

HuskySMS Powered by SciShield Quick Start Guide for Principal Investigators Biological Summary / IBC Registration

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A HuskySMS IBC Registration Demo tutorial is available is available on the UConn HuskySMS website; https://ehs.uconn.edu/huskysms-password-protected-tutorial/. It is password protected. Please use the current password noted on that site, and select "Launch Welcome to HuskySMS Tutorial". Enter the current password and click "View". Scroll down to "PI Setup Wizards" to find demos.

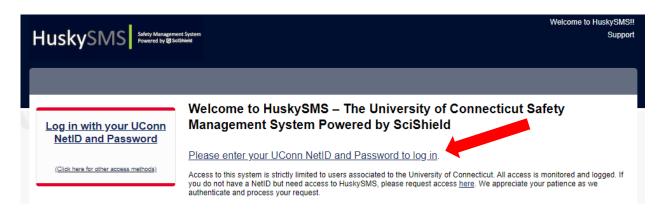


HuskySMS Biological Summary / IBC Registration Introduction

The HuskySMS IBC Module allows for easy-to-follow registration of biological activities in the laboratory. Through the Biological Registration Wizard the Principal Investigator (PI) will be asked to fill out information on their projects and conduct initial risk assessments as to the work being done in the lab. Depending on the information provided, further surveys or forms may be prompted that will assist the Institutional Biosafety Committee (IBC) in the assessment of the Biological Safety Level, potential hazards associated with the lab, and applicable NIH classifications.

Getting Started

Navigate to https://uconn.SciShield.com/, and use your UConn NetID and password to log into the system.

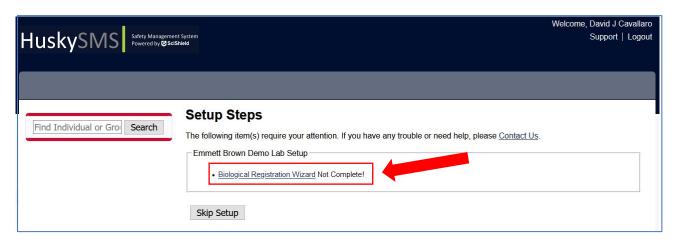


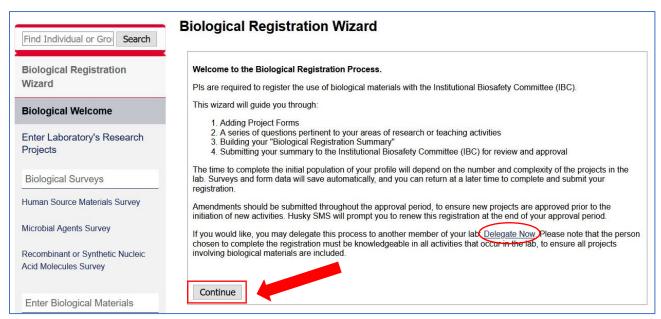


Biological Registration Wizard

Upon log in, the PI will be prompted to complete the biological summary using the Biological Registration Wizard. Select the "Biological Registration Wizard" link. At this point the PI may delegate the registration to an approved member of their laboratory. The PI should notice that there are no required Surveys or Data Entry yet because the Usage Summary has not been completed in the Project Form. Click "Continue" to begin the Biological Registration Wizard if you do not wish to delegate this task to someone else.

It should be noted that the wizard can be skipped temporarily, by selecting "Skip Setup". However, the biological registration wizard will be prompted upon login until it is complete.

