BIORAFT

BioRAFT Biological Registration

P.I. Quick Start Guide

Prepared by BioRAFT Professional Services

Confidential

Last updated: June 23, 2016

25 1st Street, Suite 104, Cambridge, MA 02141 | www.BioRAFT.com

BIORAFT

Table of Contents

BIORAFT

BioRAFT Biological Registration Module Introduction

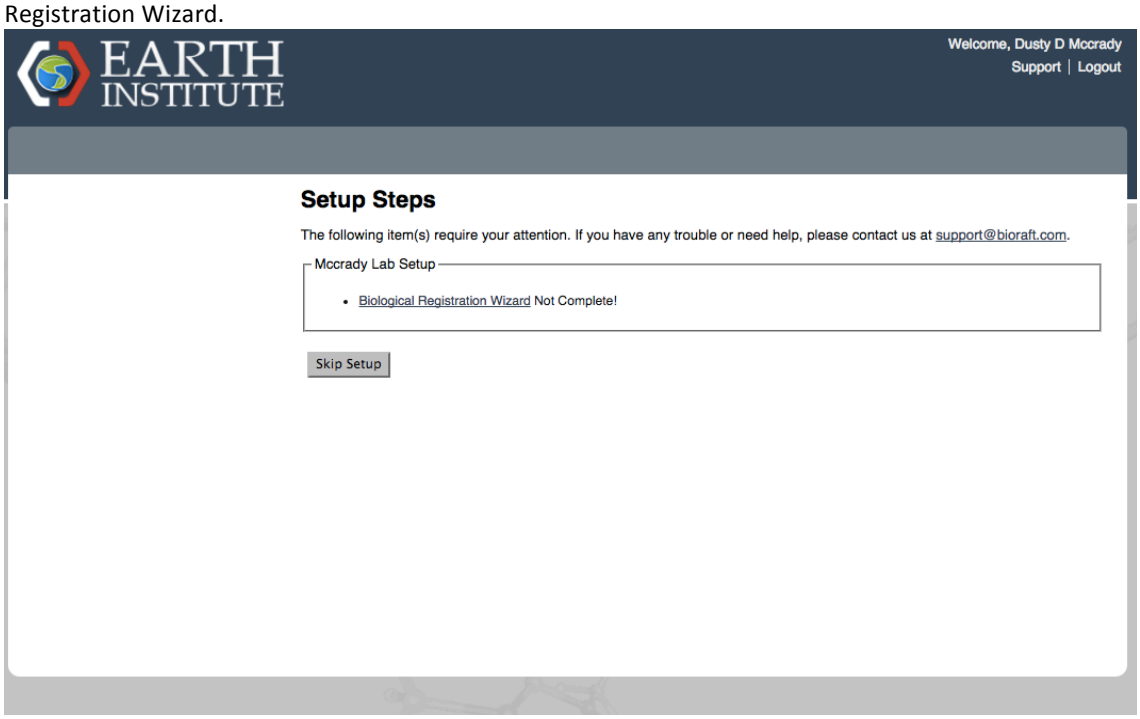
The BioRAFT Biological Registration Module allows for easy to follow registration of biological activities in the laboratory. Through the Biological Registration Wizard the Principal Investigator will be asked to fill out information on their projects and make determinations as to the work they conduct in their laboratory. Those determinations may prompt further surveys or forms that may assist a Biological Safety Officer or Institutional Biological Safety Committee in the assessment of the Biological Safety Level and potential hazards associated with that laboratory.

25 1st Street, Suite 104, Cambridge, MA 02141 | www.BioRAFT.com

Biological Registration- PI User Guide

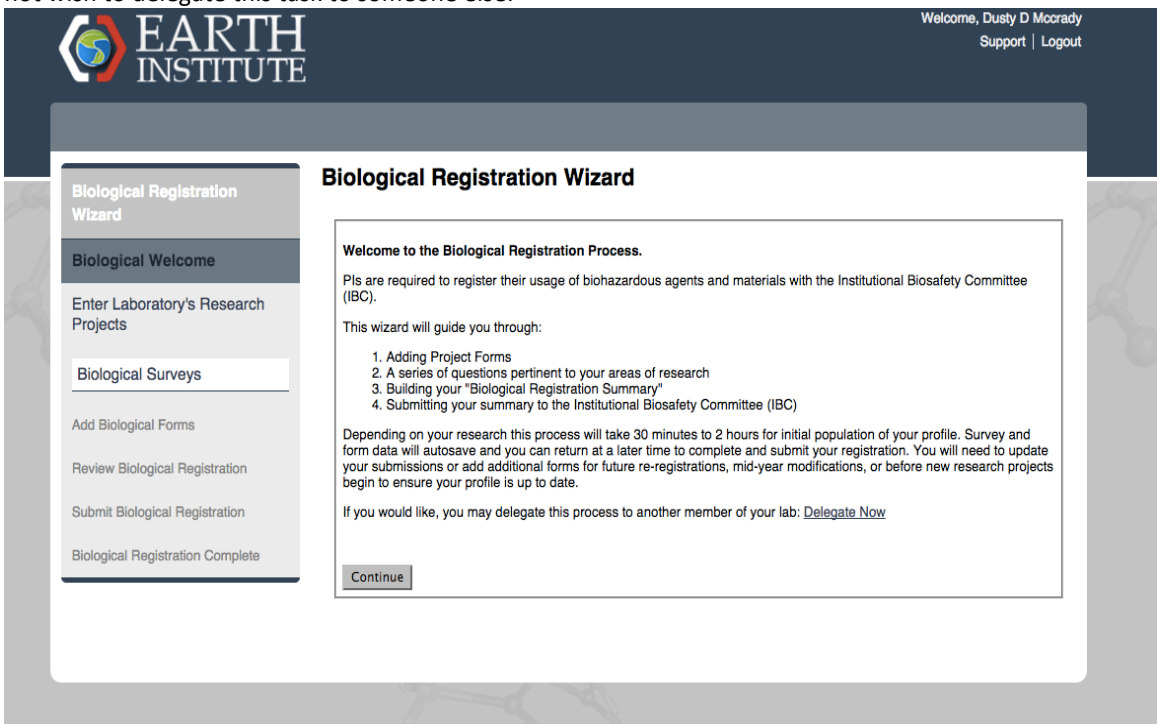
1. Biological Registration Prompt

Upon log in, the PI will be prompted to fill out their Biological Registration using the Biological Registration Wizard.



