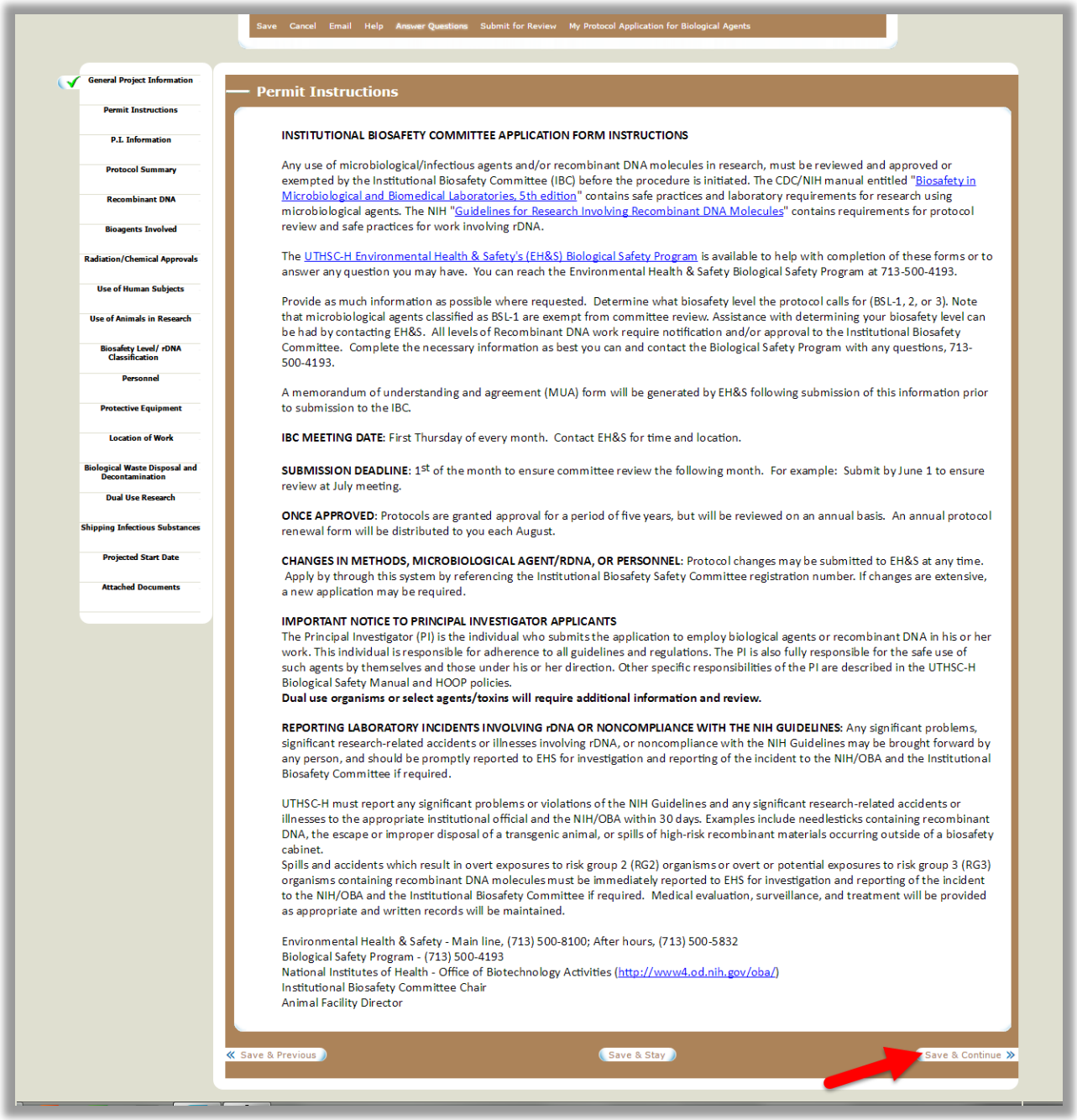
3.1. Project Title

- 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**).



3.2. Permit Instructions section

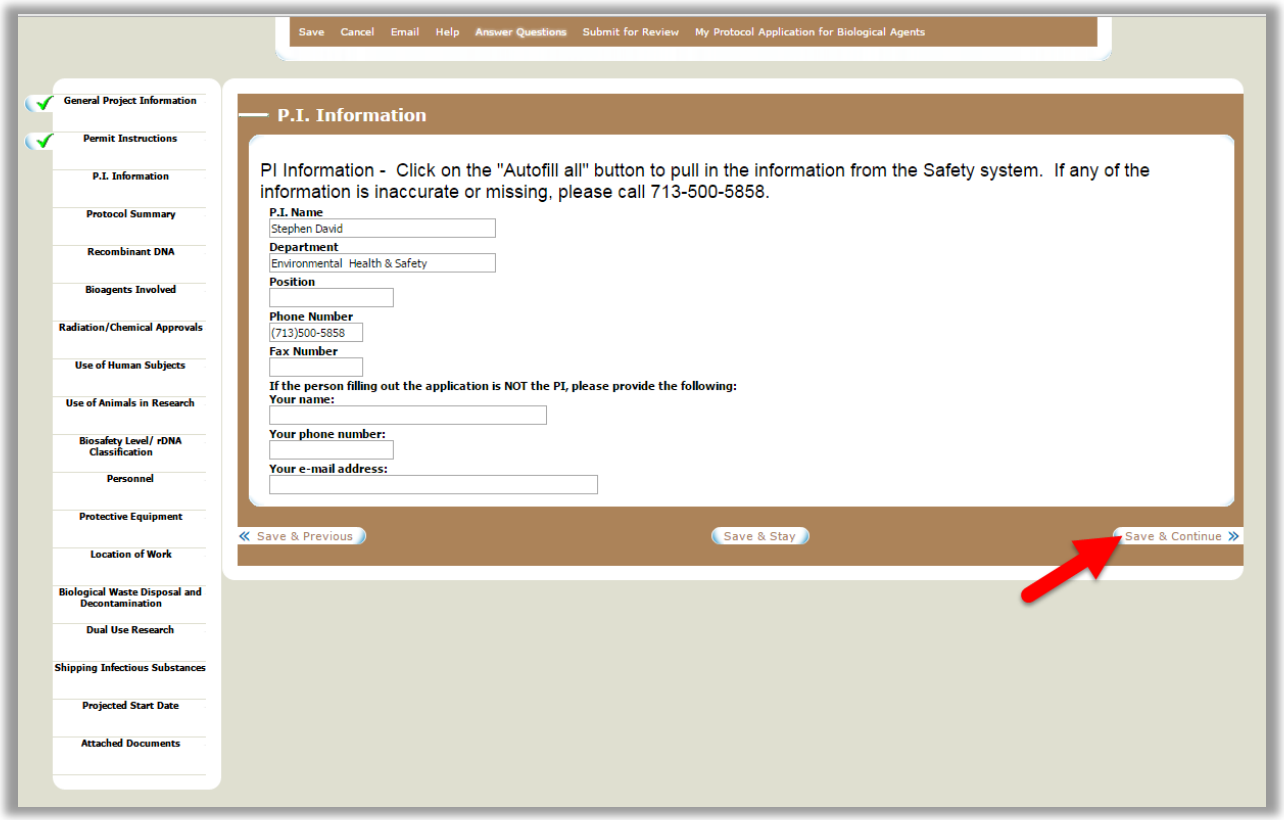
- Please read the “Permit Instructions” section carefully.
- Once you have read the Permit Instructions, click on the “Save & Continue” button (**red arrow**) to progress to the “P.I. Information” section.



3.3. P.I. Information section

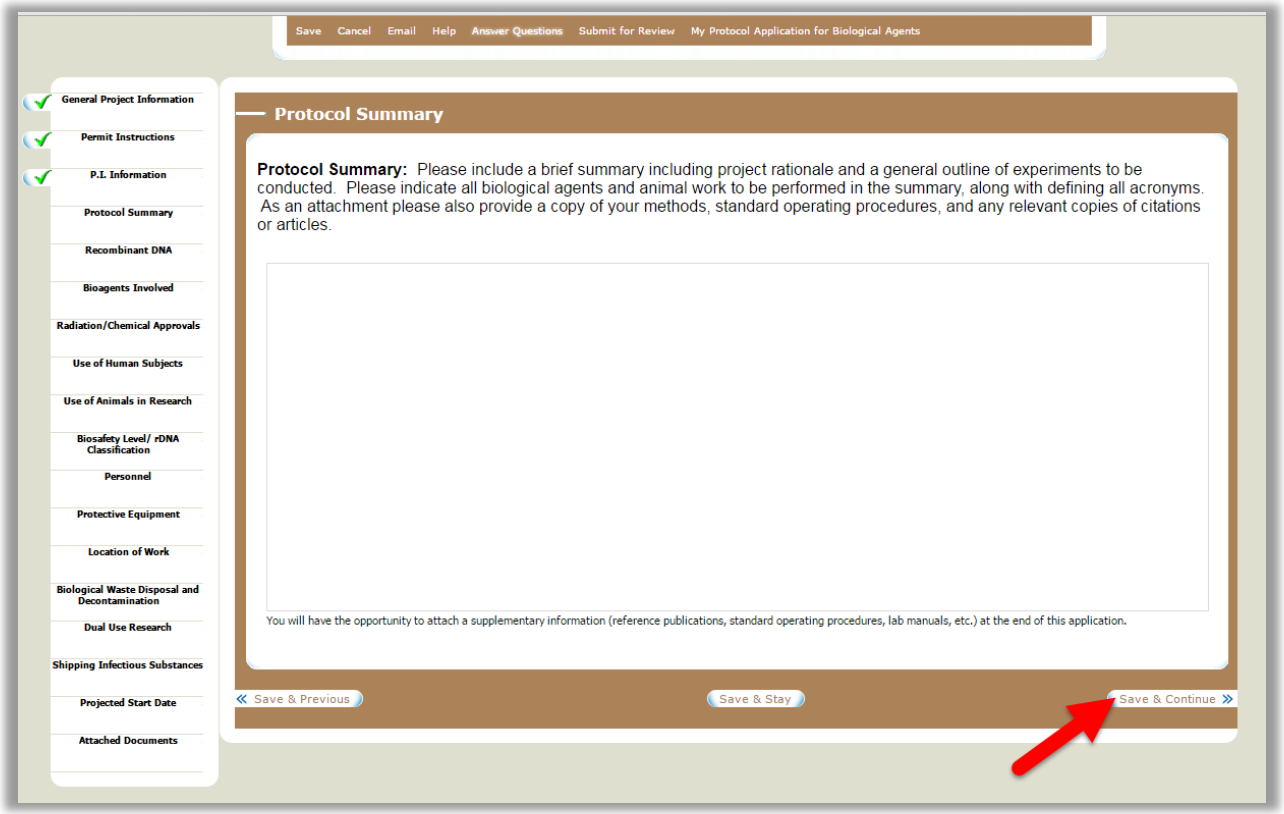
- If the person filling out the application is not the PI – such as a postdoctoral fellow, a research coordinator, a study director, or lab manager, make sure that that information is accurate as well.

- After completing the “P.I. Information” section, click “Save & Continue” (**red arrow**) to progress to the “Protocol Summary” section.



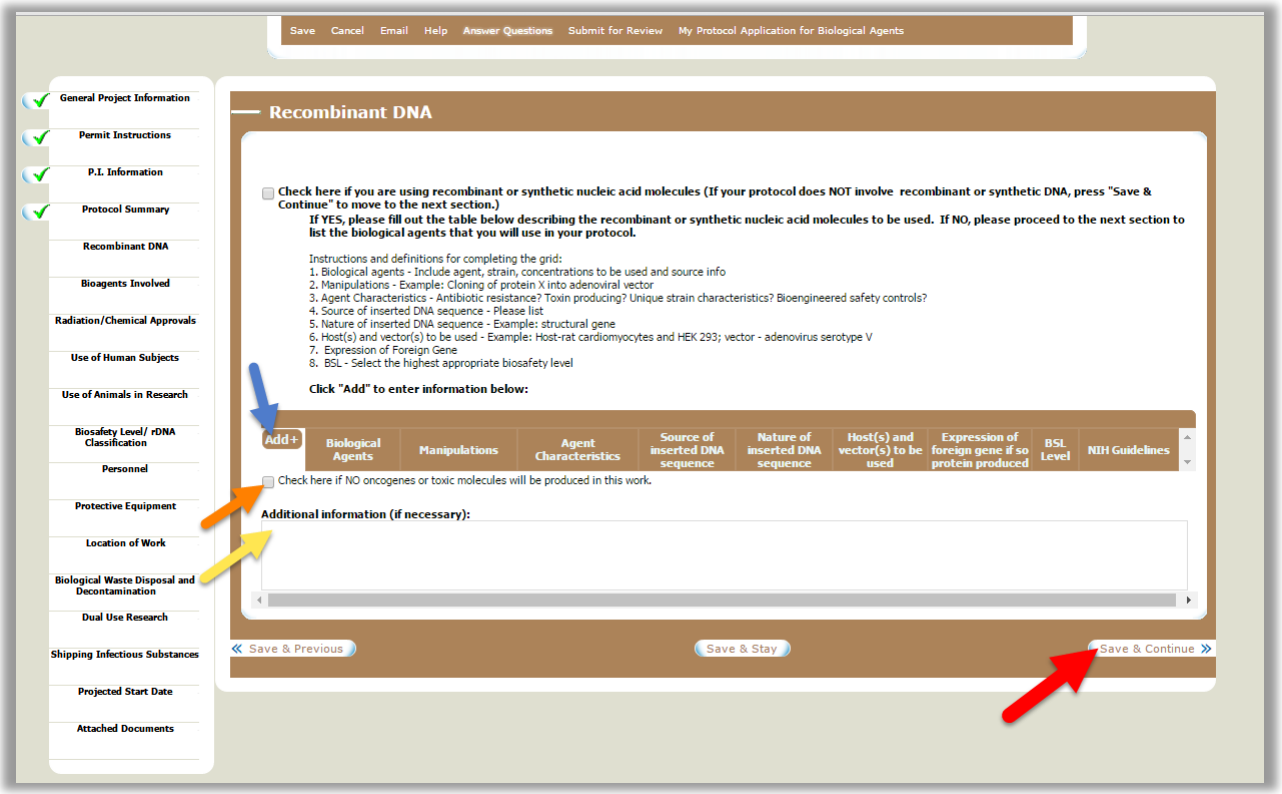
3.4. Protocol Summary section

- 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.



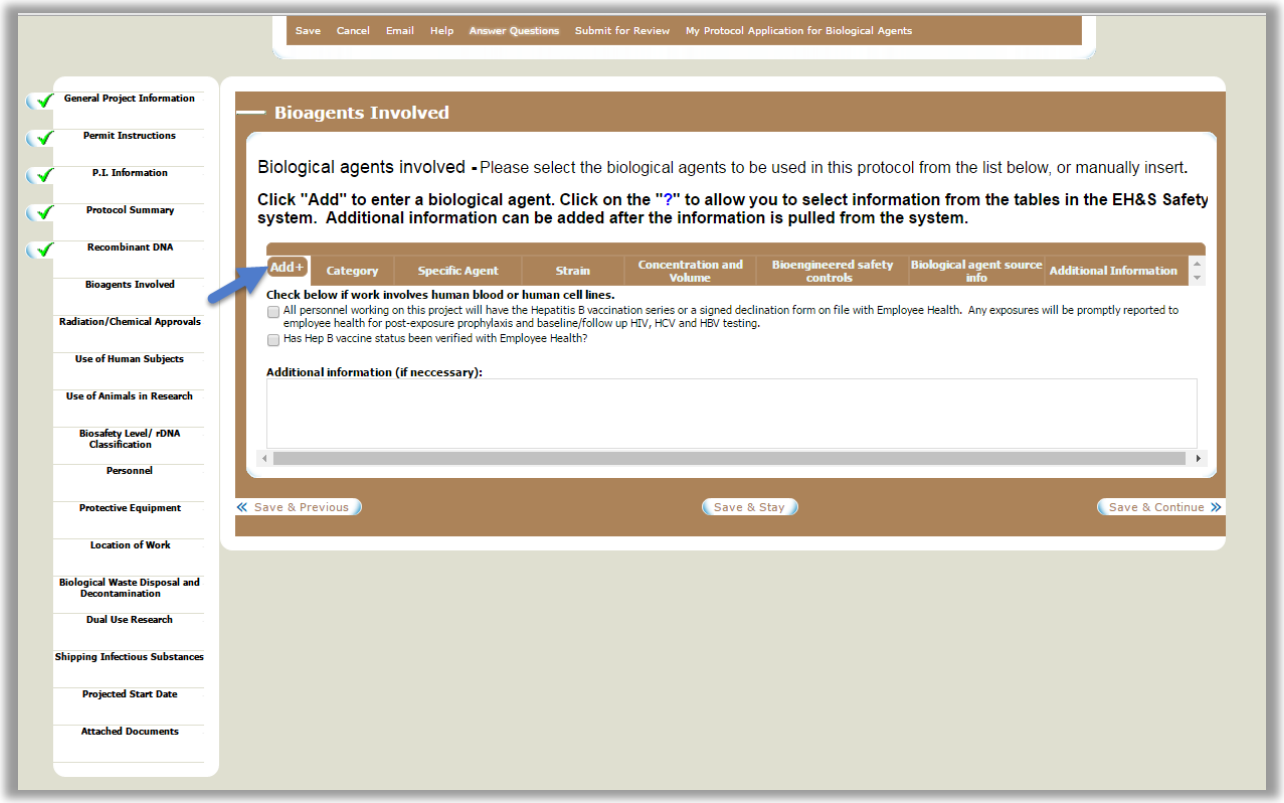
3.5. Recombinant DNA section

- 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.