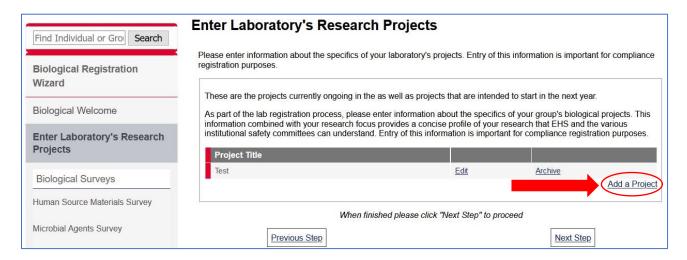






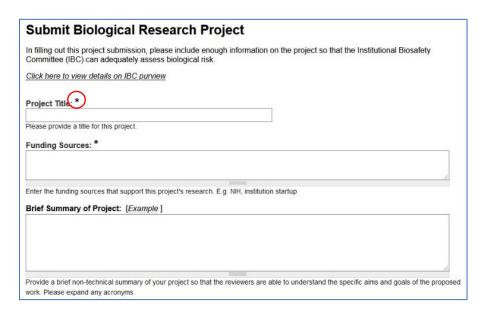
Project Form

After selecting "Continue" the PI will be brought to the "Enter Laboratory's Research Projects" page. Click "Add a Project" to include a Project Form within your IBC Registration.



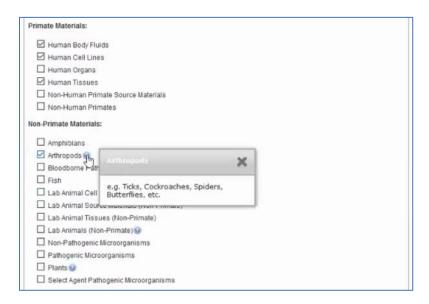
* Note: <u>Please complete one Project Form</u>. If your lab has several projects, all projects can be included in the Description of Experimental and Procedural Details section of the Project Form, and can be designated as "Project 1, Project 2", etc. Completing multiple Project Forms will prompt the same survey multiple times. To avoid confusion and help increase efficiency we are asking labs to complete one Project Form.

When adding a Biological Research Project there will be certain fields that are required for the PI to complete. These will be indicated with an asterisk next to the field.

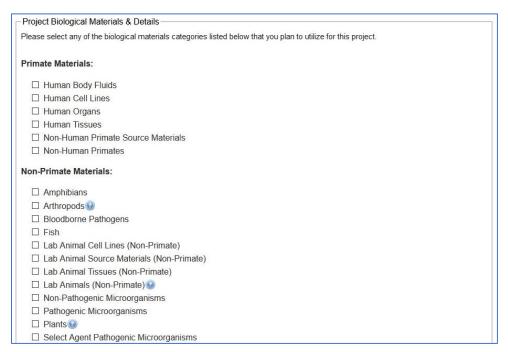




Throughout the process, there are question mark icons to hover your mouse over for help text. These will help guide the user to what should be entered in the prompted field.



Project Biological Materials and Details - The next step is to select the appropriate materials in use for this project. These selections will trigger applicable surveys to be completed for more accurate classification of experiments.





Description of Experimental and Procedural Details – Below is a screenshot of how this can be set up. However, it should be noted that this is a brief example, and for live registrations additional details need to be provided so the IBC can conduct a thorough risk assessment.

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Description of Experimental and Procedural Details: [Example]

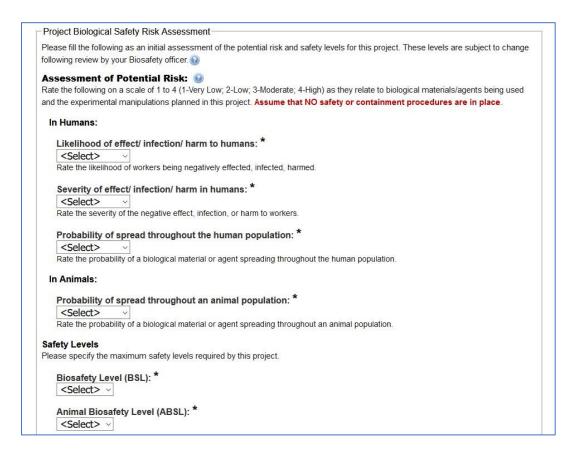
Project 1: Transfect human cells with...