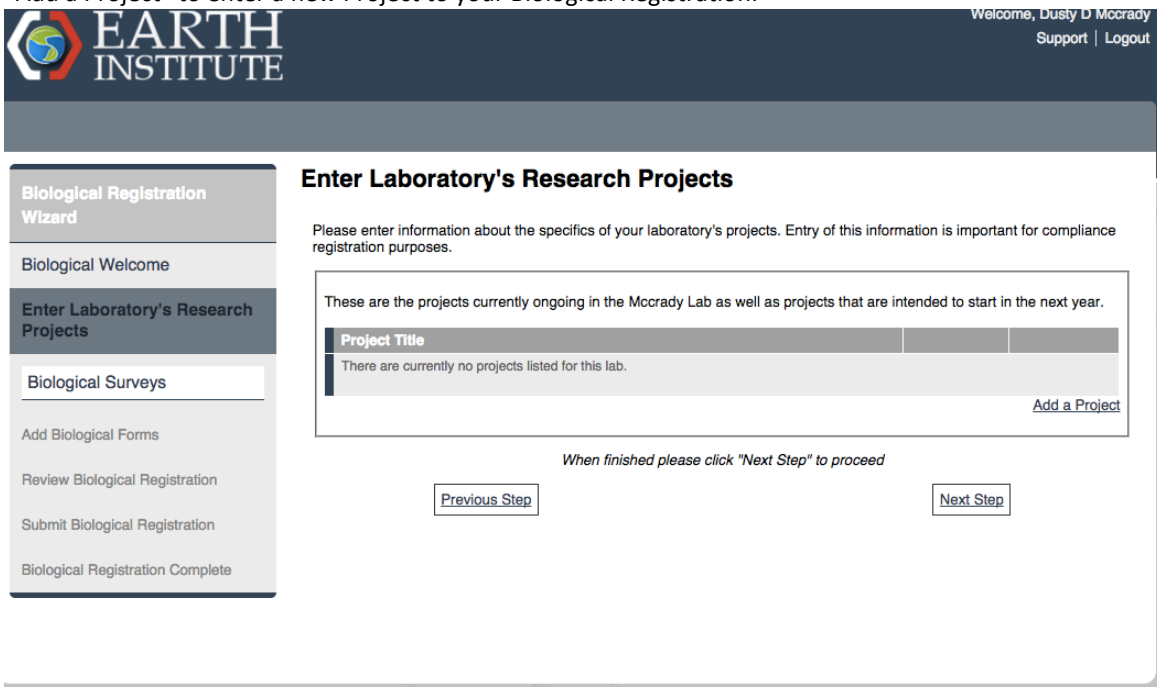
2. Biological Registration Wizard

The PI will be prompted with instructions on how to complete the Biological Registration Wizard. At this point they may delegate the Registration to an approved member of their laboratory. The PI should notice that there are no required Surveys or Data Entry at this point, because the Biological Usage has not yet been indicated in the Project Forms. Click “Continue” to begin the Biological Registration Wizard if you do not wish to delegate this task to someone else.



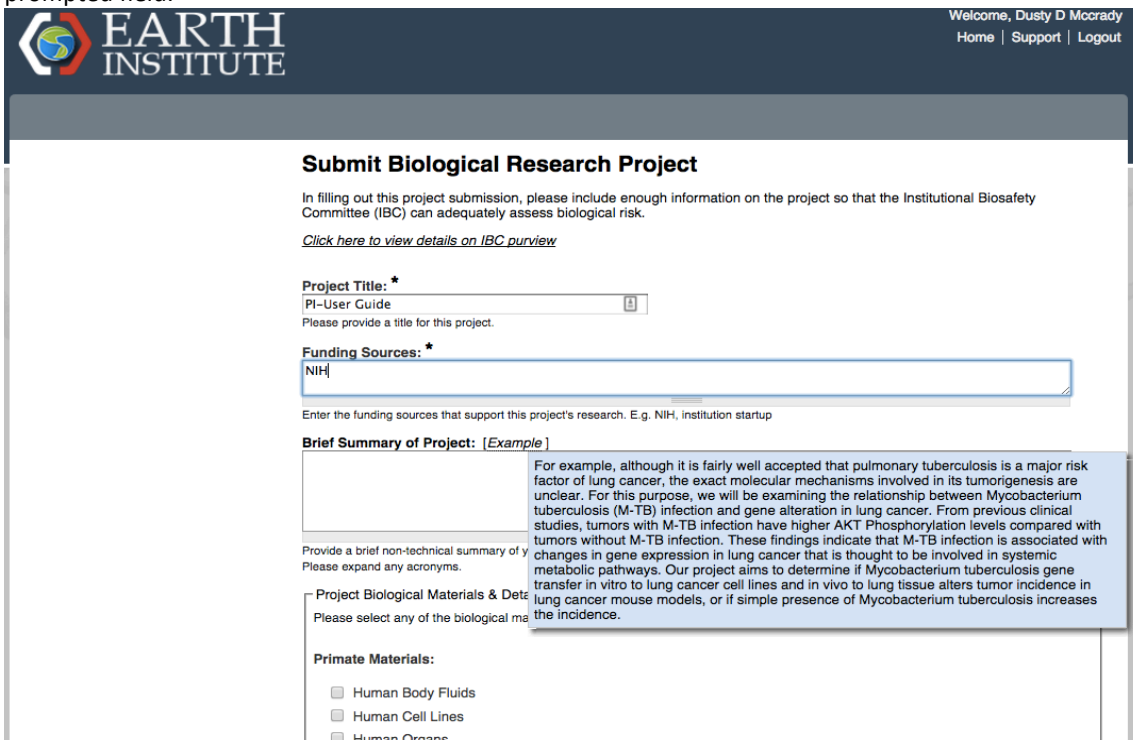
3. Adding Projects

After selecting “Continue” the PI will be brought to the “Enter Laboratory’s Research Projects” page. Click “Add a Project” to enter a new Project to your Biological Registration.



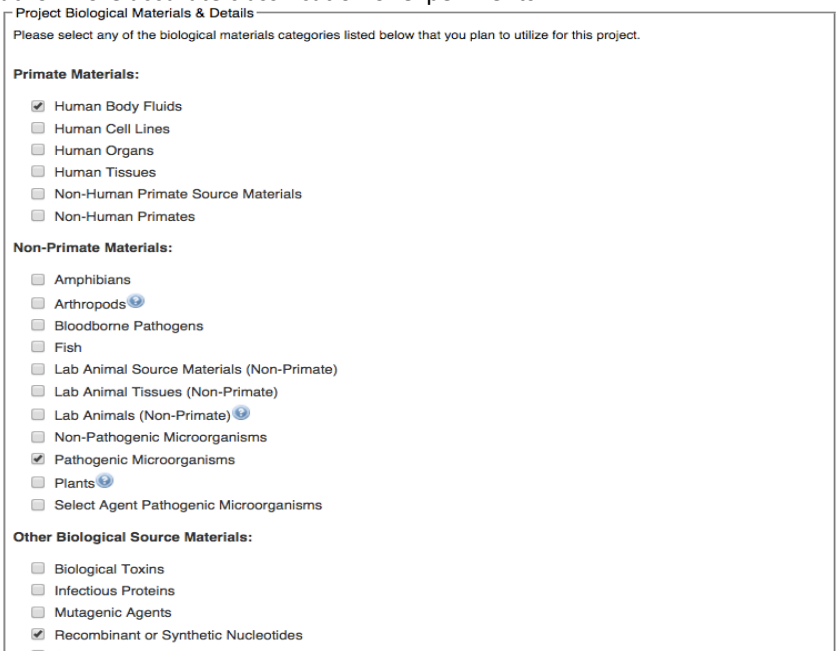
3a. Project Form

When adding a Biological Research Project there will be certain fields that are required for the PI to fill out. These will be indicated with an asterisk next to the field. Throughout the process, there are areas to hover your mouse over for "Examples." These will help guide the user to what should be entered in the prompted field.



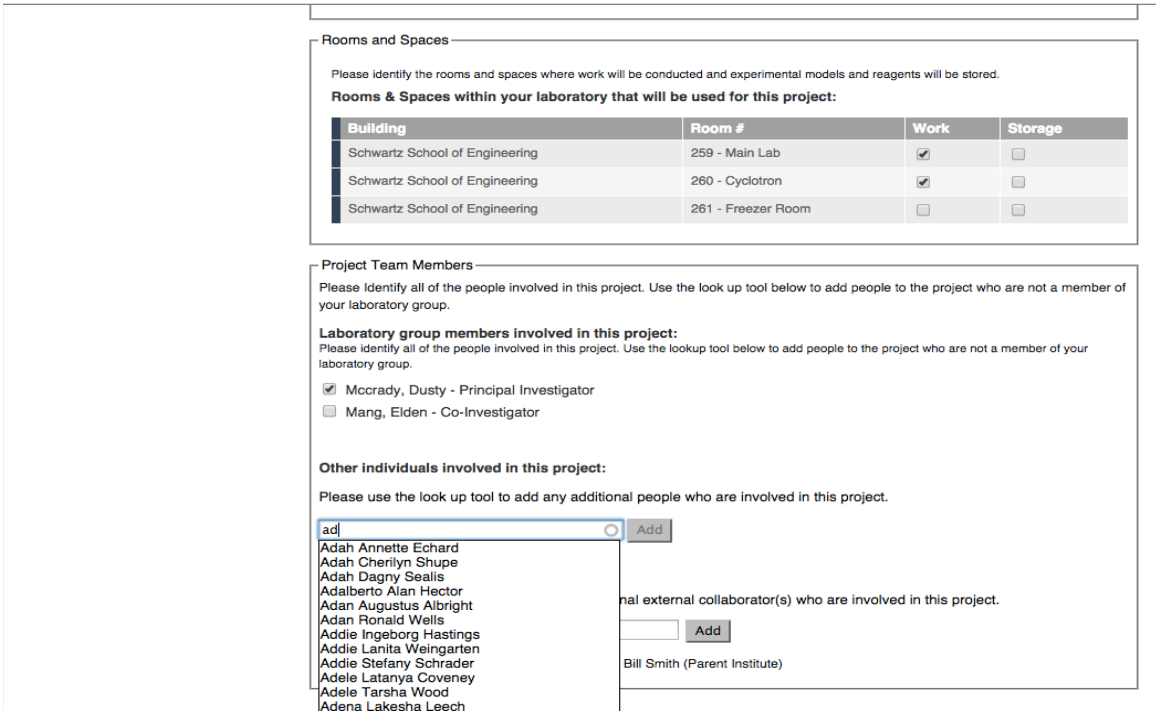
4b. Project Biological Materials and Details

The next step is to select the appropriate materials in use for this project. These selections will trigger further surveys to be filled out for more accurate classification of experiments.