3.6. Bioagents Involved section

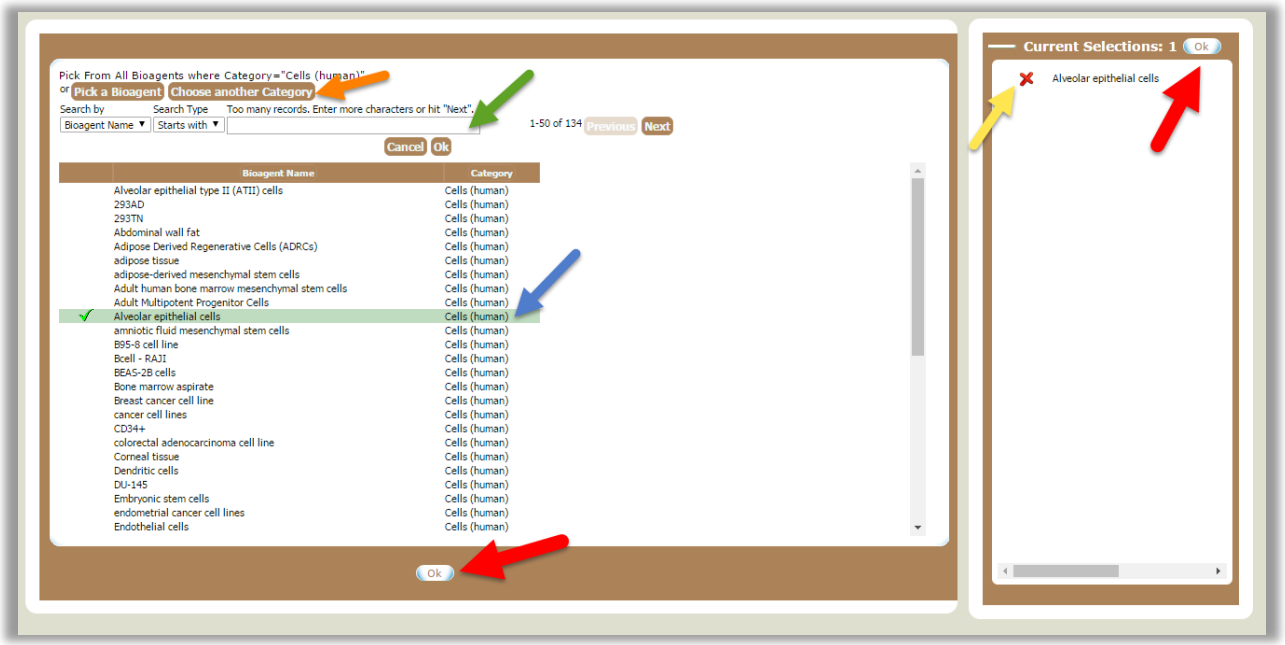
- If you are using any Risk Group II or higher microorganism or any substance that may potentially contain Risk Group II or higher microorganisms (such as blood, bodily fluids, tissues, biopsy samples, or excreta), you must fill this table out. This includes but is not limited to: transformed and primary 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.



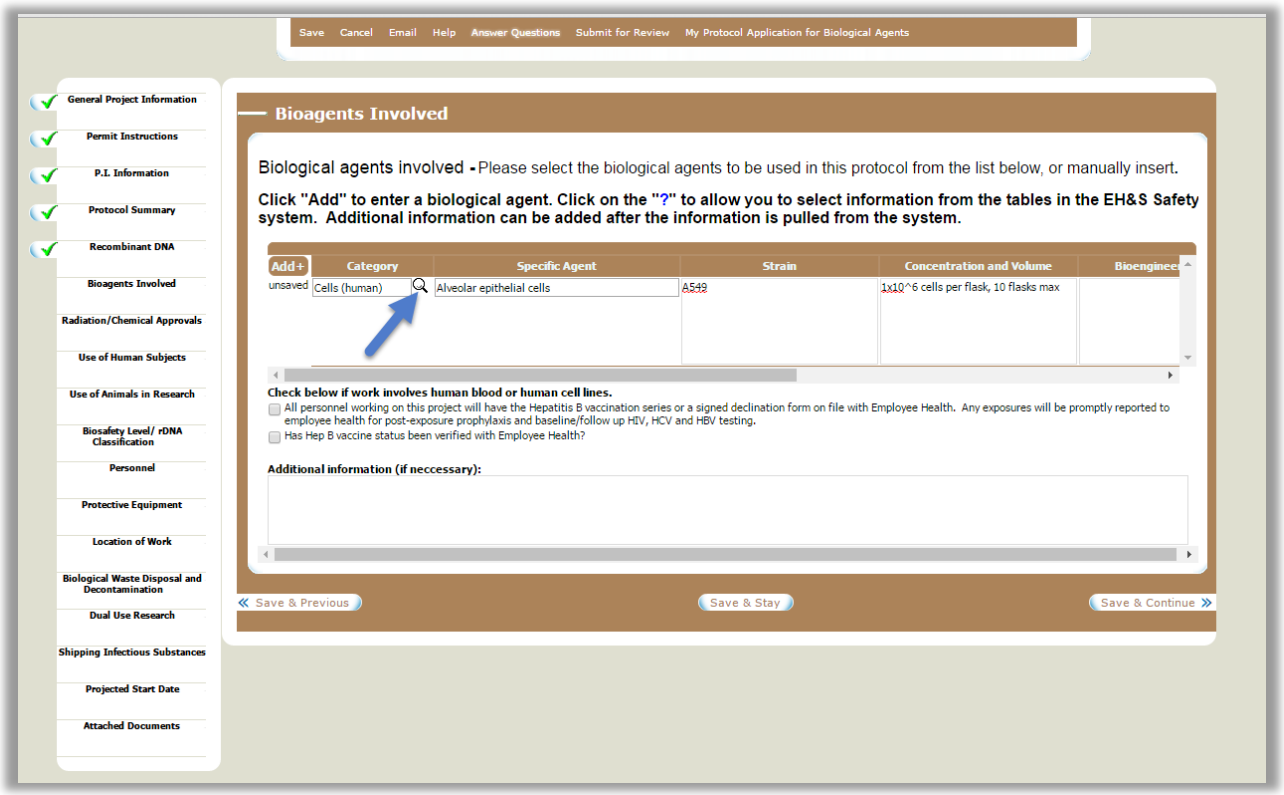
- The Bioagent Selection tool that will be populated with Bioagents you are currently approved for.
    - Select the appropriate Bioagent by clicking on the “Select” link (**blue arrow**) to the left of the name, or, if the organism you wish to add to your protocol is not on this page, use the “Pick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

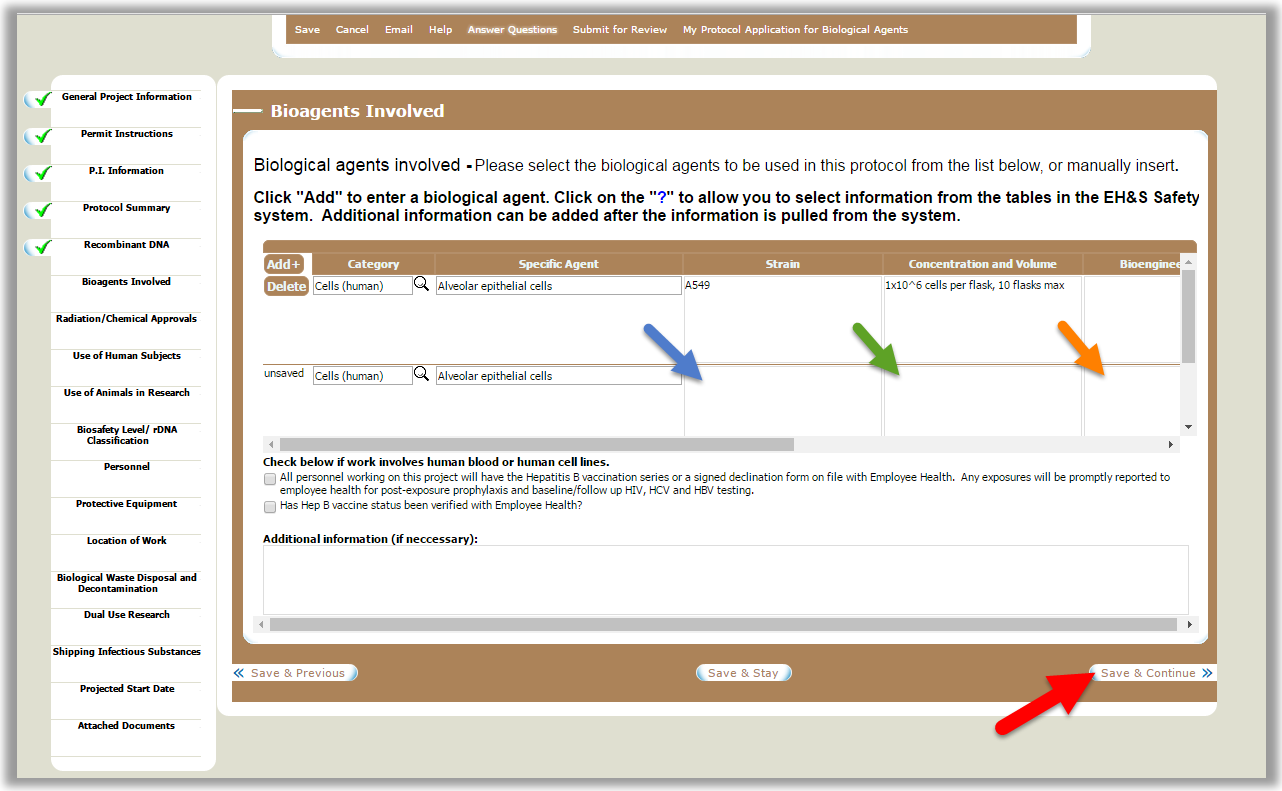
- Then select the appropriate Bioagent from the category you chose. Or search for it (**green arrow**) then click on the Bioagent name (**blue arrow**).
    - If you cannot find the Bioagent you are seeking in the category you have chosen, you can click the "Choose another Category" button (**orange 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**).

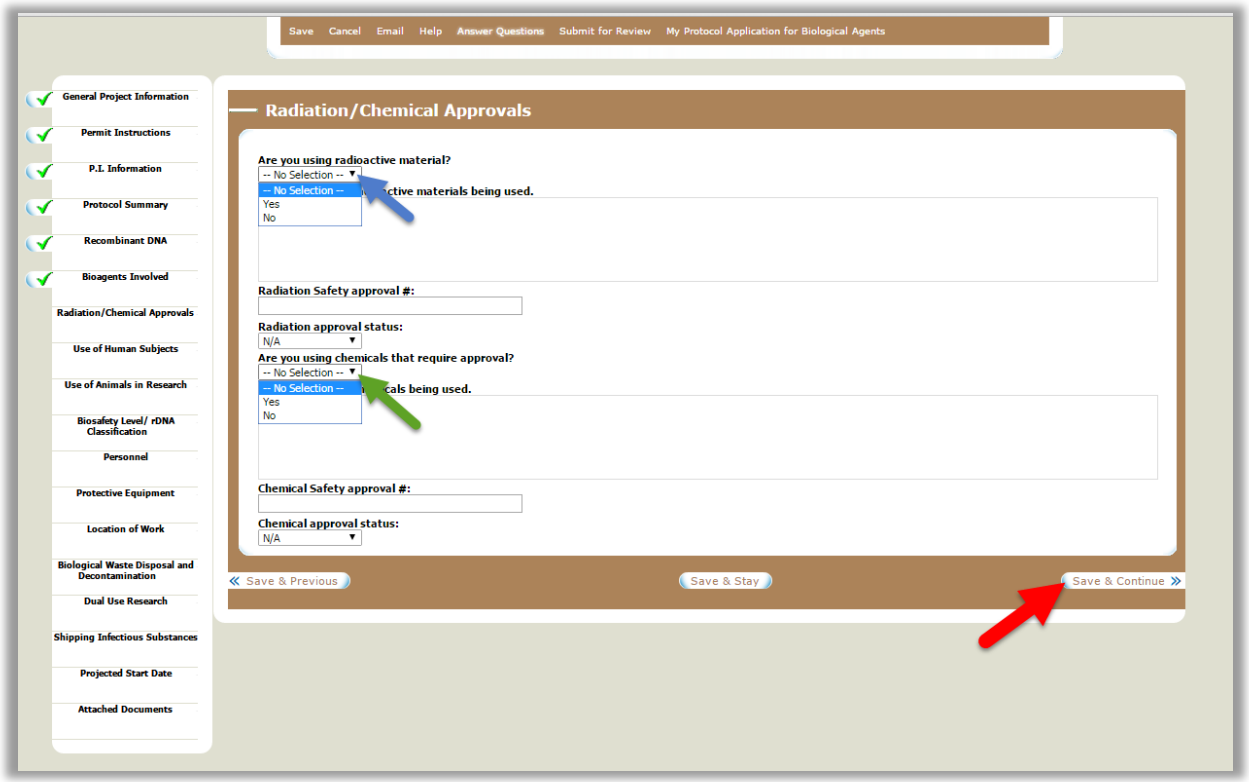


- Enter the following information as it pertains to your project:
    - Strain of Bioagent (if appropriate) (**blue arrow**).
    - Concentration and Volume – if this is unknown or the quantities will vary, list the maximum volume and concentration generated at any one given point in time (**green arrow**).
    - 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.


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
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+
Delete
Category
Specific Agent
Strain
Concentration and Volume
Cells (human)
Alveolar epithelial cells
A549
1x10^6 cells per flask, 10 flasks max
unsaved
Cells (human)
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 neccessary):
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
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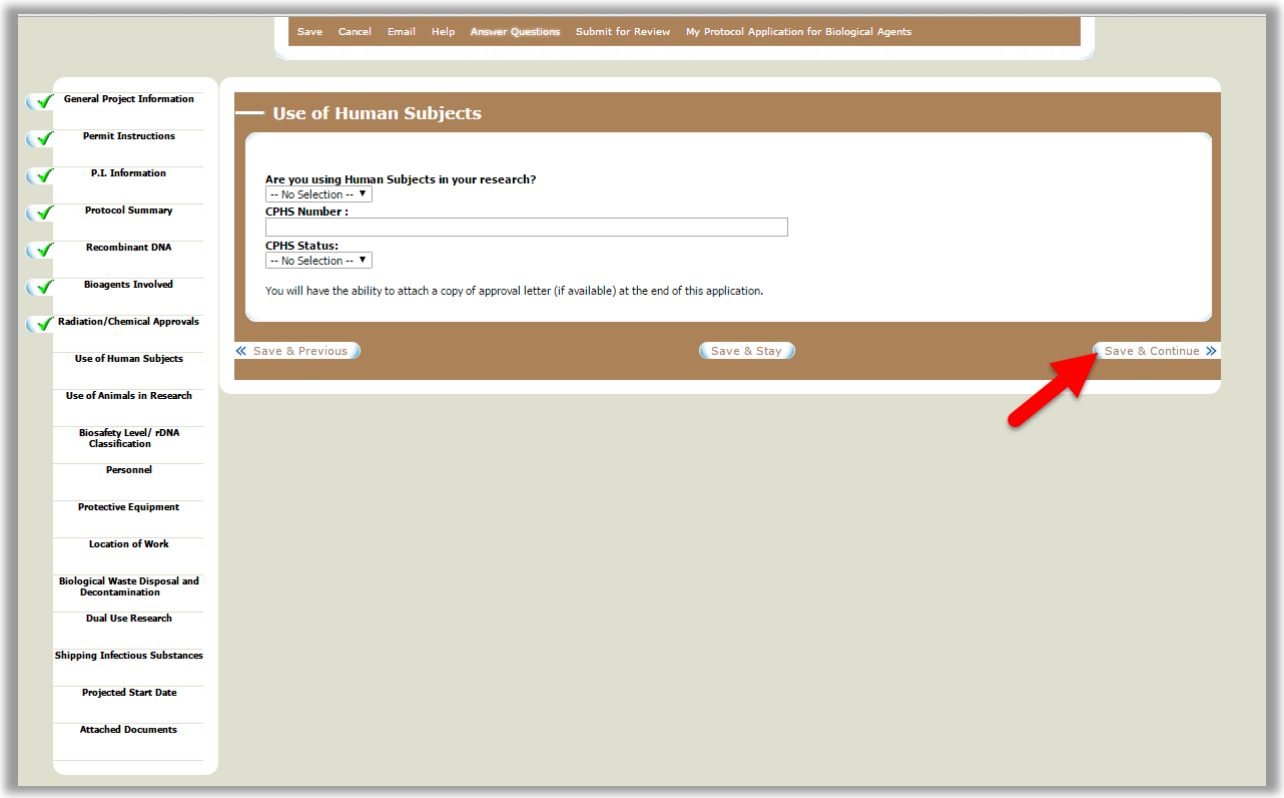
My Protocol Application for Biological Agents
General Project Information
Permit Instructions
P.I. Information
Protocol Summary
Recombinant DNA
Bioagents Involved
Radiation/Chemical Approvals
Use of Human Subjects
Use of Animals in Research
Biosafety Level/ rDNA Classification
Personnel
Protective Equipment
Location of Work
Biological Waste Disposal and Decontamination
Dual Use Research
Shipping Infectious Substances
Projected Start Date
Attached Documents
Radiation/Chemical Approvals
Are you using radioactive material?
-- No Selection --
-- No Selection --
Yes
No
Radiation Safety approval #:
Radiation approval status:
N/A
Are you using chemicals that require approval?
-- No Selection --
-- No Selection --
Yes
No
Chemical Safety approval #:
Chemical approval status:
N/A
Save & Previous
Save & Stay
Save & Continue

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.