Project 2: Extract DNA from ....

Project 3: Purify proteins that ...

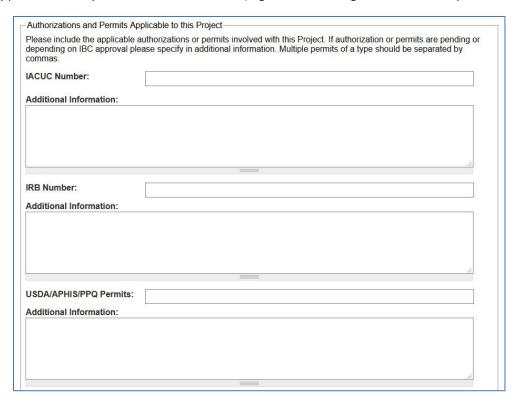
Provide details that enable reviewers to understand the flow of the experimental investigations involving the biological materials chosen above. Include details about genetic alterations to the models used, the purpose of the alterations, any potential deleterious effects of the alterations. Use references and expand acronyms.
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Project Biological Safety Risk Assessment – The PI or delegate completes this section to do an initial assessment of the risk involved with the experimental activities in the lab and determine which Biosafety Levels the lab feels are appropriate for the work. The IBC may agree or disagree, and this section can be updated administratively as needed.





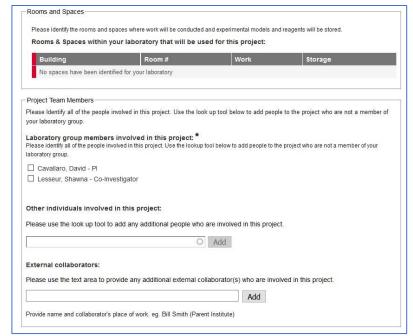
Authorizations and Permits Applicable to this Project – This section can be used to indicate which (if any) UConn Committee approvals are in place, other than the IBC (e.g. those working with animals require IACUC approval).



In HuskySMS, rooms and spaces are associated with Laboratories. Applicable locations should be pre-filled into your Project Form to select which rooms are used for work and/or storage.

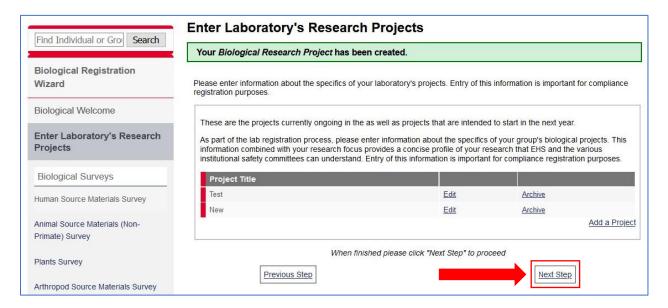
During the General Setup Wizard the PI will be asked to add members to their lab. The Project Form will automatically include those members for the PI to select personnel associated with the biological work.

If there is a collaborator within the institution, but not in the lab, that member can be added to the Project Form through the institutional look up under "Other individuals involved in this project". External collaborators can be added by including their name and institution in the appropriate form field.



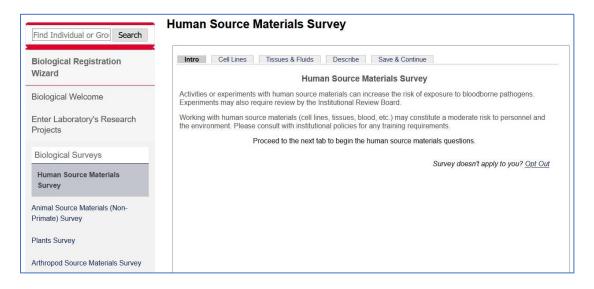


After the Project Form is complete, click "Save and Continue" and then "Next Step" to move on to the survey portion of the Biological Summary / IBC Registration.