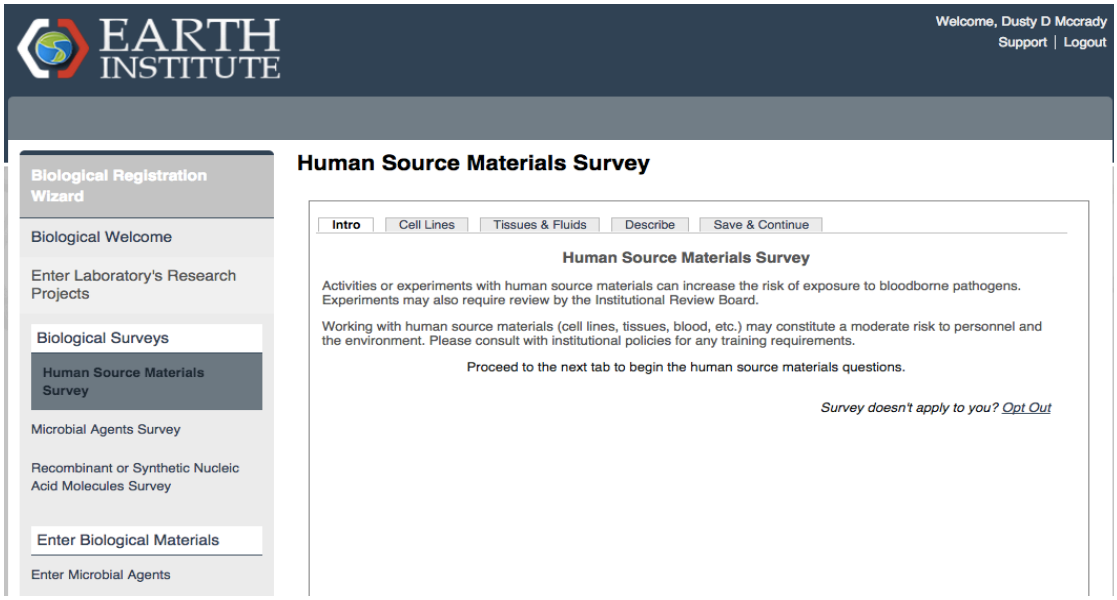
4c. Completion of the Project Form

In BioRAFT, spaces are associated with Laboratories. Those spaces will be pre-loaded into your Project Form for easy selection. 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 selection for each Project. 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. After all the information is complete, the PI will be asked to "Submit" the project, at which point they will be prompted to add additional projects, or to continue to the Survey portion of the Registration.



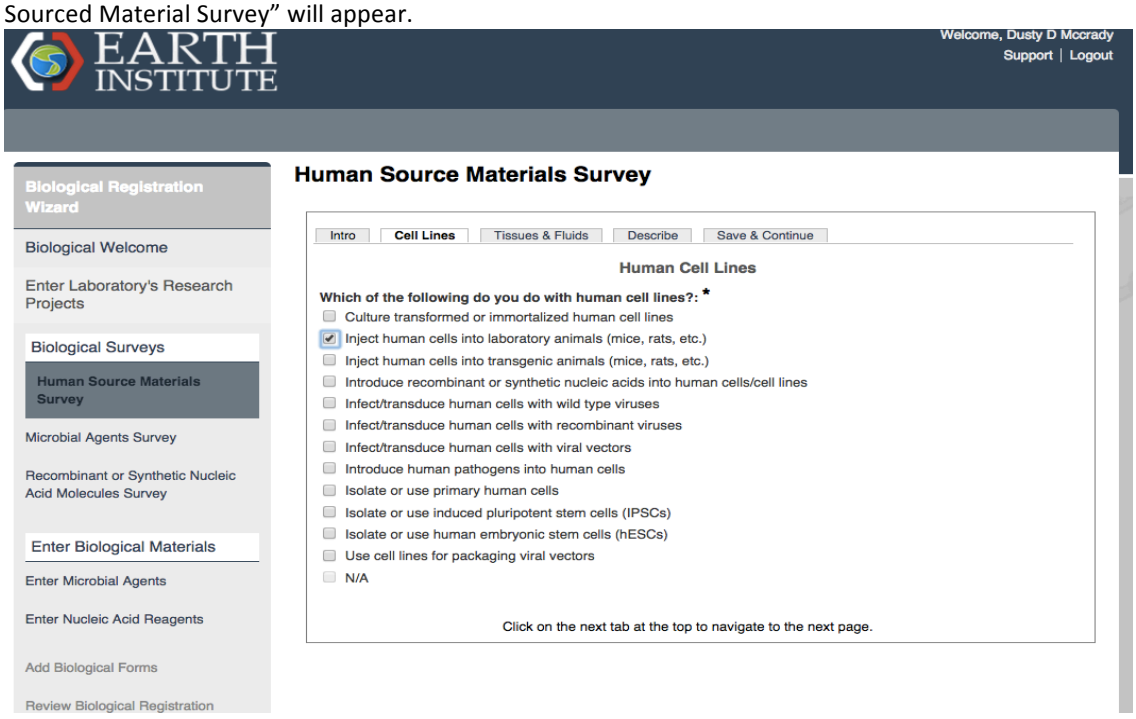
5a. Biological Material Surveys

In step 5 the PI selected work associated with Human Sourced Materials, Pathogenic Microbial Agents, and Recombinant DNA on the Project Form. Those selections are now what appear on the left hand menu for the Surveys required for submission. Surveys are associated with all selections but do not appear if not required.