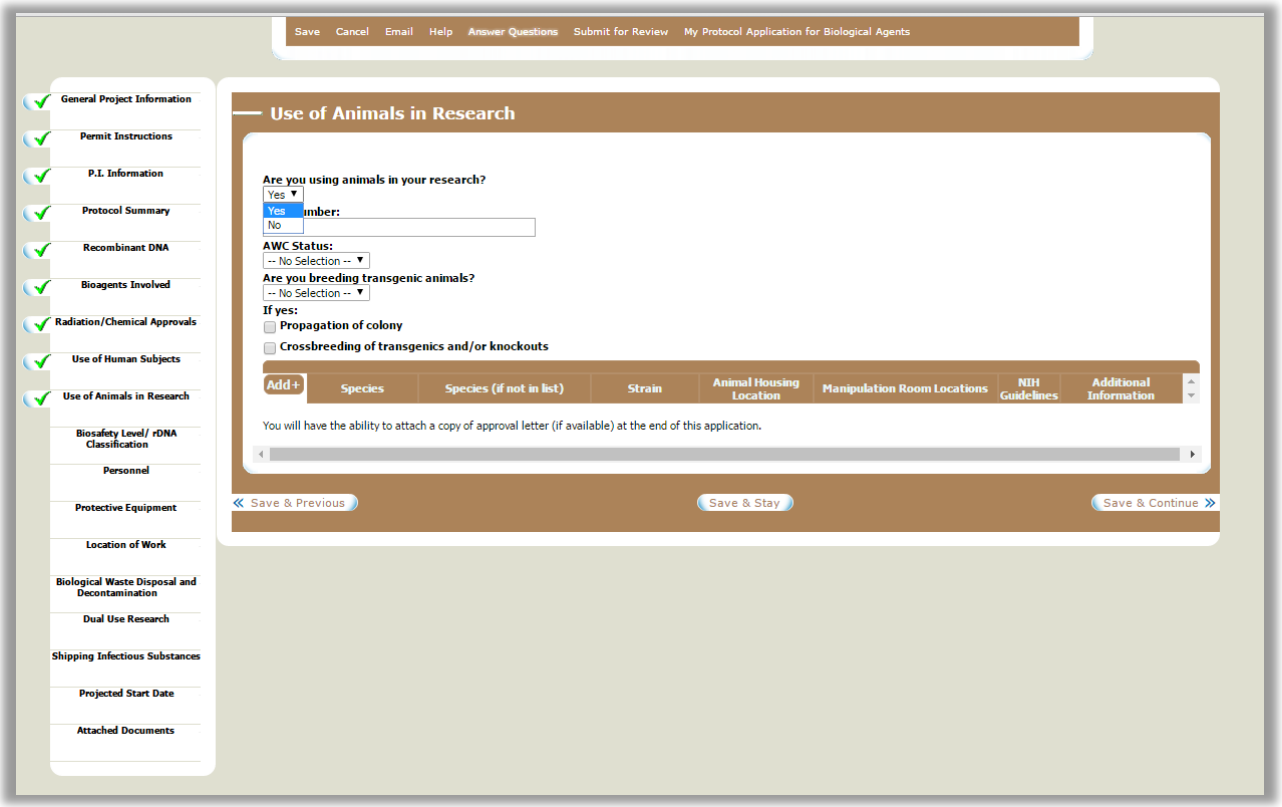


3.9. Use of Animals in Research section

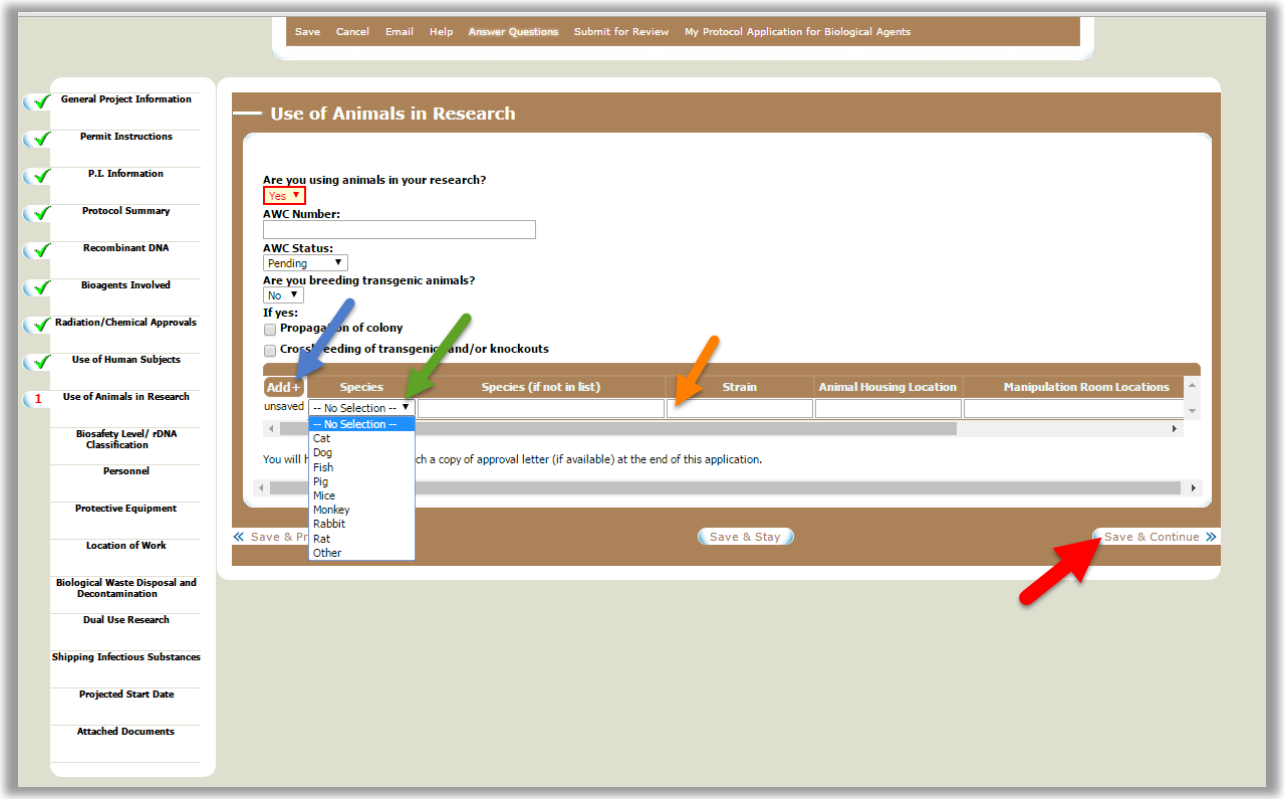
- If you are using animals in your research, including transgenic animals, you will need to fill out this table. You will also require Animal Welfare Committee (AWC) approval.

- 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.

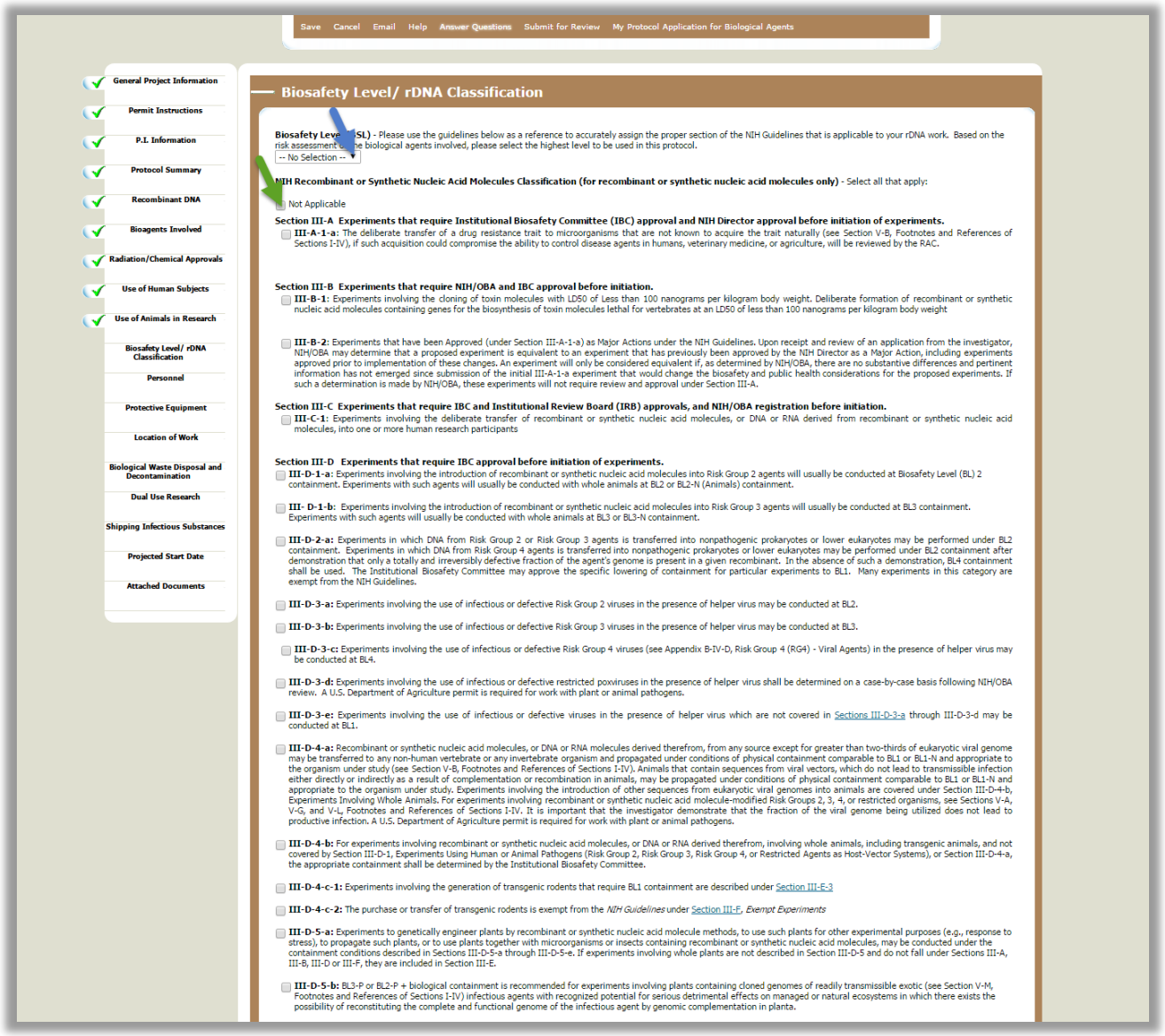


- If you are using animals, select the appropriate responses from the drop-down menus and fill in the AWC Number field as appropriate.
- To add an animal species to the table, click on the “Add+” button (**blue arrow**). This will generate a new row for the table.
- Select the appropriate species from 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.



3.10. Biosafety Level/NIH Guidelines section

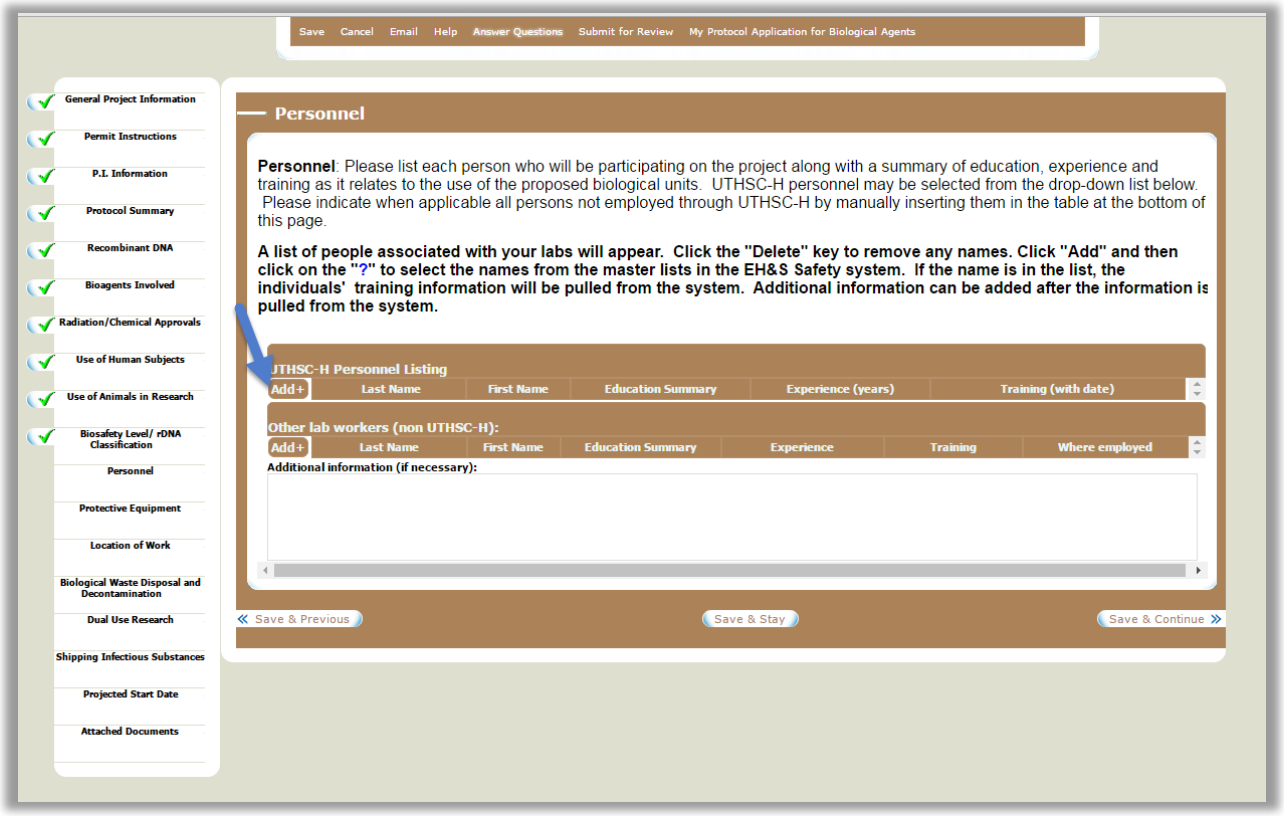
- Select the highest appropriate Biosafety Level for your work (**blue arrow**).
- Please read this section carefully and choose the classification(s) appropriate to describe your research. If you have questions on which classification to choose, contact the Biosafety office at (713) 500-8170.
- If you 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.



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**).



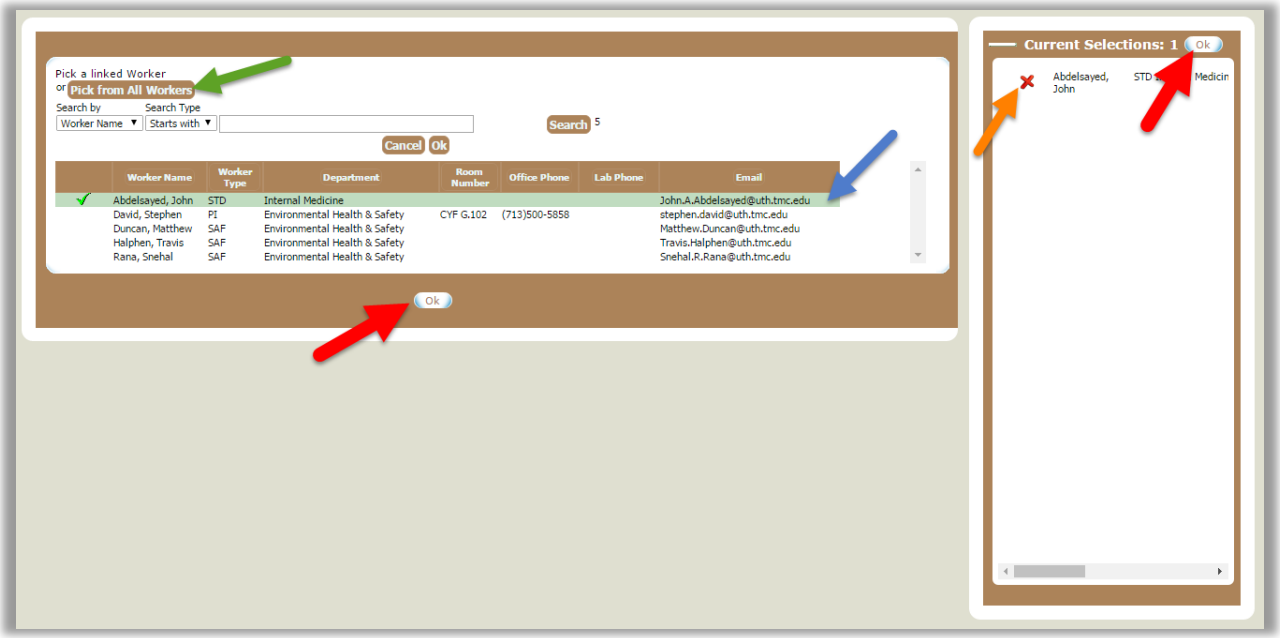
- You should be sent to the Worker selection tool. Persons already associated with other protocols you may have will appear here. Click on the “Select” link next to the appropriate person’s name to add them to the protocol (**blue arrow**).