Biological Material Surveys

In this example the PI selected work involving Human Sourced Materials, Animal Source Materials (non-primate), Arthropods, Biological Toxins, and Recombinant or Synthetic Nucleic Acids Molecules on the Project Form. Those selections now appear in the left-nav menu for the surveys required for submission. Surveys are associated with selections made in the Project Form but will not appear if not required.



Surveys include questions and answers that may trigger additional surveys as needed. Questions can be found under each tab of the survey. Once all questions in in each tab have been completed, click "Save" under the



<u>"Save & Continue" tab</u>. The survey process will continue in this format until all triggered Biological Surveys are complete. Each Survey has similar tabs with questions and formats.

*Note: Not all surveys will be required for all labs. These surveys are populated based on the work conducted in the lab.

Overview of Surveys within HuskySMS

Human Source Materials Survey – Reviews use of materials obtained from a human source (e.g. human cell lines, blood, tissues, etc.).

Animal Source Materials (Non-Primate) Survey – Asks general questions regarding the use of materials obtained from an animal source (e.g. mouse cell lines, blood, tissues, etc.). It should be noted that this survey excludes the use of non-human primate materials, since that is covered in a separate survey.

Non-Human Primate Source Materials Survey – Reviews use of materials obtained from a non-human primate source (e.g. COS-1 cell lines, macaque blood, tissues, etc.).

Plants Survey – Reviews questions regarding research involving plants. Both transgenic and wild-type plant work is included in this survey.

Arthropod Source Materials Survey – This survey goes over general questions regarding the use of arthropods and materials from arthropods.

Microbial Agents Survey – Evaluates the use of microorganisms (bacteria, viruses, fungi, etc.). This includes both the use of pathogenic organisms *as well as non-pathogenic microorganisms*.

Biological Toxins Survey – Requests information regarding the use of toxins obtained from a biological source. Please note that <u>toxic chemicals are not biological toxins</u> and should not be included in this section.

Recombinant or Synthetic Nucleic Acid Molecules Survey – This survey contains questions regarding the use of rsNA molecules in the lab. Questions are taken directly from the NIH Guidelines. When a question is answered, that section may expand and show more relevant subsections of the NIH Guidelines. Once completed, the applicable NIH Guidelines will be documented in the biological summary.

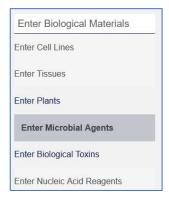
*Note: The selection of the applicable links (i.e., "NIH Guideline Section-III-A-1") will bring you to the website for the NIH Guidelines. Hovering over the (?) icon will display help text for the applicable topics.

rsNA Survey - Exempt Experiments – If you indicate that you perform Exempt Experiments, the survey will trigger additional information to capture details about this research.



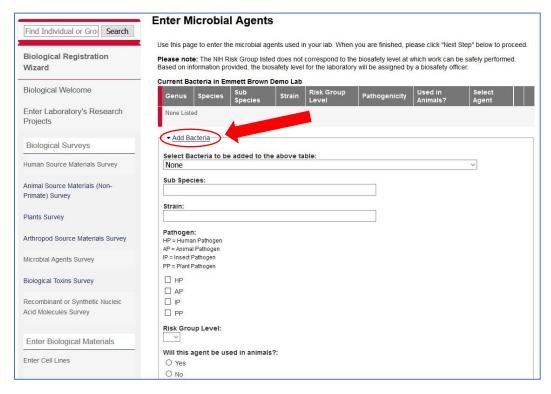
Material Data Entry

After all Biological Material Surveys are completed, the PI will be prompted to provide additional information about the materials they work with. This PI indicated that they work with cell lines, tissues, plants, microorganisms, biological toxins and Recombinant DNA; therefore, those Material Data Entry points are triggered in the left-nav for the PI to add, as can be seen in the screenshot to the right.



Example: Enter Microbial Agents

From this view the PI will be able to enter what Bacteria, Fungi/Yeasts, Viruses, and Parasites they use in their research. By Selecting "Add Bacteria," "Add Virus," etc. the PI will be prompted to choose the genus/species or applicable information for the submission of this agent from a dropdown menu.