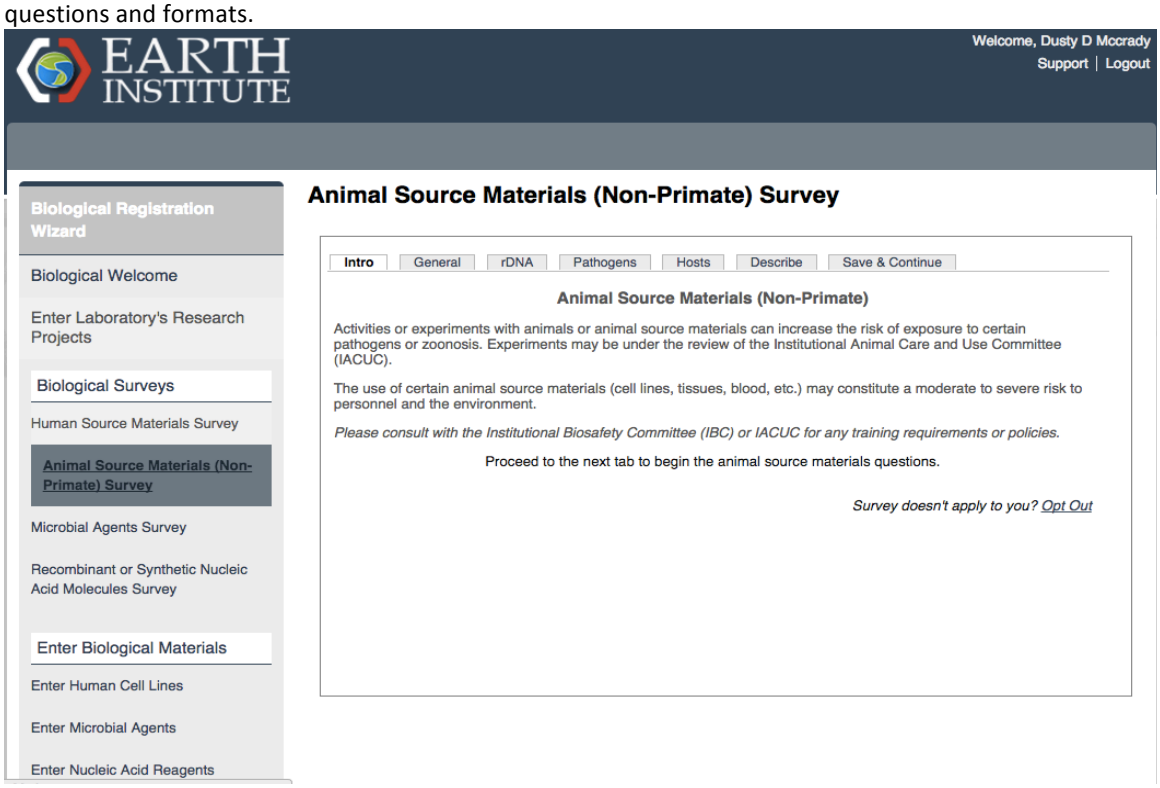
5b. Material Surveys

The Material Surveys include questions and answers that may trigger additional surveys as needed. For instance, this PI indicated that their experiments "Inject human cells into laboratory animals," therefore they will be prompted to fill out the Animal Material Survey. As you can see this is not prompted on the screen in the left hand menu at this time. When the PI completes and submits this survey, the "Animal Sourced Material Survey" will appear.



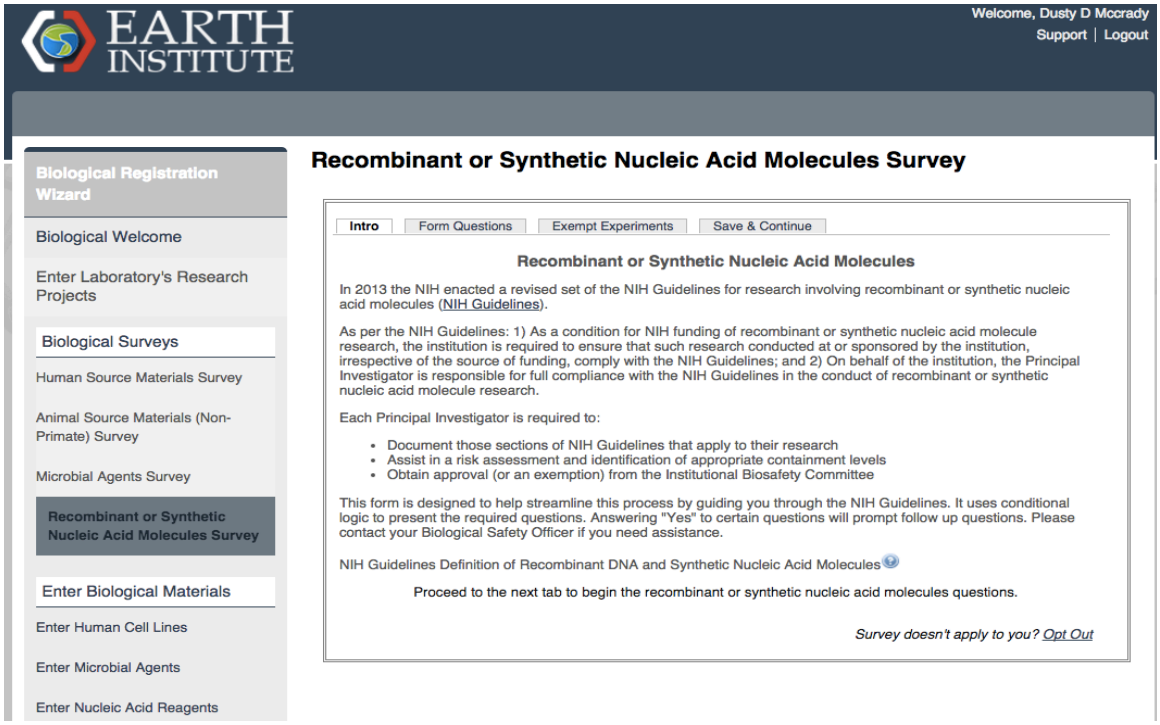
5c. Survey Process

The survey process will continue in this format until all triggered Biological Surveys are complete. As you will see here, the "Animal Sourced Material Survey" is now prompted. Each Survey has similar tabs with questions and formats.



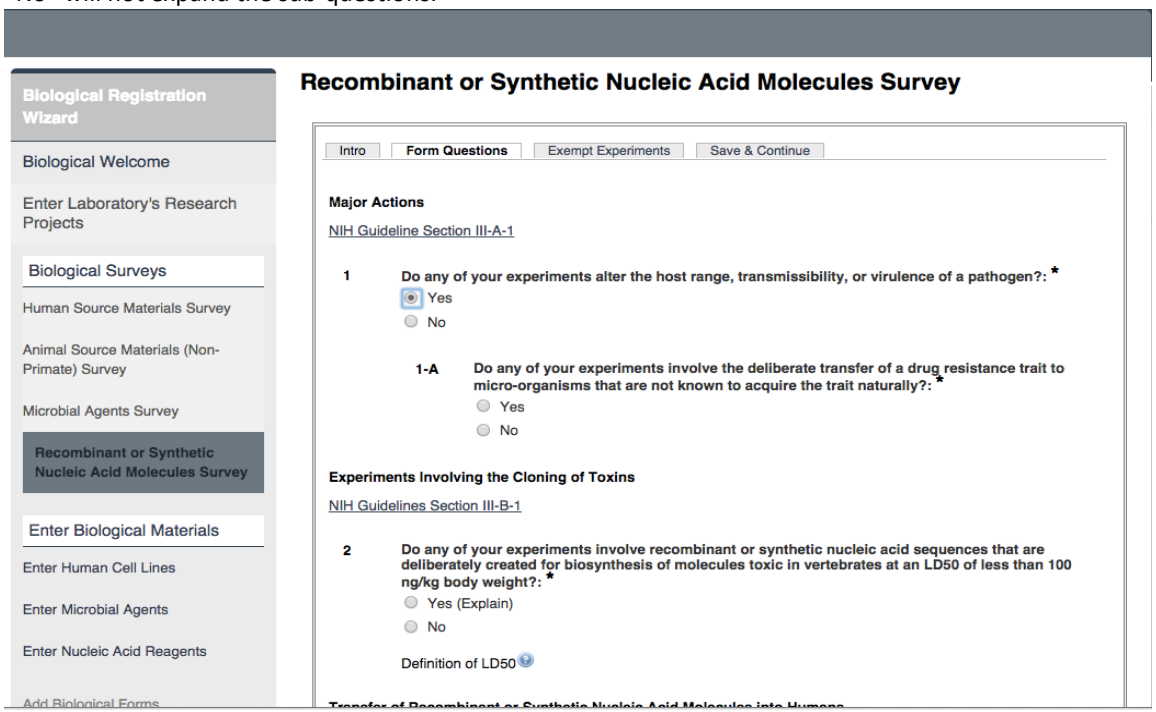
6a. Recombinant or Synthetic Nucleic Acid Molecules Survey

This survey will ask general questions regarding the overall use of Recombinant or Synthetic Nucleic Acid Molecules in the laboratory. When a topic is selected, that topic will expand, showing more relevant subsections of the NIH-Guidelines. This information will display the applicable NIH-Guideline to that specific question to the Labs Registration.