- 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**).

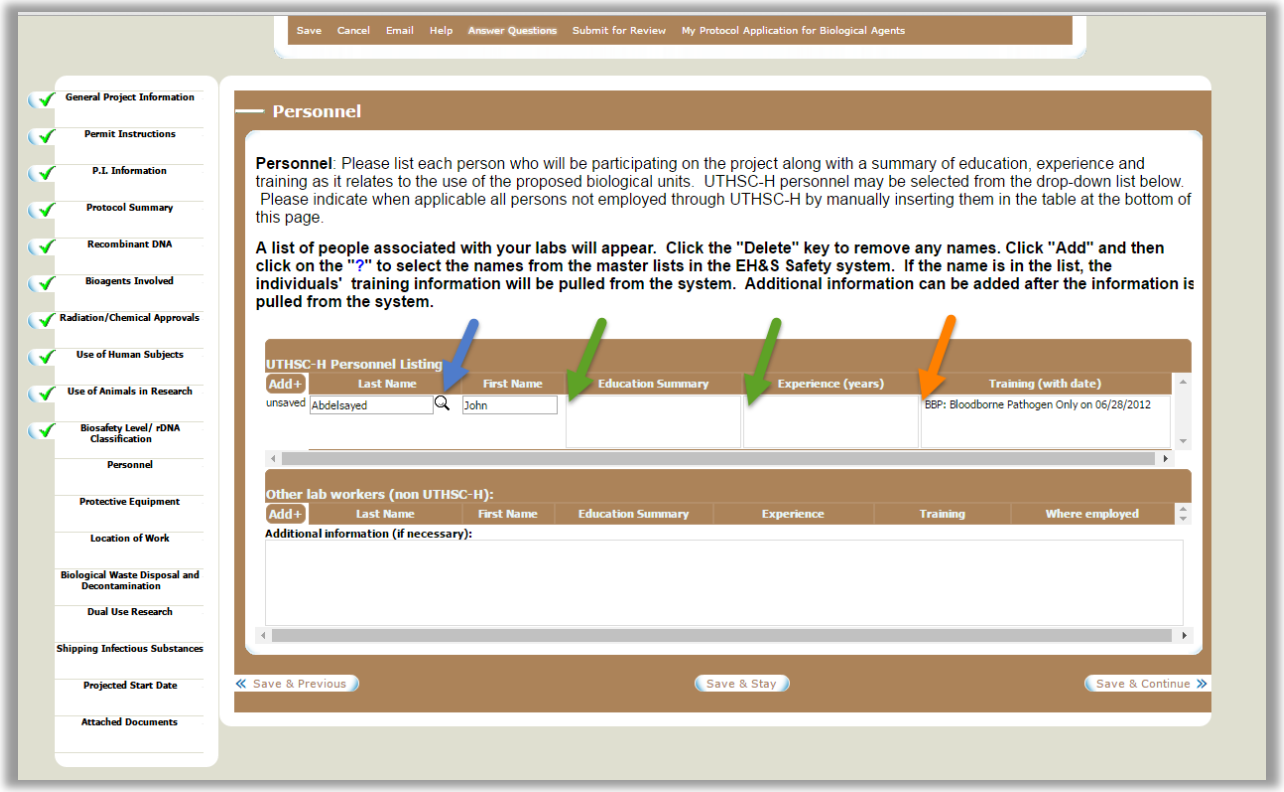
- Once you have the correct personnel selected, click “Ok” (**red arrow**) to return to the “Personnel” table and protocol section.



- 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**).

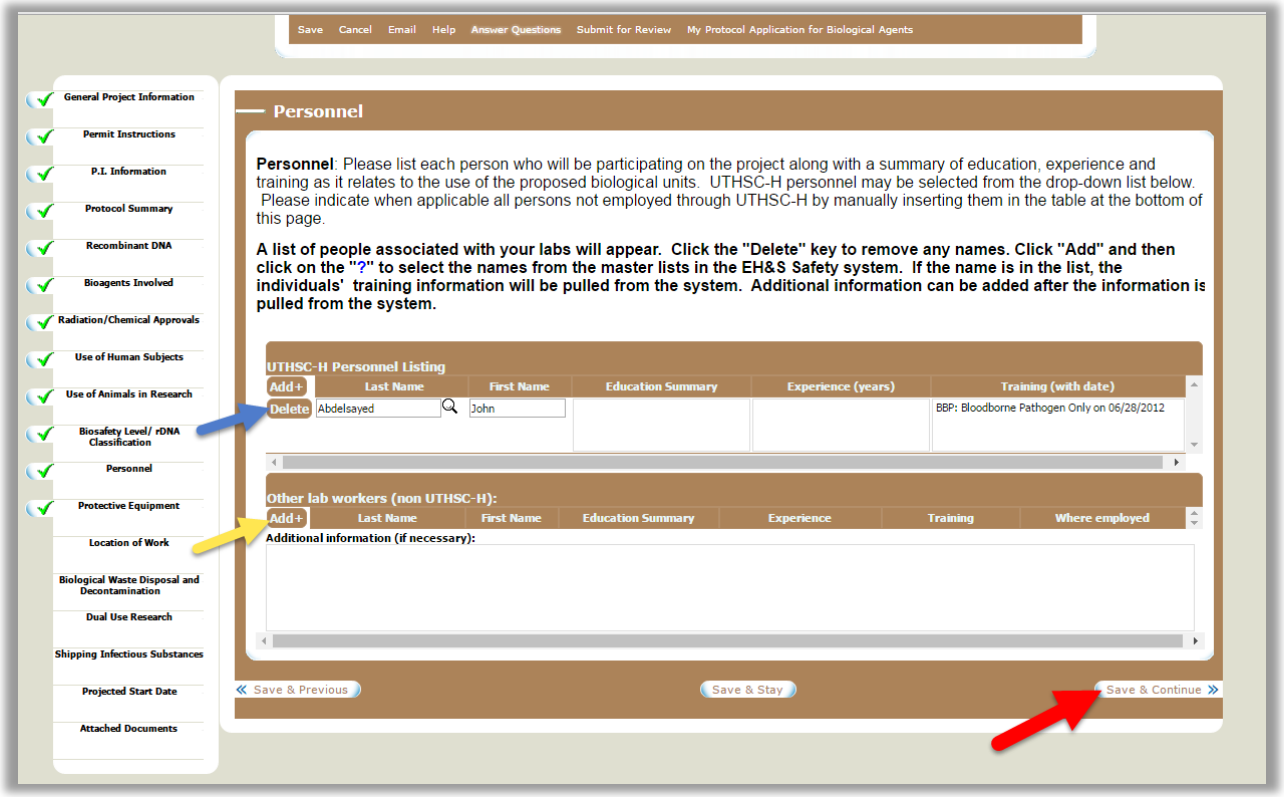
- Training information should be auto-populated by EHSA (**orange arrow**), however please double-check it for accuracy before submitting the protocol.



- To delete personnel, select the “Delete” button (**blue arrow**) which will appear after the content has been saved.

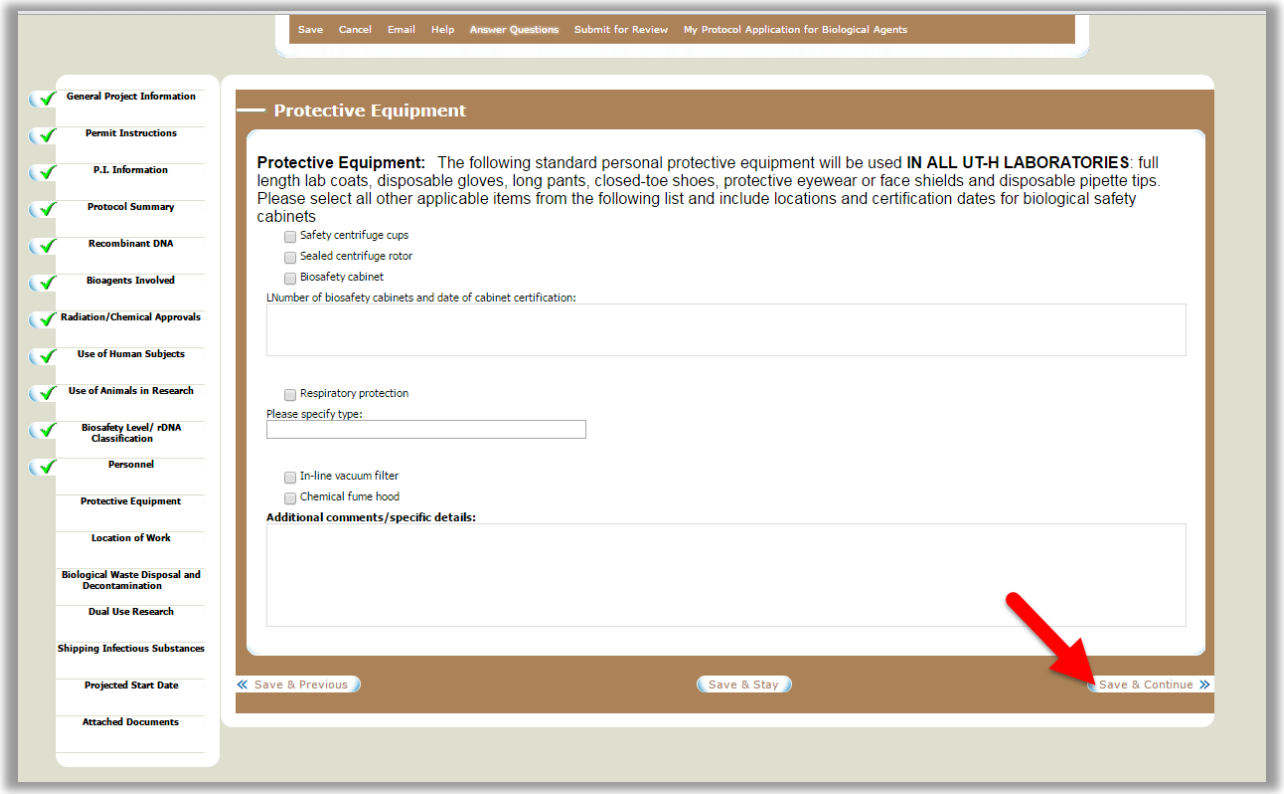
- For personnel on the protocol who are not UTHealth employees, students, or trainees, use the “Other lab workers” table and manually enter the necessary information (**yellow arrow**).

- Once you have completed the “Personnel” section, click on ‘Save & Continue' (**red arrow**) to progress to the “Protective Equipment” section.



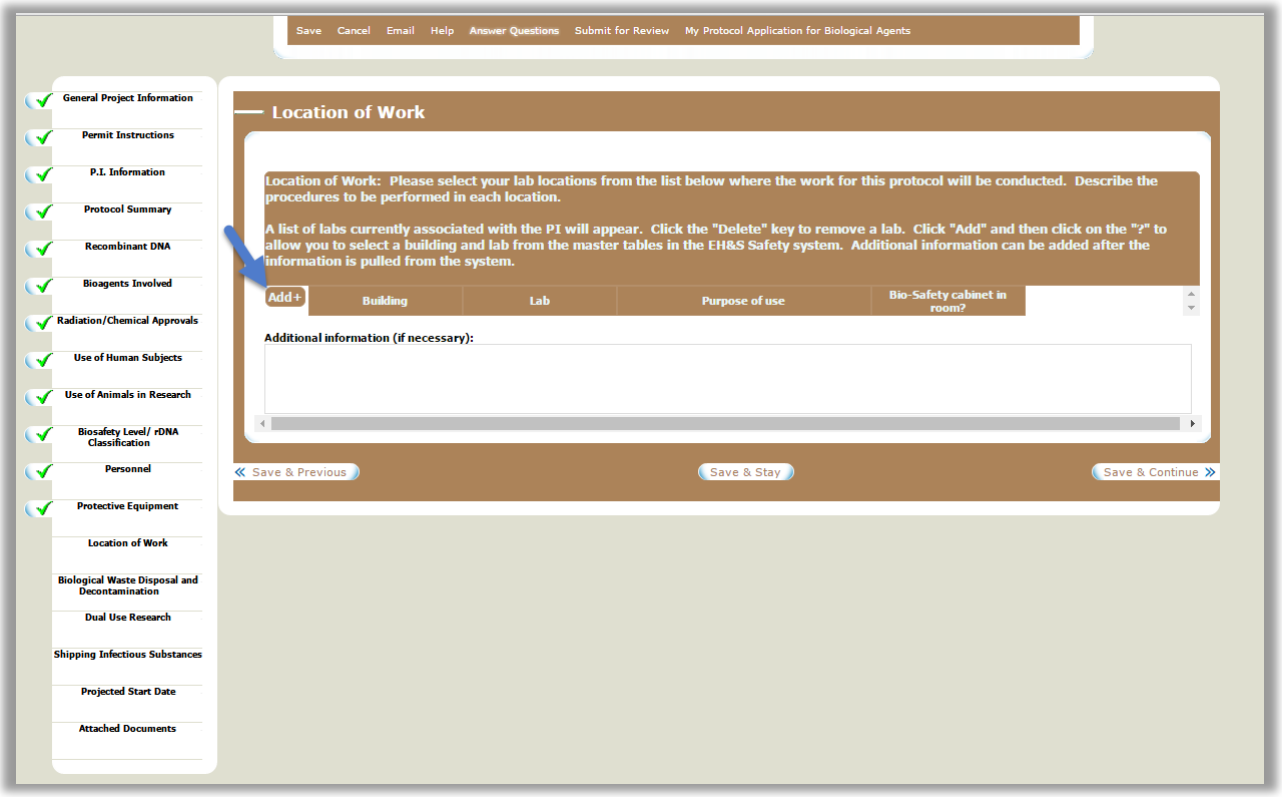
3.12. Protective Equipment section

- 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.