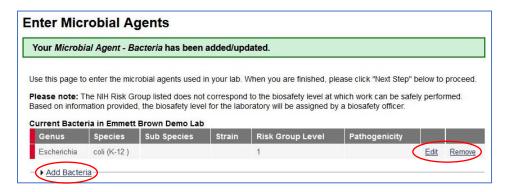






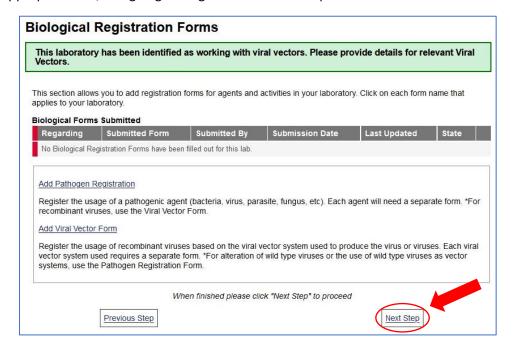
Addition/Update of the Microbial Agents

We can now see that the microbial agent is listed as a bacterium in the lab. The PI has the ability to Edit or Remove these agents or add additional bacteria by selecting "Add Bacteria."



Biological Registration Forms - Pathogens and Viral Vectors

A Pathogen Registration and/or a Viral Vector Form will provide additional safety information for the IBC to conduct a proper risk assessment. Pathogen forms are required for risk group 2 microorganisms that cause disease in healthy human adults (bacteria, fungi, parasite). The Viral Vector Form must be completed for labs using viral vectors in cells, animals, etc. (e.g. AAV, lentiviral vectors). Applicable forms can be completed by selecting the appropriate link, and going through the tabs at the top of the form.

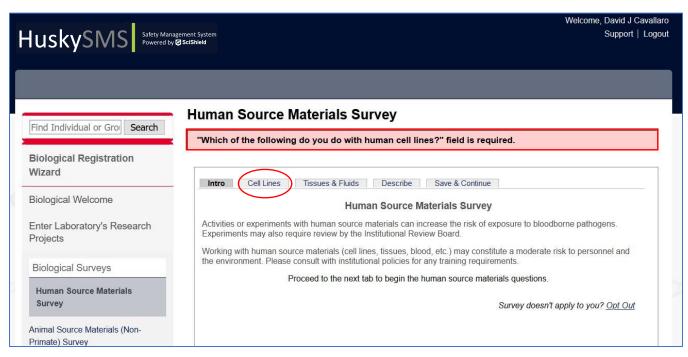


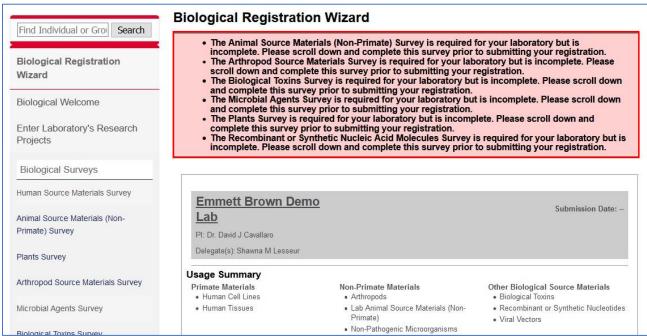
^{*}Note: These forms DO NOT need to be completed if your lab does not use human pathogens or viral vectors.



Survey and Form Submission Correction

The HuskySMS Biological Registration database ensures that all applicable information is captured by using prompts and messaging if a required question is left blank. The applicable section will be highlighted in red at the top of the screen until it is completed as appropriate.







Registration Completion

Once the Biological Summary / IBC Registration is complete, the PI is prompted to review the information provided. At the top of the biological summary, we can see the Usage Summary for the materials selected in the project, the lab focus that was provided during the General Set up Wizard, and the links to the relevant NIH Guidelines. The PI will be asked to scroll down to certify accuracy of the biological summary.