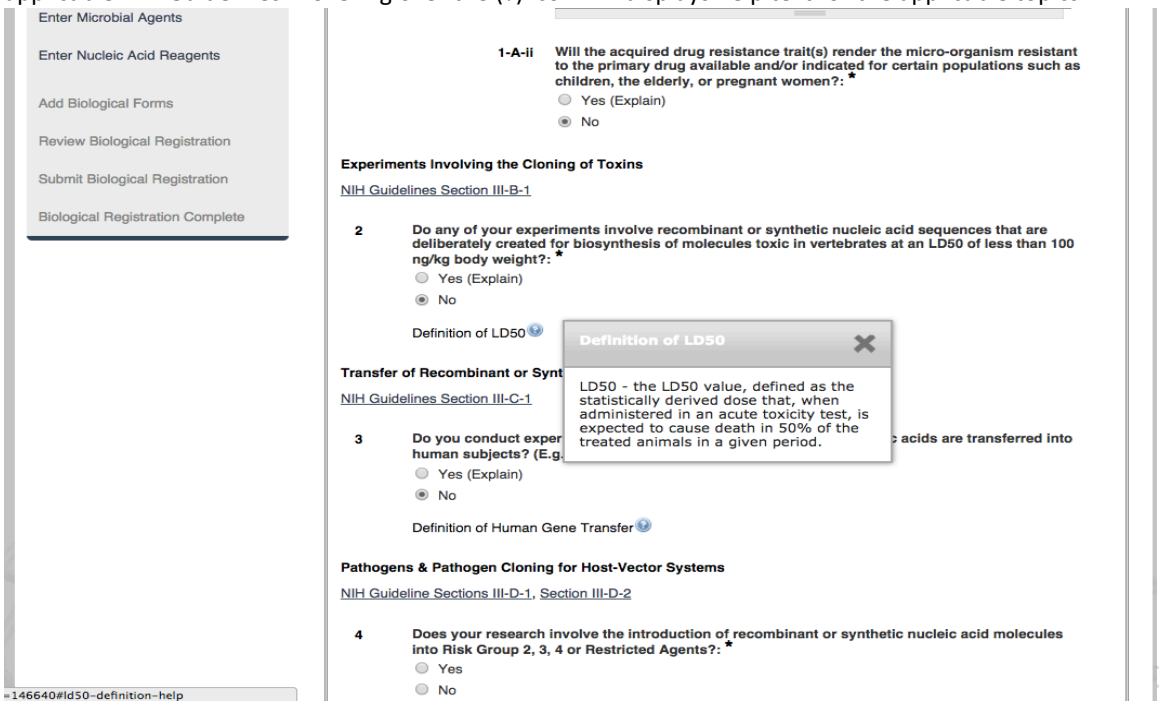
6b. rDNA Survey Expansion

Answering "Yes" to the question below will show further questions with the related topics, the answer of "No" will not expand the sub-questions.



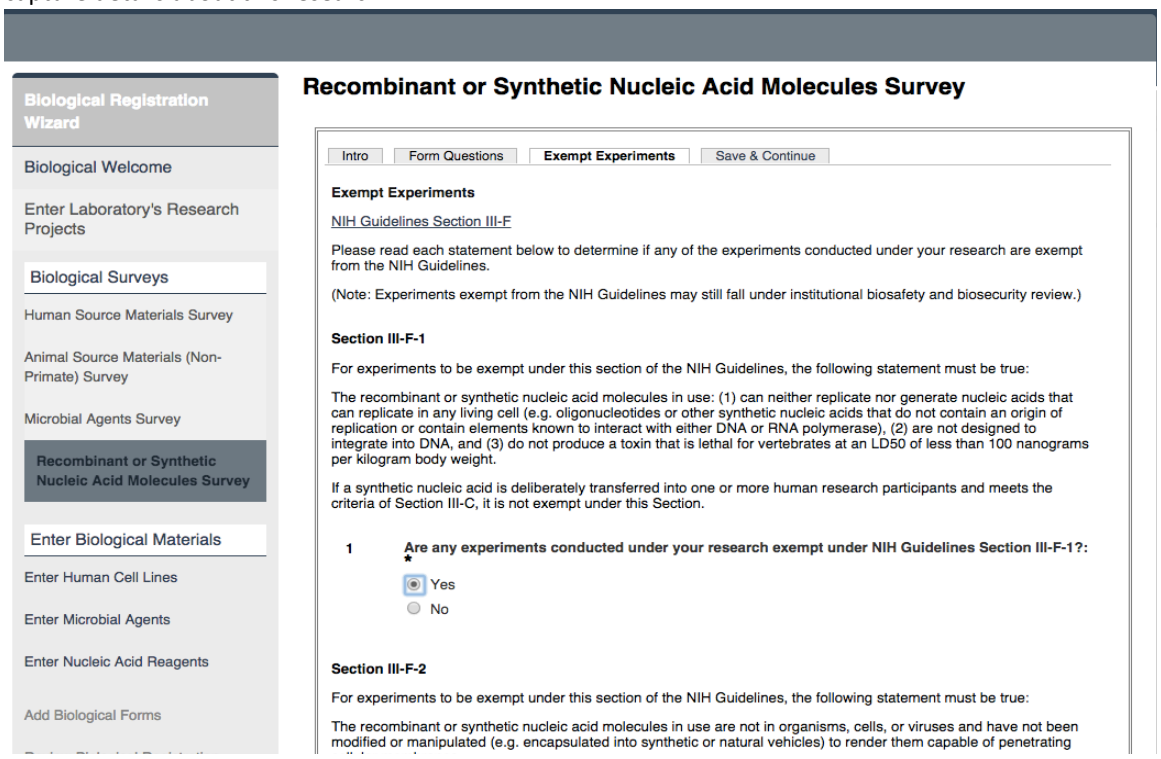
6c. Additional information in the rDNA Survey

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



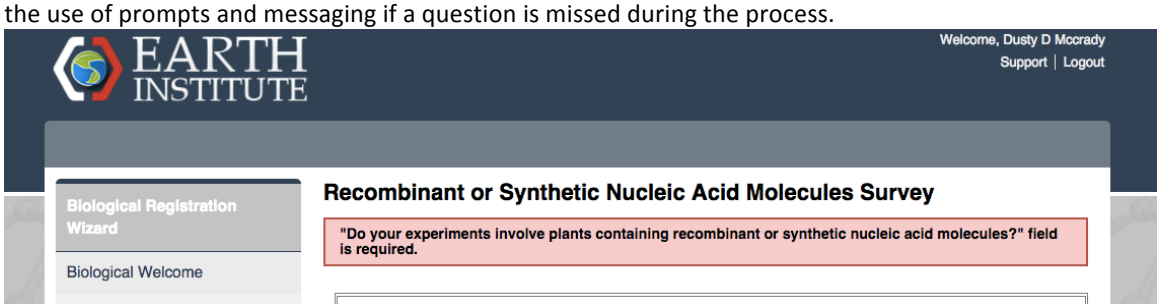
6d. The rDNA Survey also covers Exempt Experiments

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

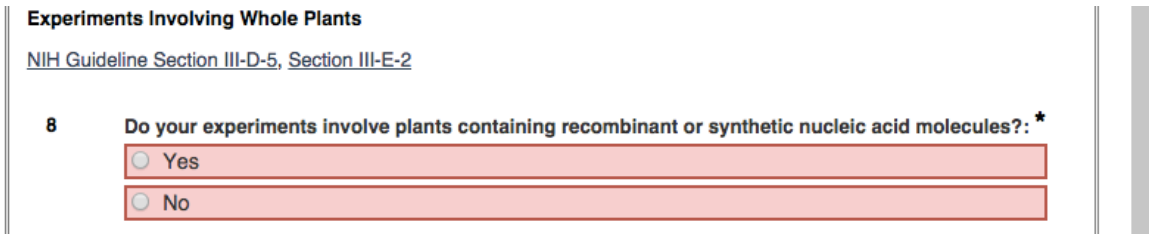


6e. Survey and Form Submission Correction

BioRAFT's Biological Registration Process will ensure that all applicable information is captured through the use of prompts and messaging if a question is missed during the process.