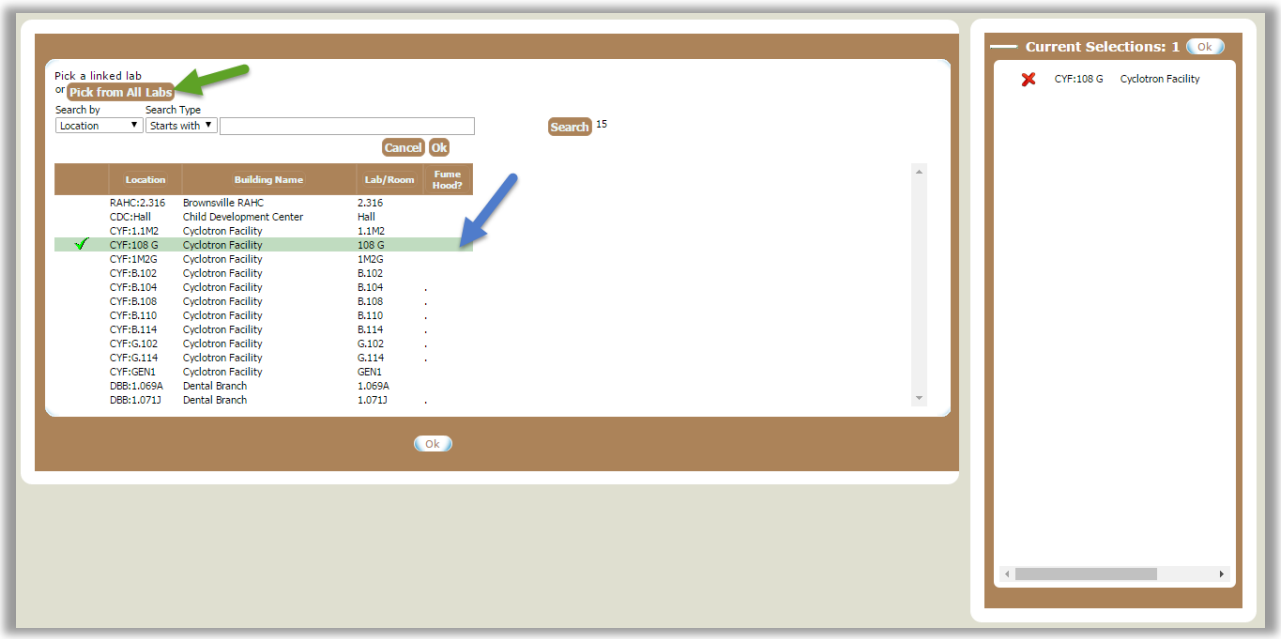
3.13. Location of Work section

- 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

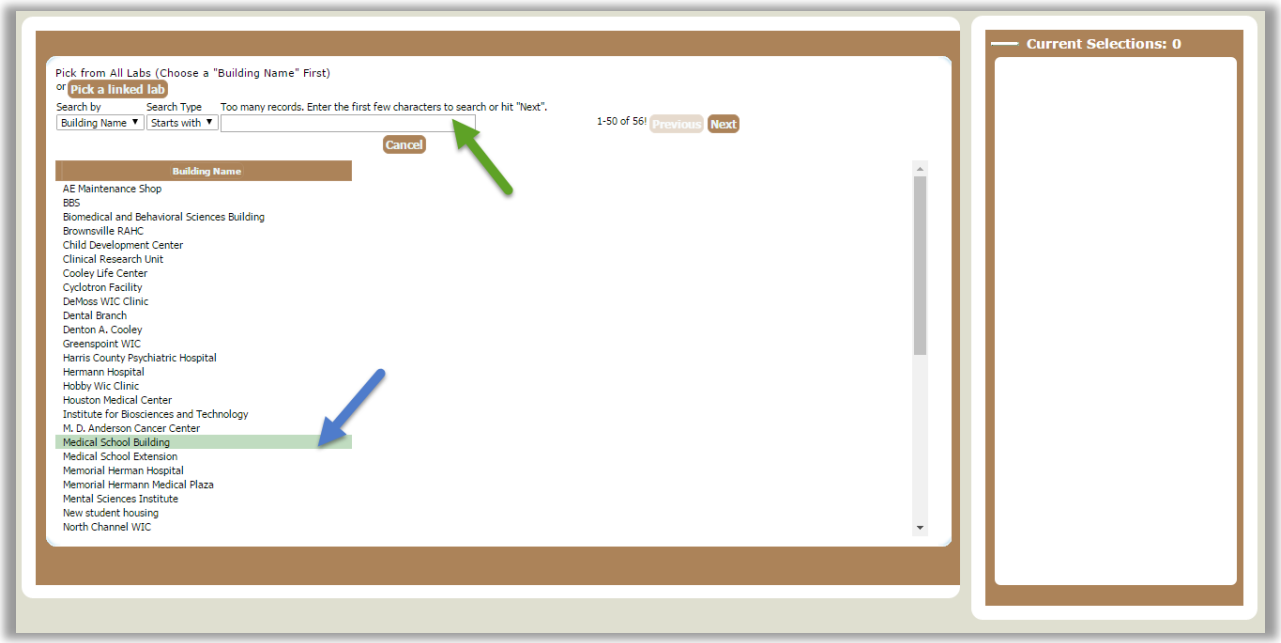


- To select one of your already assigned spaces for the new protocol, click on the “Select” link to the left of the room number (**blue arrow**).

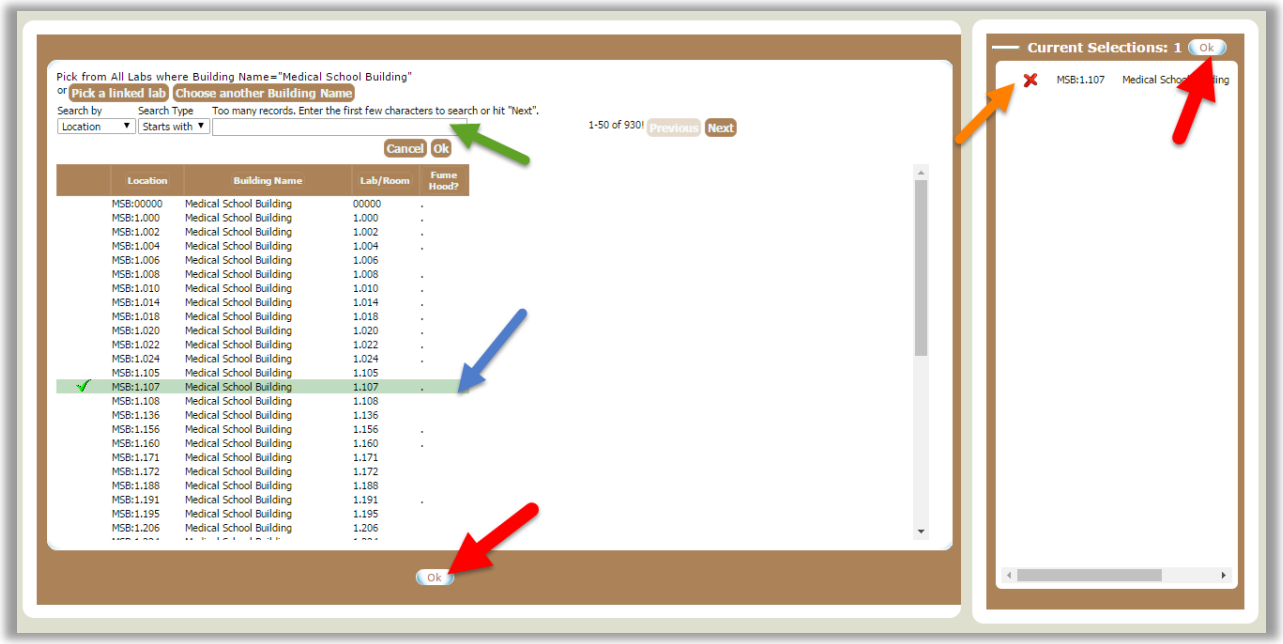
- If you don’t see the space you wish to add, click on the “Pick from All Labs” button (**green arrow**) to pick from all labs.



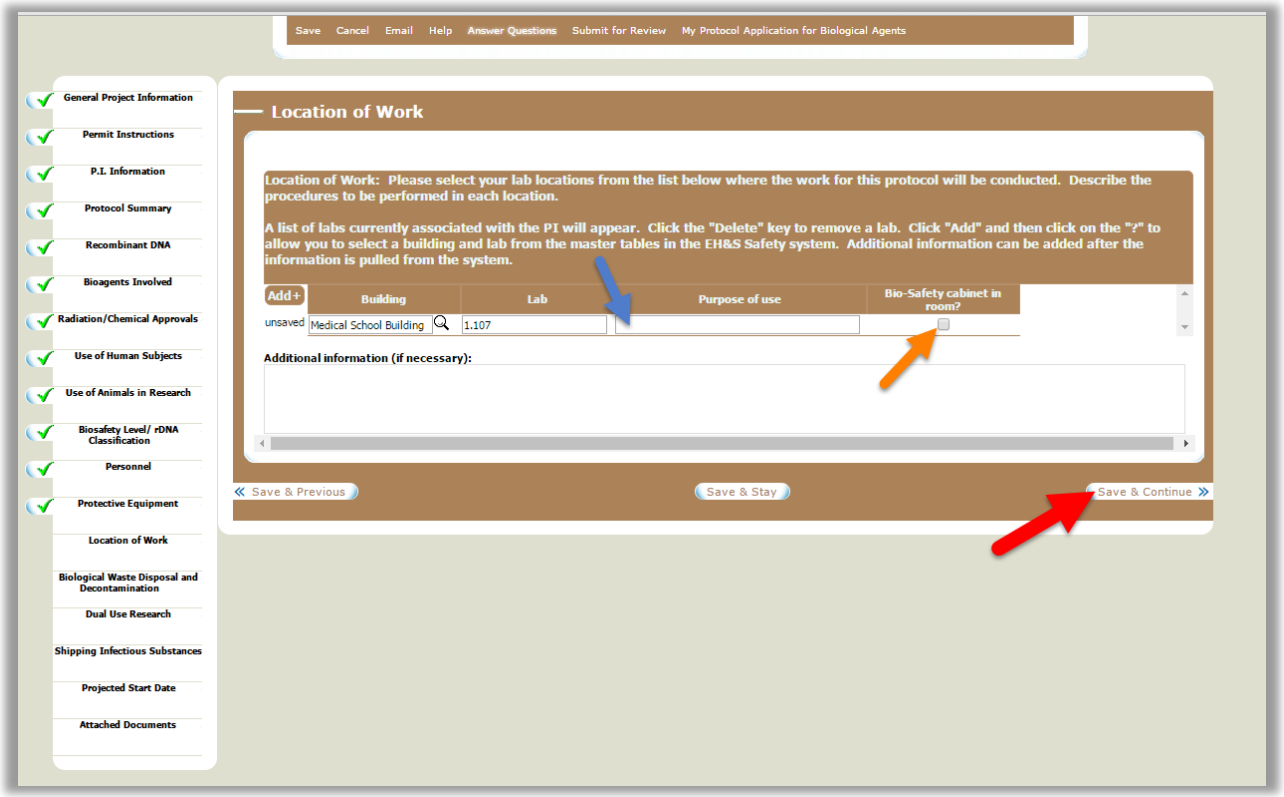
- Select the building in which your lab is located (blue arrow) or search for it (green arrow).



- 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.

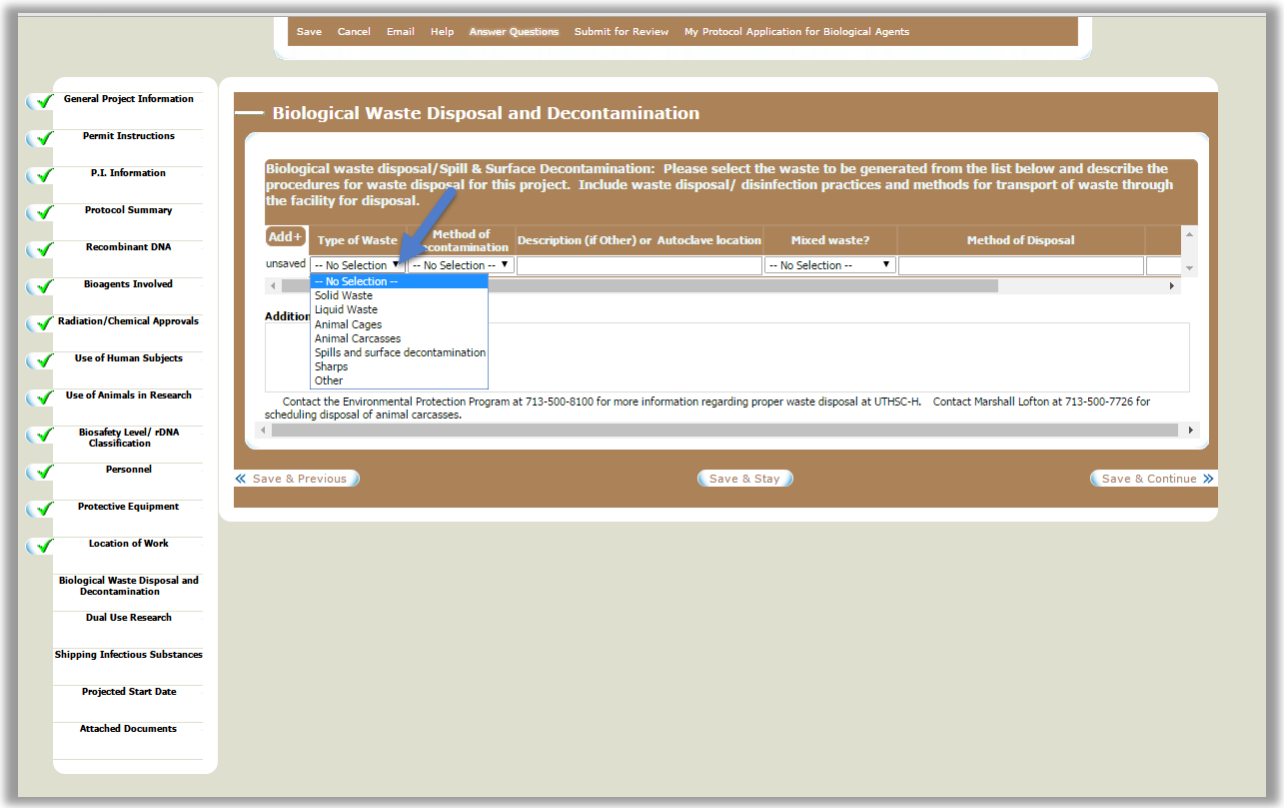


- Describe the work to be performed in the listed space (e.g. Tissue Culture, reagent preparation, animal surgery, etc.) (**blue arrow**).
- If there is a Biosafety Cabinet in the room, please check the appropriate box (**orange arrow**).
- If you wish to clarify some aspect of a space listed in this 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.



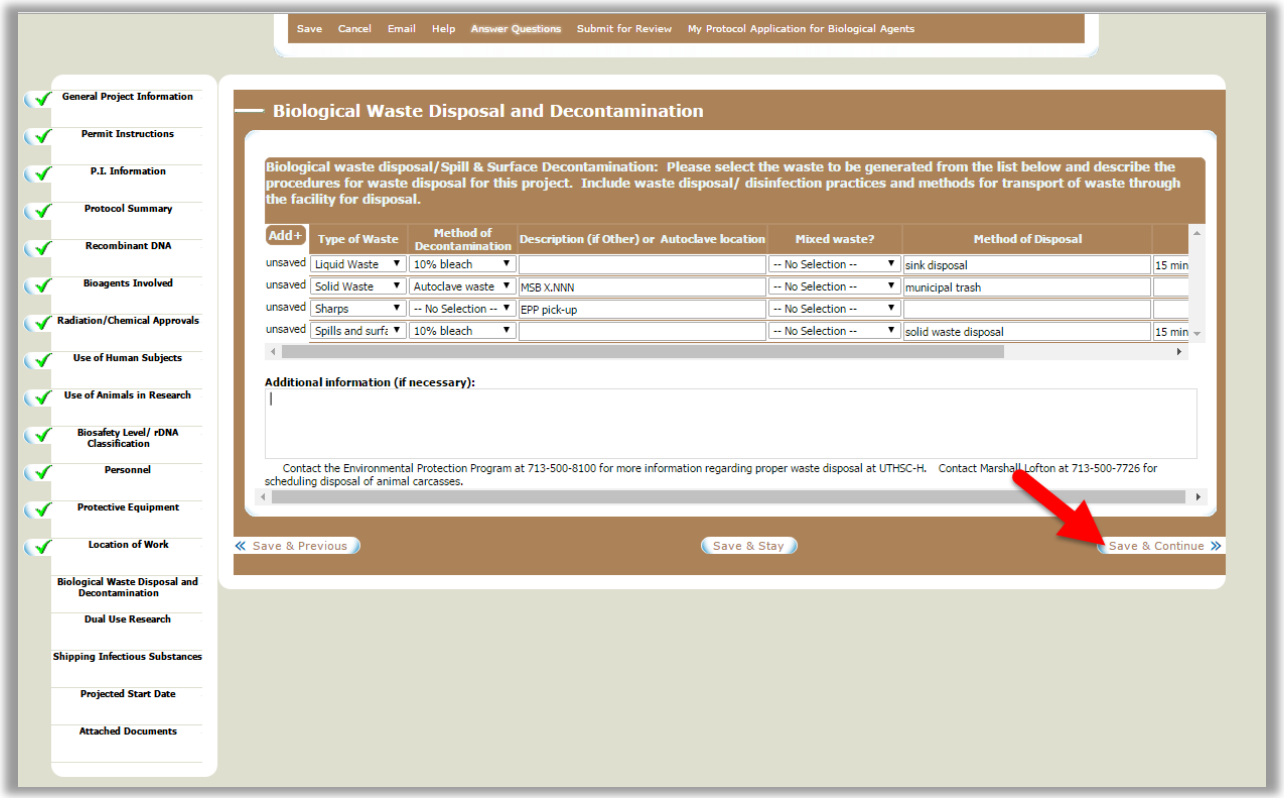
3.14. Biological Waste Disposal and Decontamination section

- 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.