Review, Certify, and Submit

After a full review of the Biological Summary / IBC Registration the PI will be asked to "Certify" the registration. The PI will be prompted to initial each statement to indicate that they will comply with institutional policies, and then submit the registration for IBC review and approval. After certification, a message is displayed to confirm submission.





Certification Page

Certify and	Submit to the Institutional Biosafety Committee
Please read	the following and initial each section.
	this form you are agreeing to all of these statements and certifying that all of the information currently displayed in the Registration section of your lab profile is accurate and complete to the best of your knowledge.
Please Initia	al using DC.
amiliar wit	rtify that the information provided in this form represents the current and planned activities in my lab. I am h and agree to abide by the provisions of the current NIH Guidelines, the NIH Guide for Grants and other specific NIH instructions pertaining to the proposed project: *
dc	
esearch wi Committee	initiate recombinant/synthetic nucleic acid (rsNA) molecule activities subject to the NIH Guidelines, or ith pathogenic organisms until work has been reviewed and approved with the institutional Biosafety , or unless otherwise notified by the IBC/IBSO: *
dc	
uman pat	able, I certify that registration with the CT Department of Public Health for work with Risk Group 2 or above thogens has been completed and is current: *
dc	
DC/NIH E	ure that those working in my laboratory will follow laboratory techniques and practices outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) and the institutional Biosafety Manual,
1-1-1	e for the designated biosafety level and the activities conducted in my lab: *
dc	
i. I attest t	hat prior to the start of this project, all persons involved will be:
2. Inst 3. awa 4. fam exp 5. trail 6. trail	quately trained in good microbiological techniques and practices, tructed on any specific hazards associated with the project and worksite, re of any specific safety equipment and practices required for the procedures and use of the facilities, alliar with appropriate emergency response procedures and reporting requirements (e.g., spills, accidental osure, environmental release), ned on the NIH Guidellines, and hazards associated with research involving rsNA, ned on the Lab Specific Biosafety Manual, its contents, and where it can be accessed, siving appropriate safety trainings offered by EH&S
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	hat all shipping and transfer of biological materials is being conducted according to all applicable s and University policy: *
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	ow applicable emergency response plans and inform the IBC and/or EH&\$ Office of any significant research ident or illness as soon as possible after its occurrence: *
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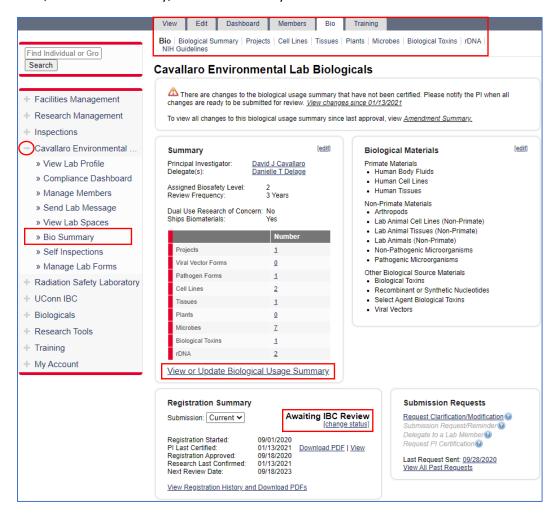


Review and Approval Process

After submission, the registration status is now awaiting EHS Review. The IBC Coordinator will receive a notification to review the submitted Biological Summary / IBC Registration. Once the IBC Coordinator has reviewed the submission, it will be slated for IBC Review, where the Biosafety Officer will conduct their preliminary review. The PI will be notified of the status change via the Compliance Mailbox in HuskySMS.

PI and delegate will receive an email after the preliminary review to "Request Clarification/Modification". This email will indicate the next steps of the review process and specify whether the registration requires full committee review at the next IBC meeting, or if it can be administratively approved by the Biosafety Officer.