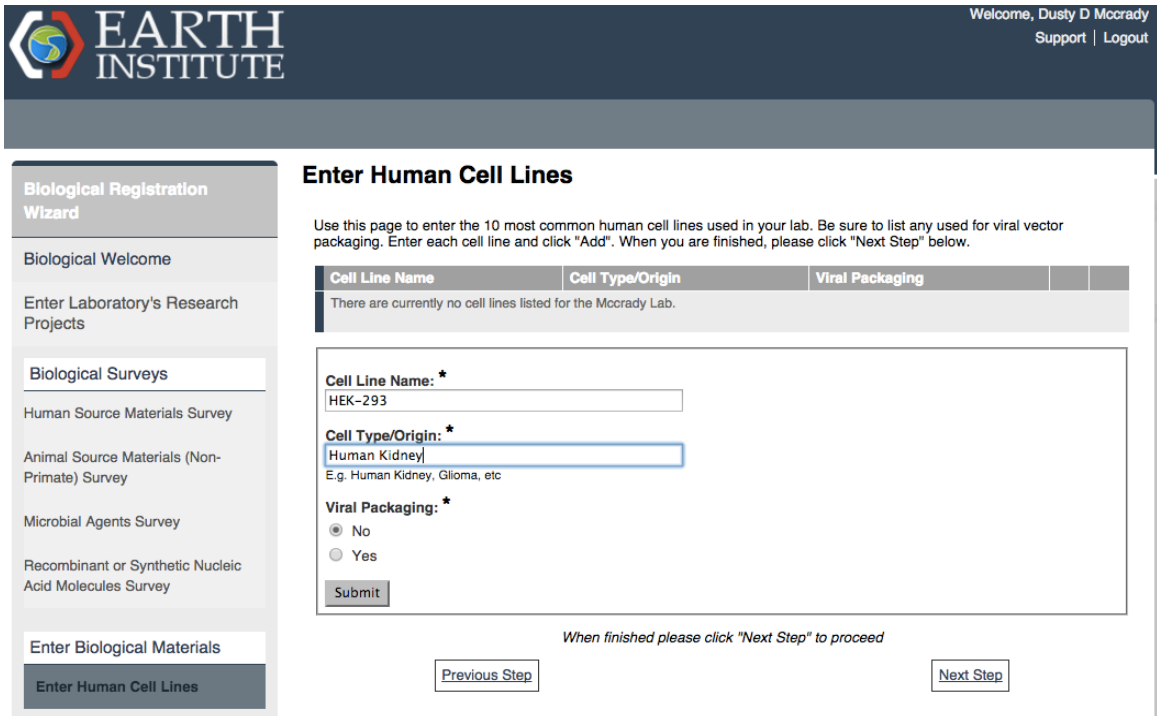


-The applicable section will be highlighted until it is filled out with either a "Yes" or a "No"



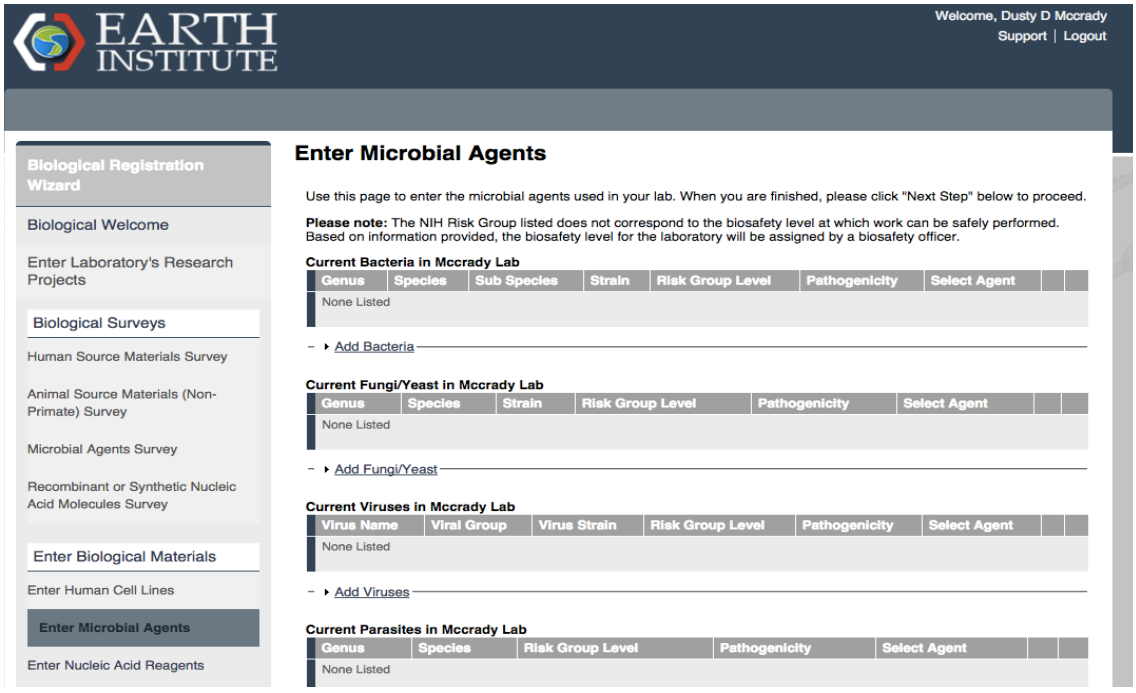
7. Material Data Entry

After all Material Surveys are completed, the PI will be prompted to provide additional information about the materials they work with. This PI indicated that he works with Human Sourced Materials, Pathogenic Organisms, and Recombinant DNA; therefore those Material Data Entry points are triggered for the PI to add.



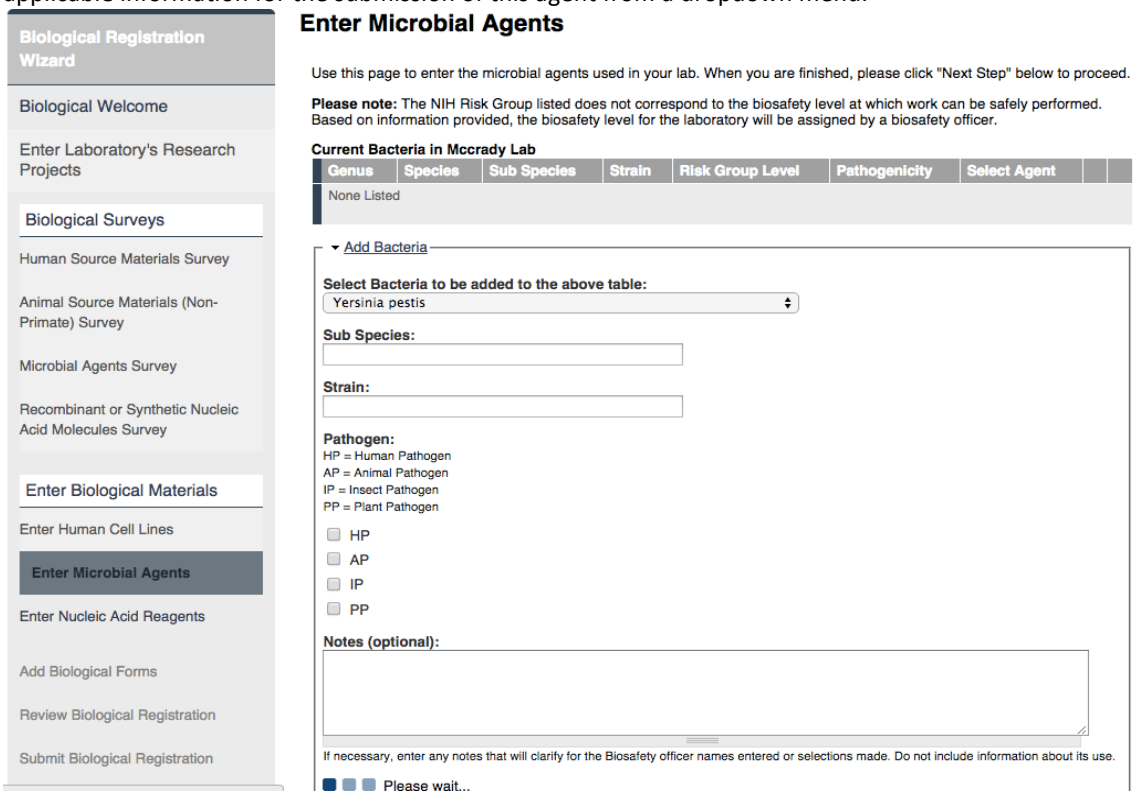
8. Enter Microbial Agents

From this view the PI will be able to enter what Bacteria, Fungi/Yeasts, Viruses, and Parasites they use in their research.