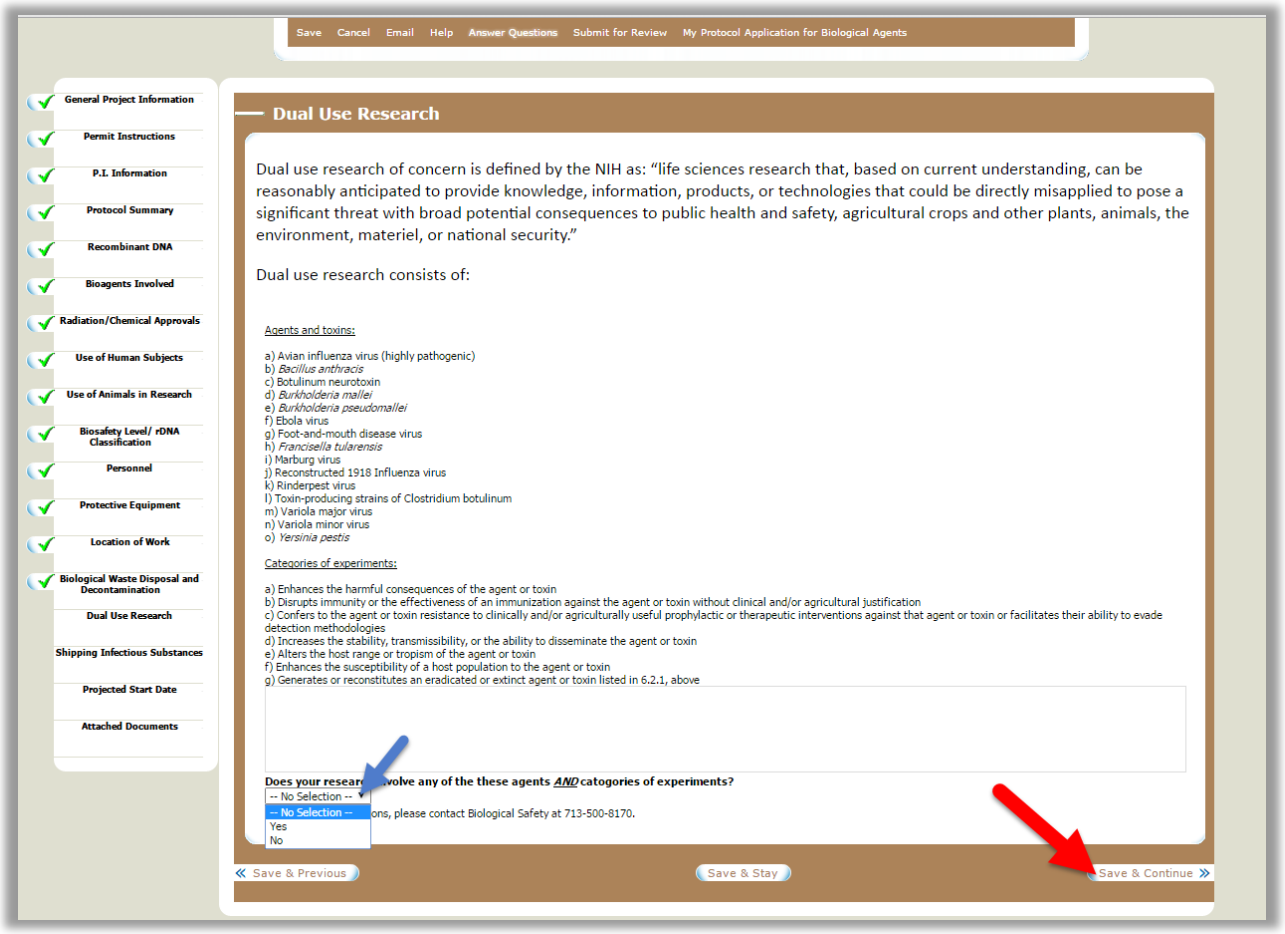
- Add as many lines as necessary to cover all the types of waste you will generate during your work and fill out the table as necessary. An example of a completed table is included below. If you have any questions about waste disposal, contact the Environmental Protection Program (EPP) at (713) 500-5835.

- 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.



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.

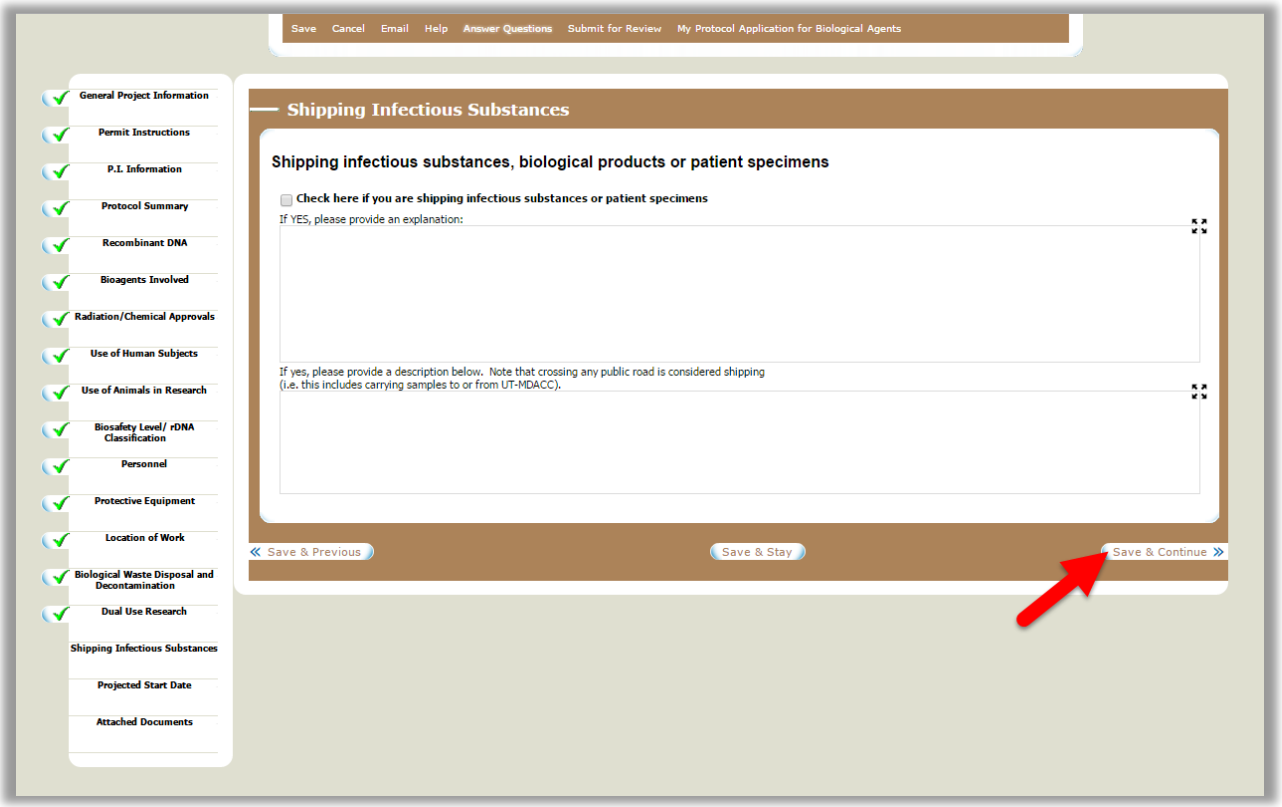


3.16. Shipping Infectious Substances section

- 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.

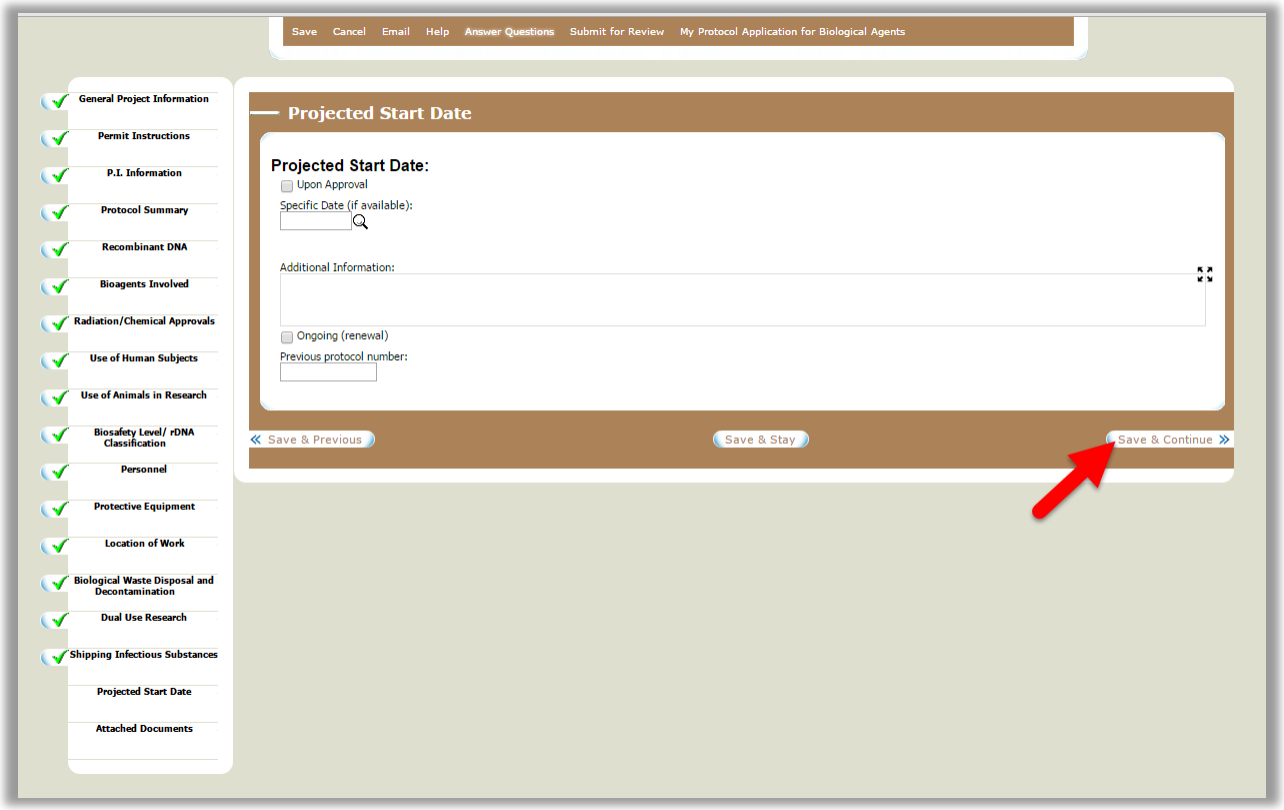
- If you are transporting an infectious or potentially infectious substance outside of your laboratory, please describe what you will use to contain the substance. Typically the IBC suggests using secondary containment – containment that is shatter-, puncture-, and leak-proof and contains the primary 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.



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.

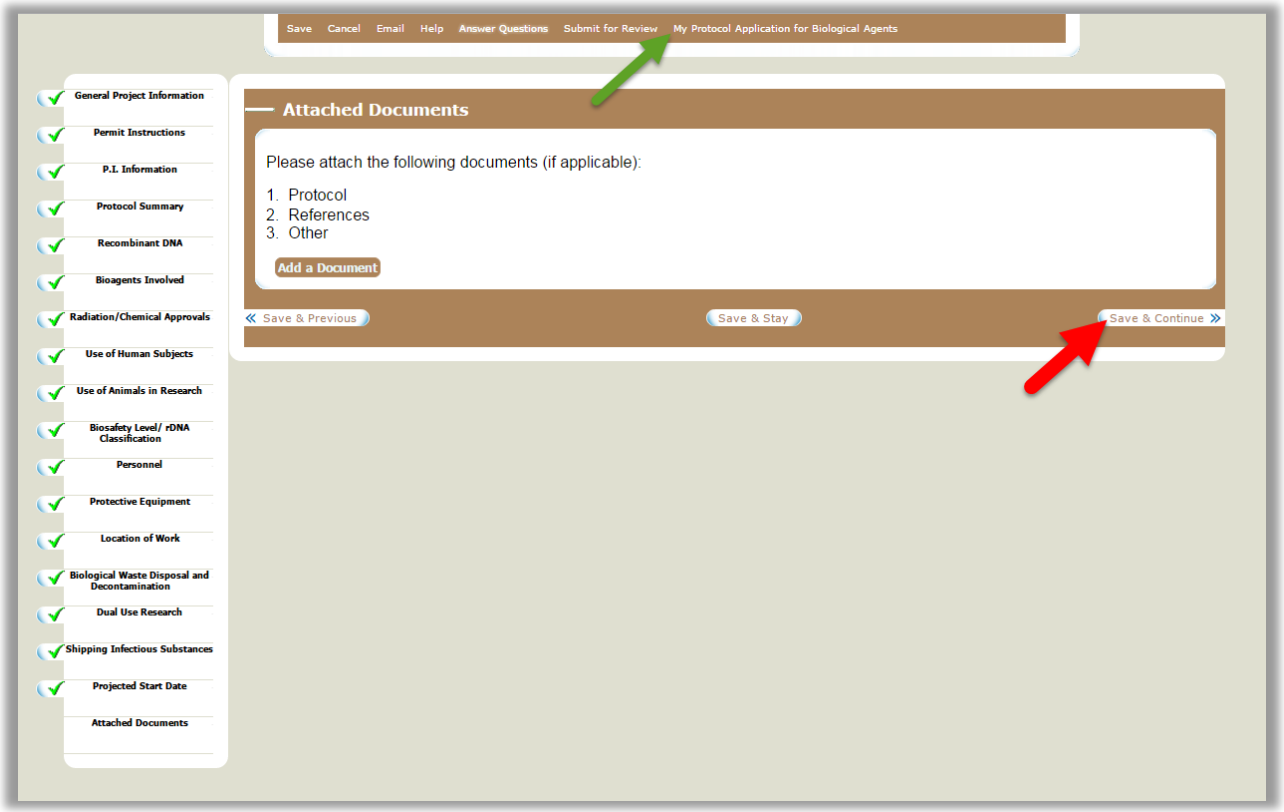


3.18. Attached Documents section

- 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.

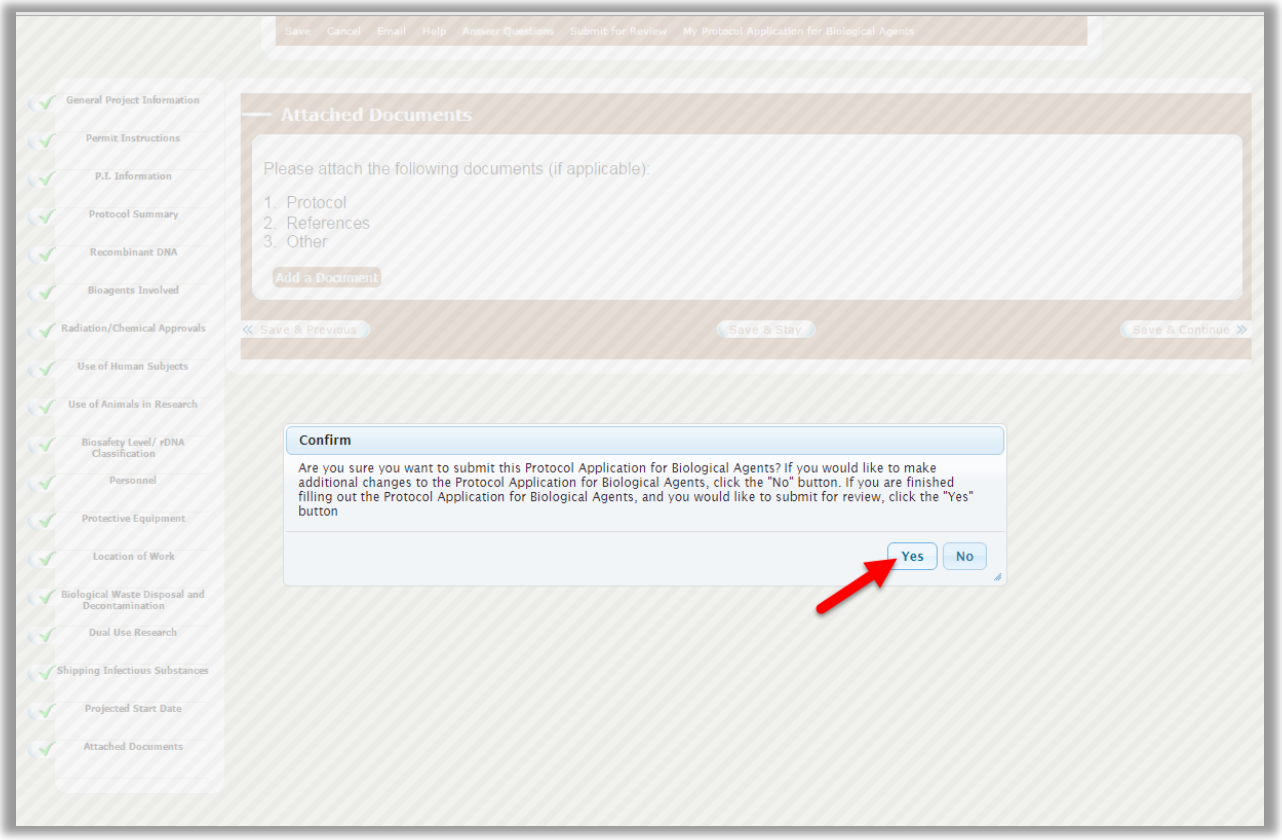
- Once you have completed the "Attached Documents" section, click on 'Save & Continue' (**red arrow**) to submit the application and return you to your protocols overview. You may also click on the "My Protocol Application for Biological Agents" link (**green arrow**) to return to the summary screen containing all of your IBC protocols.