Status updates can also be found in the "Bio" page. The Bio Profile (see screenshot below) provides a brief overview of the lab's biological summary. To get here, click the (+) next to your lab to initiate the drop-down menu, and click "Bio Summary". From here, you can navigate to the Biological Summary, and make changes to the Project Form, Material Data Entry, or Material Surveys as needed.





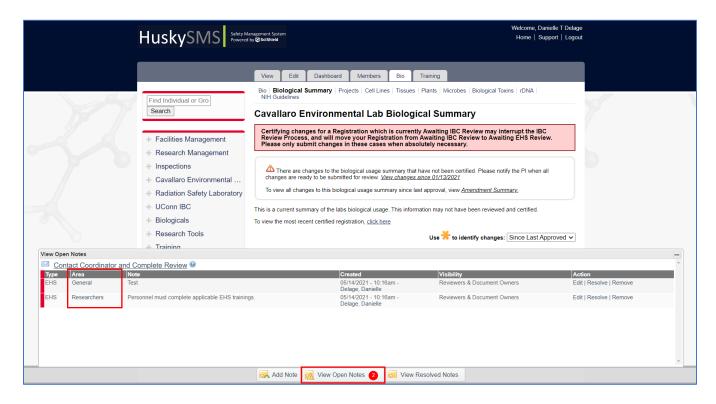
Reviewer Notes Functionality

For streamlined review of the registration, the tool bar at the bottom of the Biological Summary provides the functionality for EHS and the IBC to "Add Notes", "View Open Notes" and "View Resolved Notes". EHS will send notes to the PI/delegate for clarification. Below is a screenshot of what a biological summary might look like, with the Reviewer Notes section open at the bottom of the screen.

A red circle will be found next to "View Open Notes", which indicates how many comments were made by EHS and the UConn IBC.

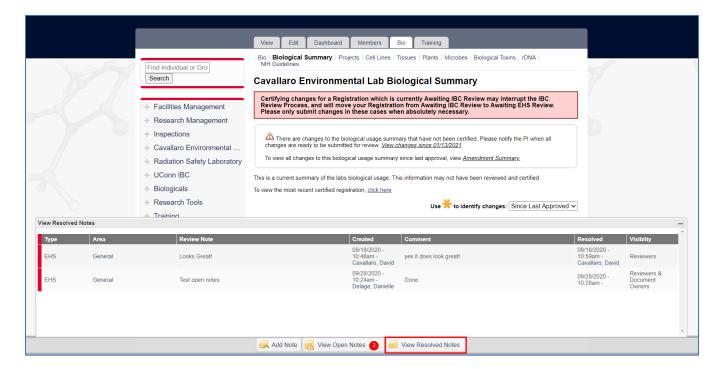
<u>Directions to View Open Notes</u>: Easily navigate to review notes that have been added, and make the required changes.

- 1. The Area column contains links to the section associated with the open note. Selecting the applicable area will bring you to the highlighted area of the biological summary where revisions are requested.
- 2. Clicking "Resolve" next to the note will move it to the resolved notes tab and allows the individual who resolves the note to add a comment on how it was addressed.





<u>View Resolved Notes</u>: To review an archive of past notes and comments that have been addressed.



Amendments

After the Biological Summary / IBC Registration is approved, the PI can still submit changes to their registration. If the PI or a delegate would like to update this information, they can select the appropriate category within the biological summary (Projects, Cell lines, Microbes, rDNA Materials). Once an amendment has been made, select the link for "View or update Biological Usage Summary" to Certify the Amendment and resubmit it for review. If it is not certified and submitted, the IBC will not receive notification that changes have been made, and it will not move forward for approval.

Amendment Review

After the amendment is submitted, the status of the Biological Summary / IBC Registration will then change to "Amendment Awaiting Review," at which time the process of the IBC Coordinator and Biosafety Officer review/IBC approval will be repeated as needed.