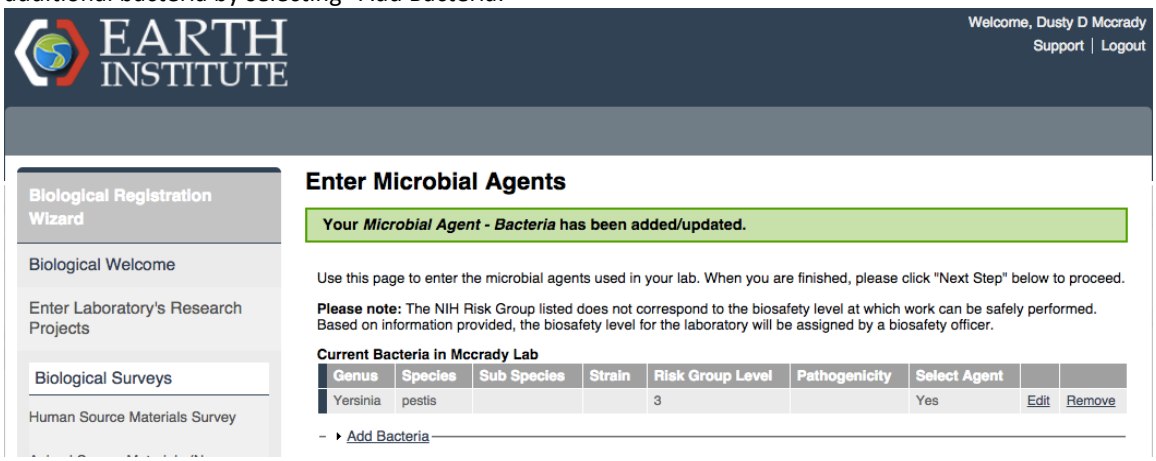
8b. Selecting Microbial Agents

By Selecting "Add Bacteria," "Add Virus," etc. the PI will be prompted to choose the Genius/Species or applicable information for the submission of this agent from a dropdown menu.



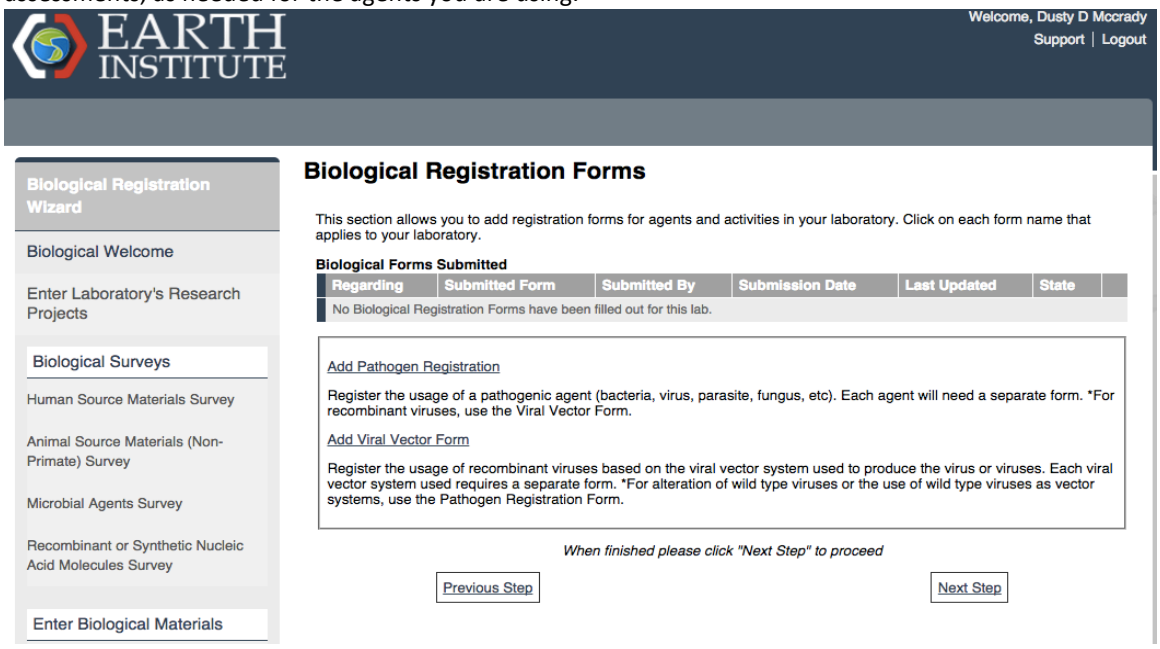
8c. Addition/Update of the Microbial Agents

We can now see that the microbial agent is listed as a bacterium in the lab, as well as the appropriate Risk Group and Select Agent designation. The PI has the ability to Edit or Remove these agents, or add additional bacteria by selecting "Add Bacteria."



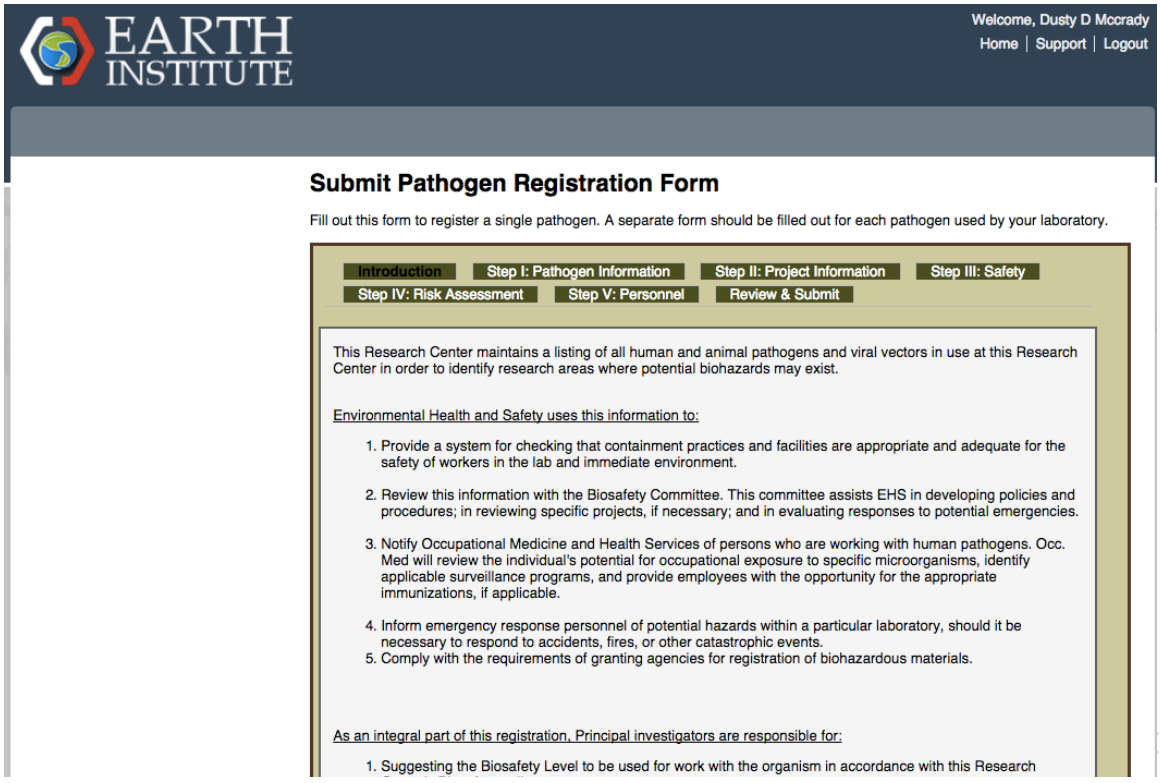
9. Pathogen and Viral Vector Forms

A Pathogen Registration or a Viral Vector Form will provide additional safety information for risk assessments, as needed for the agents you are using.