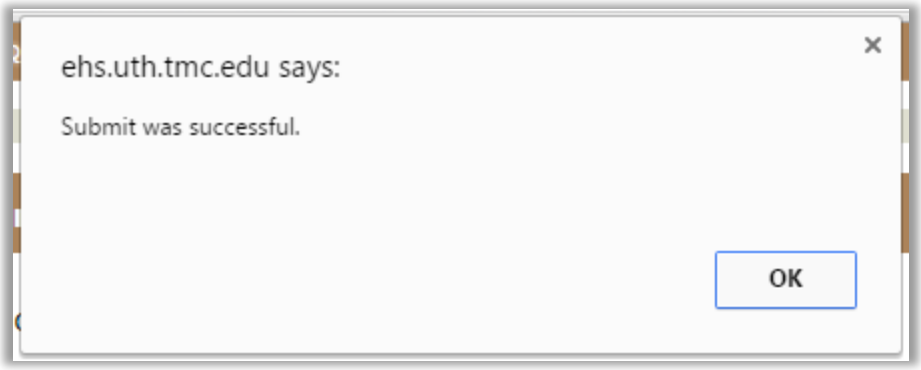
- If you need to return to the protocol to edit, revise, or update information, click on the “Edit” link (**green arrow**).
- To submit the protocol to the Biosafety Office for review, click on the “Submit for Approval” link (**red arrow**).
- If you need to delete a protocol that has not yet been submitted,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

3.19. Submission

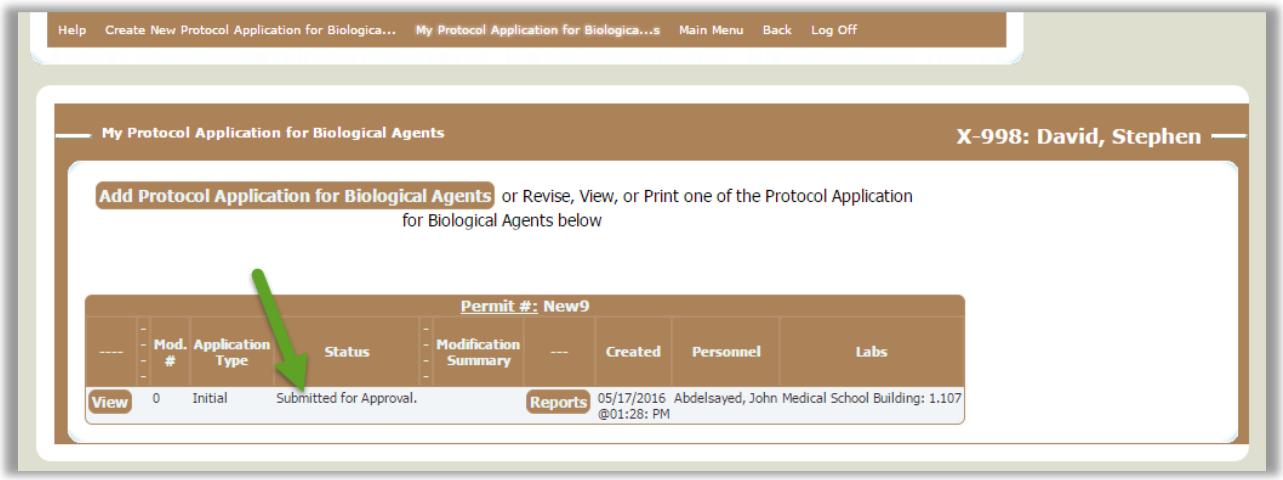
- Submitting the protocol from your protocol review page will present you with the following dialogue. If you have no further changes to make, click the “Yes” button (**red arrow**).



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



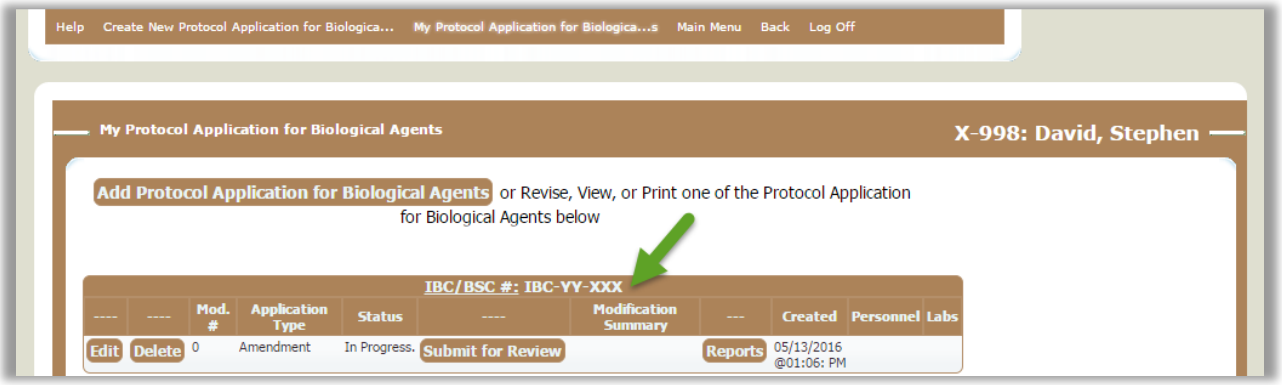
- The system should return you to your protocol only now in the status field, it will say “Submitted for Approval” (**green arrow**).



4. Protocol Review and Approval Process

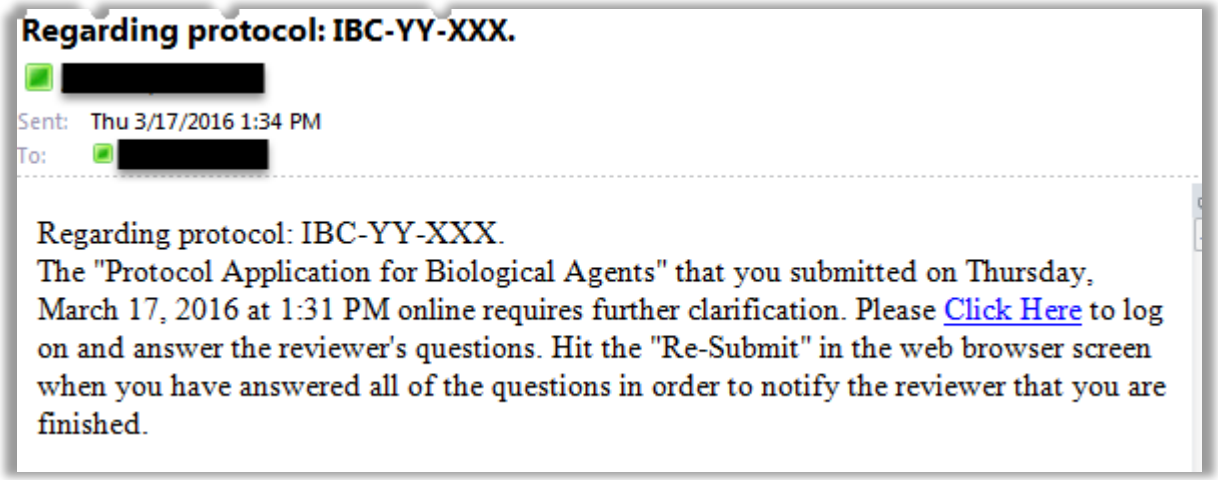
4.1. Protocol Review

- 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.



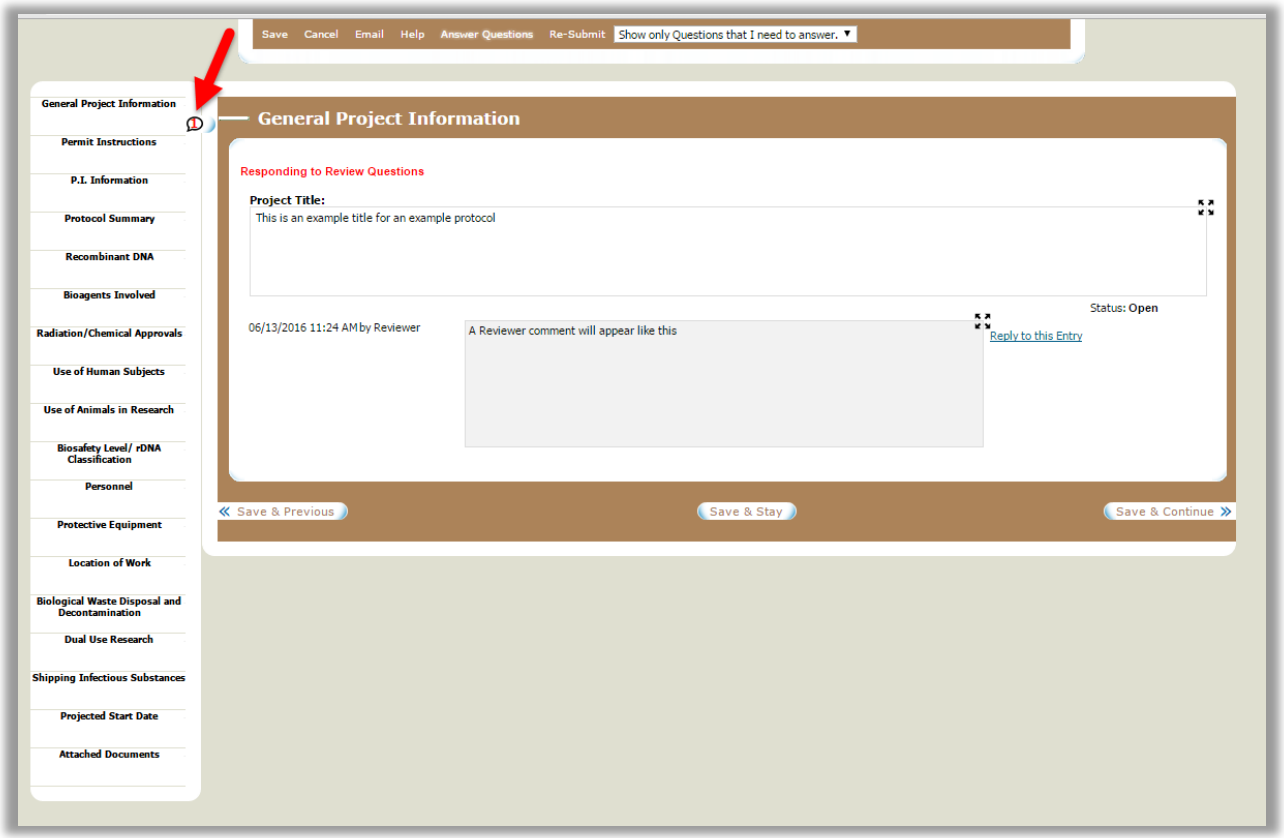
- After the Biosafety office reviews the protocol, it will be determined if the submission also requires review by the IBC. If the protocol requires review by the IBC, it will be reviewed first by a sub-committee of subject-matter experts. They will review the protocol and may have questions about the 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.

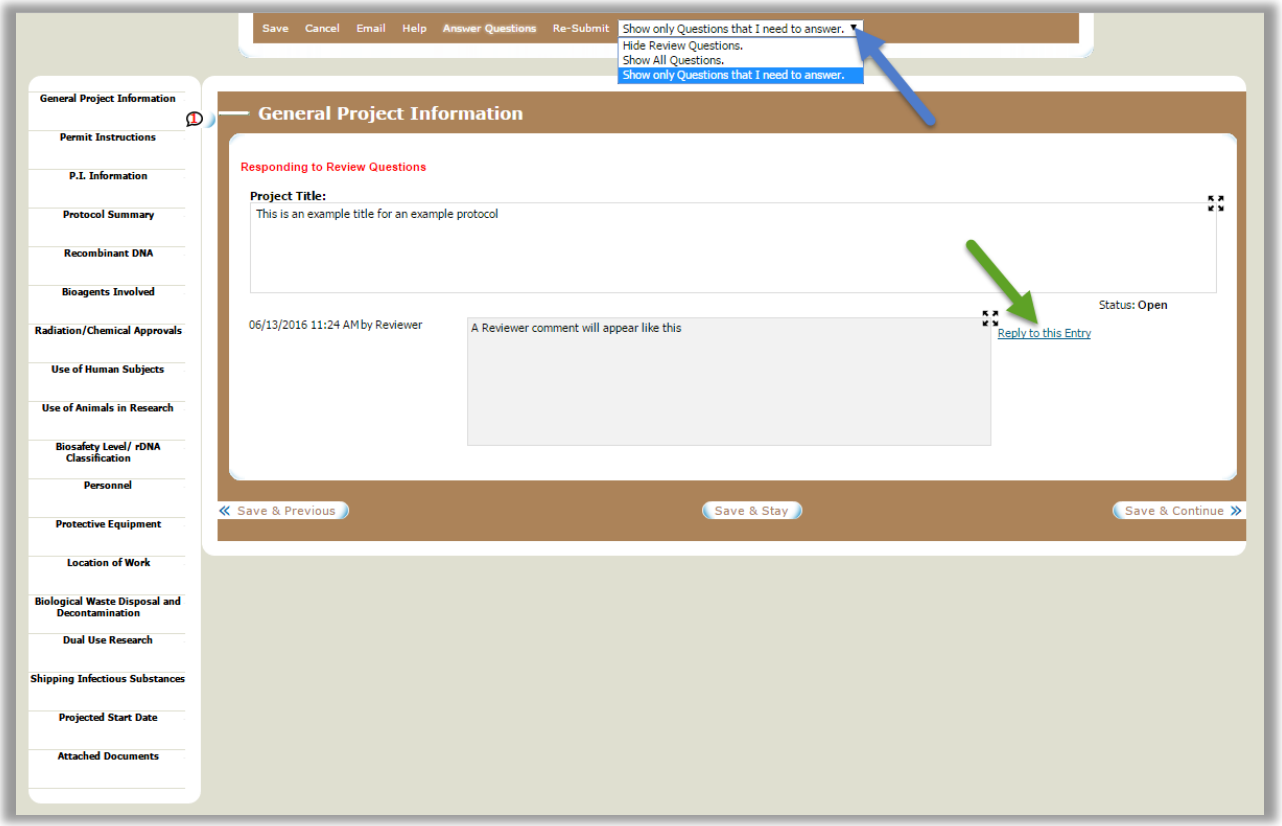


4.2. Responding to Reviewer Questions and Comments

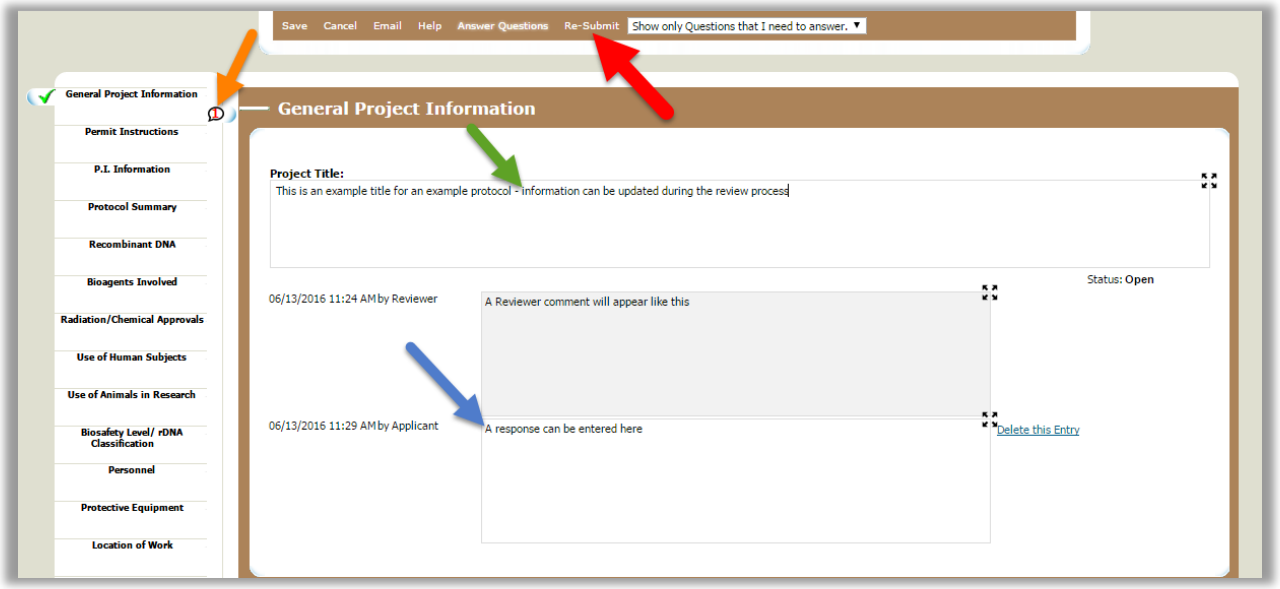
- Click on the link in the email. It should take you to the log-in screen for EHSA. Log in with you university credentials and it should take you to your protocol. There will be call-outs next to each section that has comments for you to address (**red arrow**).



- 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**).



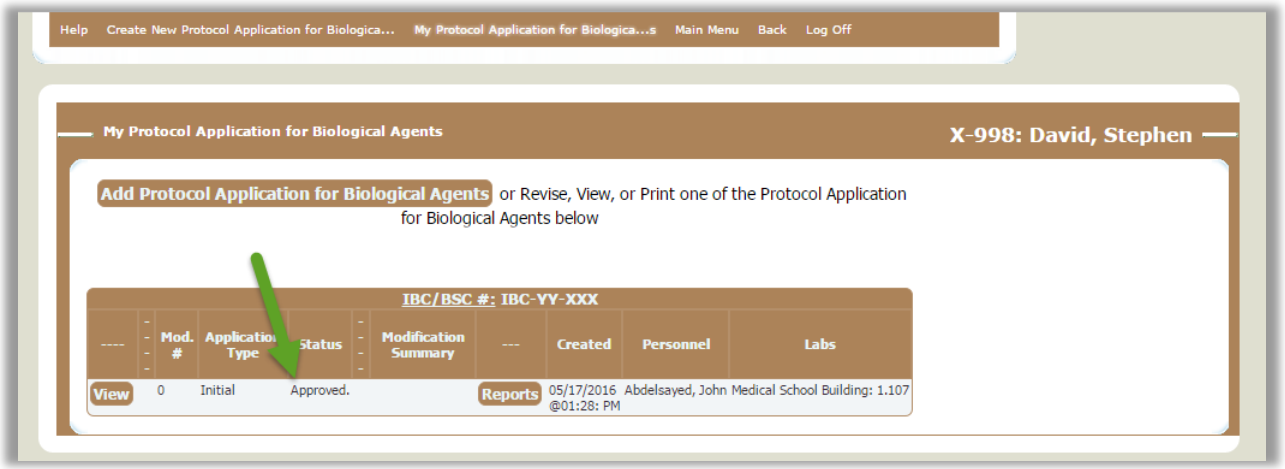
- Then enter the text in the response field (**blue arrow**).
- You may also enter text in the corresponding text field of the protocol itself (**green arrow**).
- If you wish to enter text in both the response field and the text field, we recommend saving between each change.
- Please check all sections 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

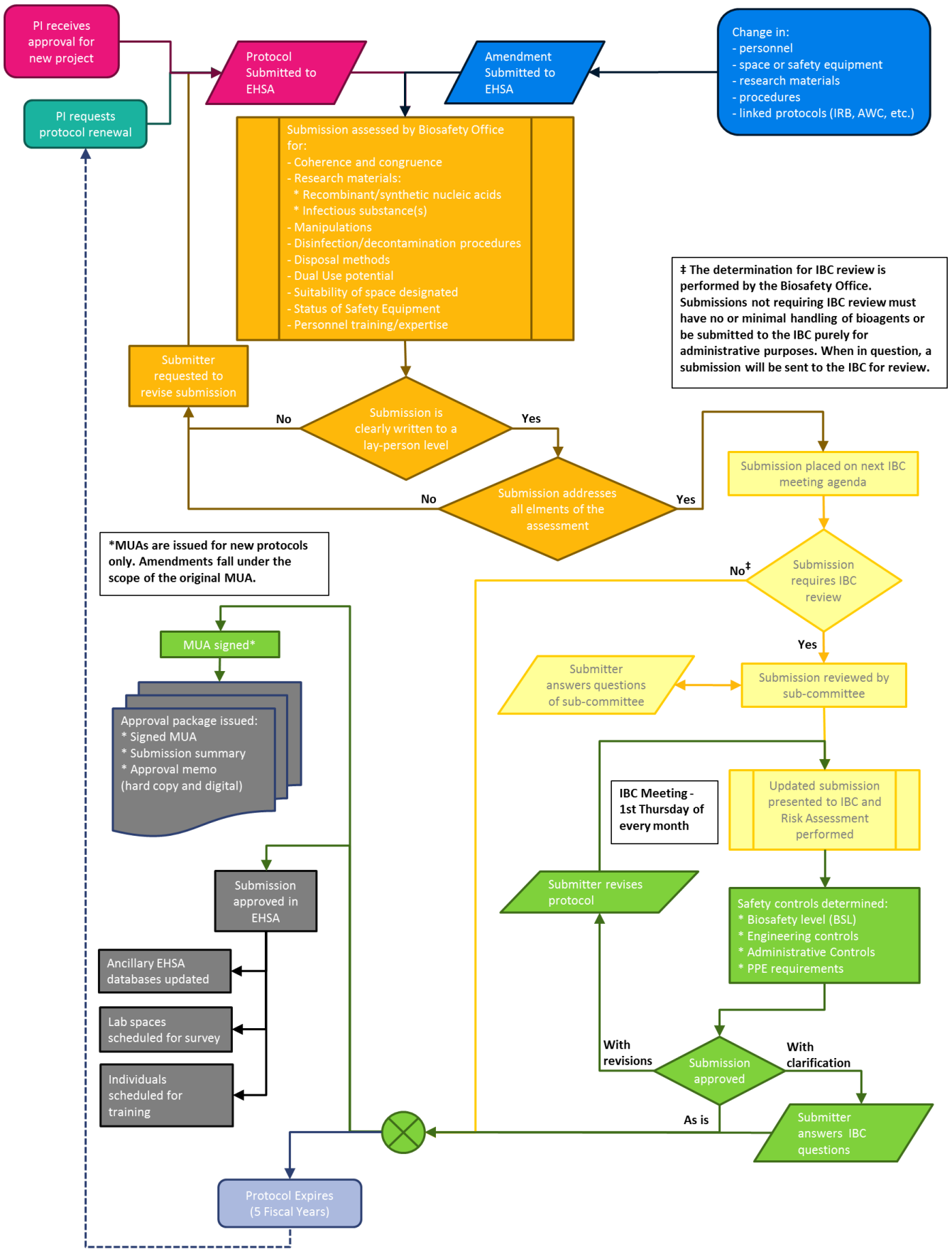
- After submitting your updated protocol, it will be reviewed by the IBC at their monthly meeting (First Thursday of every month).
- The IBC will be presented with your protocol by a Safety Specialist then the IBC will perform a Risk Assessment of the protocol which will:
    - Determine what hazards 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



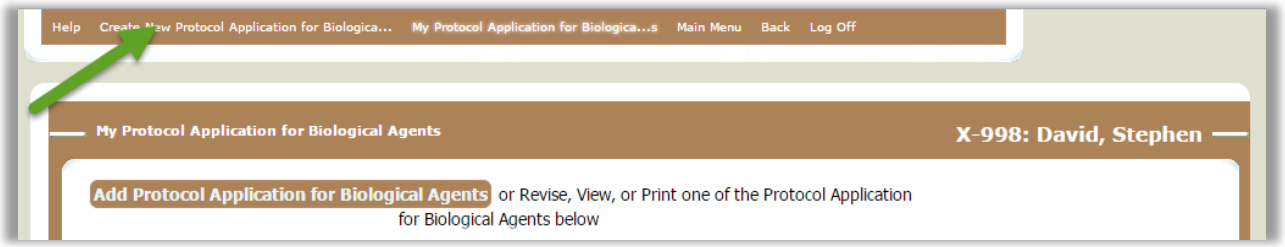
5. Protocol Amendments

5.1. Conditions Requiring an Amendment

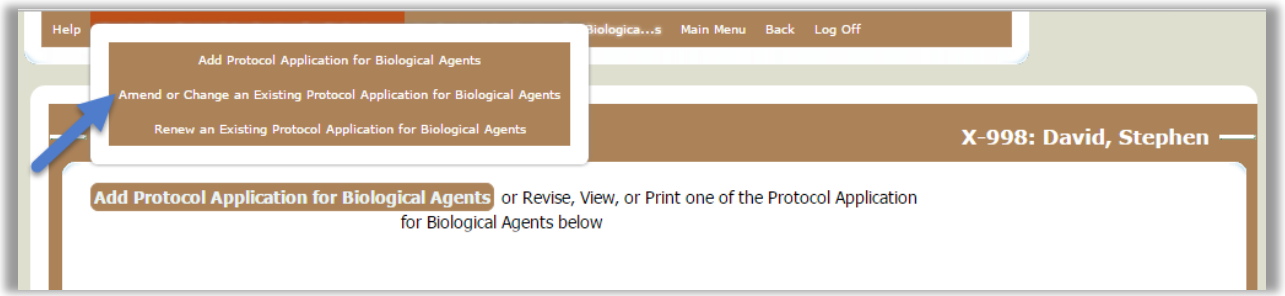
- Since research often changes, amendments to an IBC protocol are frequently necessary. The following changes require submission of an Amendment to the IBC:
    - Personnel changes – addition or removal.
    - Research material changes – for example, addition of new microorganisms, animal models, subject 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**).

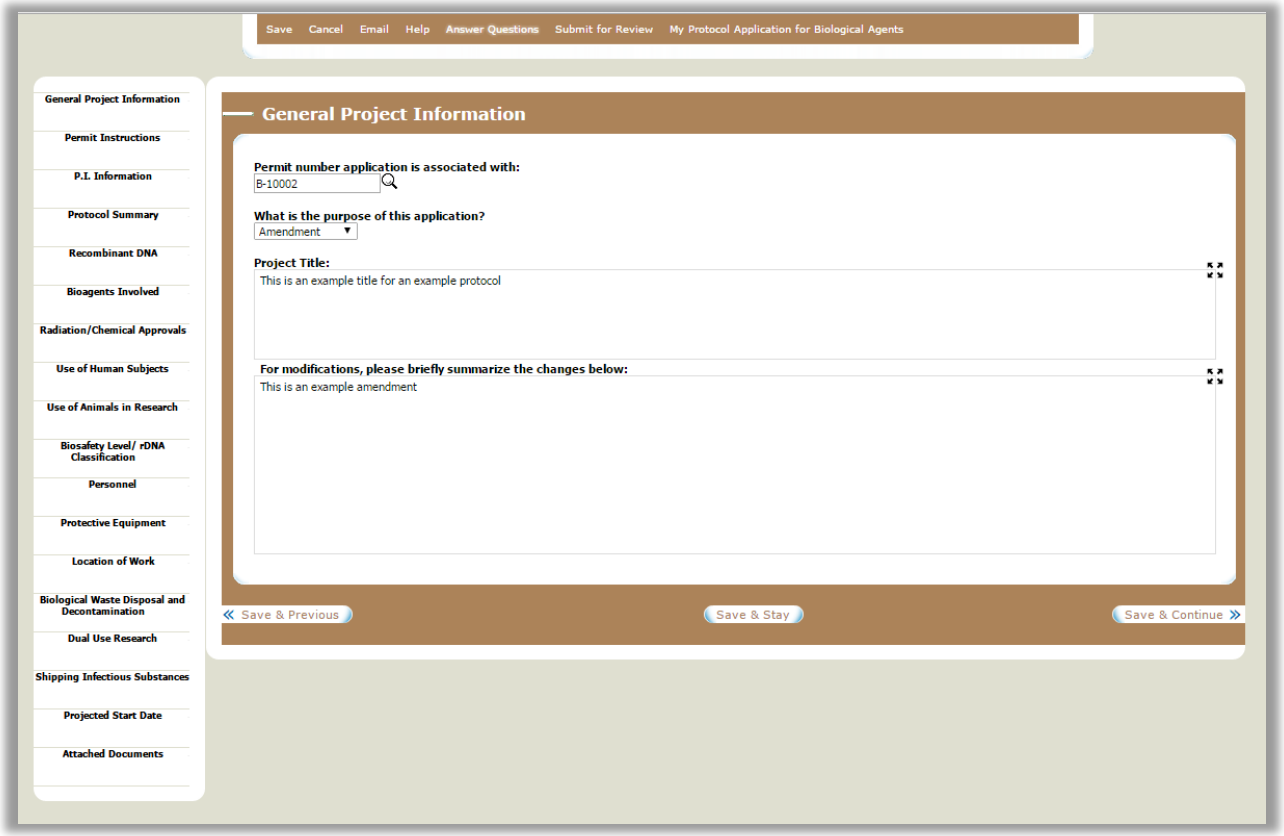


- Select the “Amend or Change an Existing Protocol Application for Biological Agents” option (**blue arrow**).



- 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.).



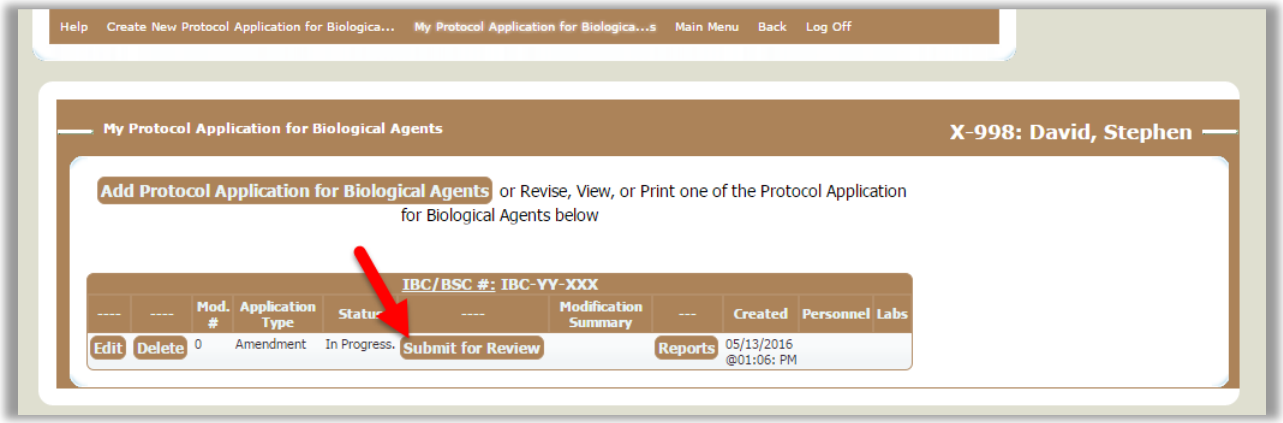
- Although the system attempts to put the appropriate information in the correct place, double-check that all information is correct in each section.

5.3. Information Updates

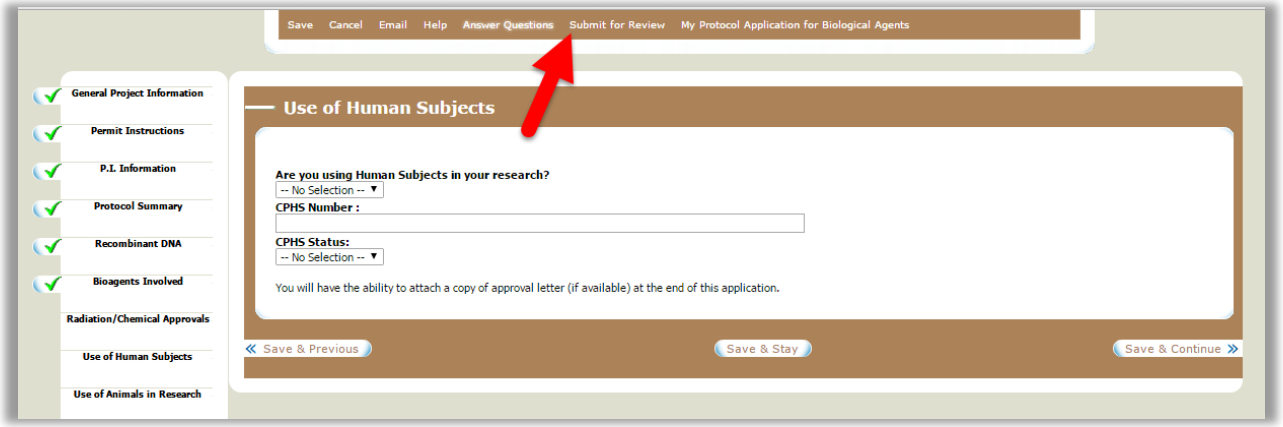
- Navigate to the section(s) that need(s) to be updated.
- Amend the information as necessary to reflect the changes in the research.
    - Now is also a good time to update any committee information such as AWC, or IRB committee approval numbers.
    - We also request that you update information on 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.

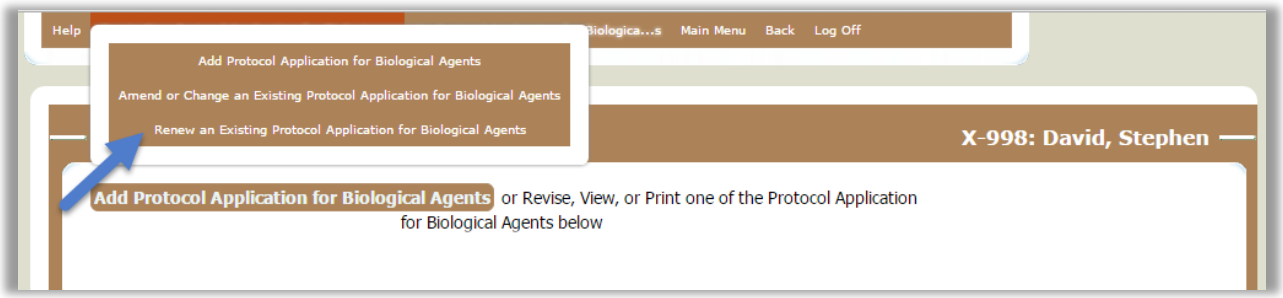
6. Protocol Renewals

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