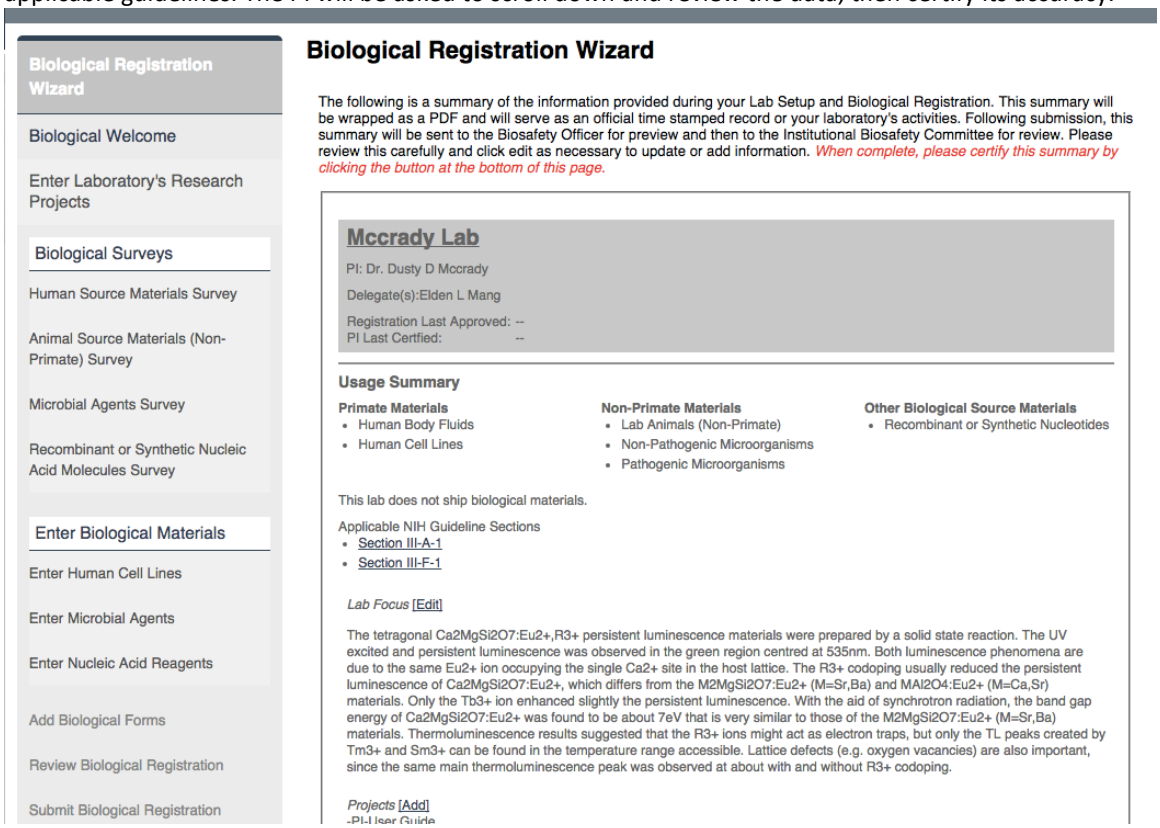
9a. Filling out a Pathogen Form or Viral Vector Form

This form can be filled out by using the tabs at the top of the form to navigate between the required information.



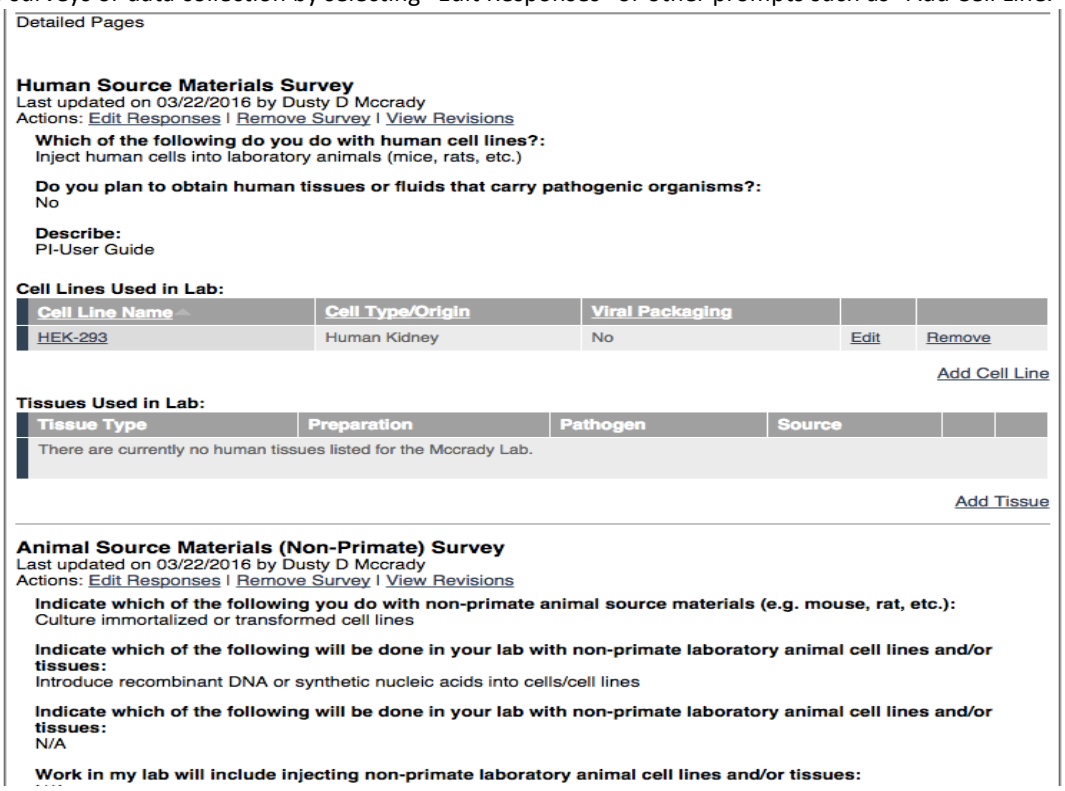
10. Registration Completion

Once the Biological Forms are completed, the PI will be prompted to review all the content that has been provided. At the top of the page 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 (completed in the Recombinant and Synthetic DNA Survey, section 7) with external links to the applicable guidelines. The PI will be asked to scroll down and review the data, then certify its accuracy.



10a. Bio Summary Review

The Survey selections and applicable material data are summarized for review. At this point edits can be made to surveys or data collection by selecting “Edit Responses” or other prompts such as “Add Cell Line.”



Detailed Pages

Human Source Materials Survey
Last updated on 03/22/2016 by Dusty D Mccrady
Actions: Edit Responses | Remove Survey | View Revisions

Which of the following do you do with human cell lines?:
Inject human cells into laboratory animals (mice, rats, etc.)

Do you plan to obtain human tissues or fluids that carry pathogenic organisms?:
No

Describe:
PI-User Guide

Cell Lines Used in Lab:

Cell Line Name	Cell Type/Origin	Viral Packaging		
HEK-293	Human Kidney	No	Edit	Remove

Add Cell Line

Tissues Used in Lab:

Tissue Type	Preparation	Pathogen	Source		
There are currently no human tissues listed for the Mccrady Lab.					

Add Tissue

Animal Source Materials (Non-Primate) Survey
Last updated on 03/22/2016 by Dusty D Mccrady
Actions: Edit Responses | Remove Survey | View Revisions

Indicate which of the following you do with non-primate animal source materials (e.g. mouse, rat, etc.):
Culture immortalized or transformed cell lines

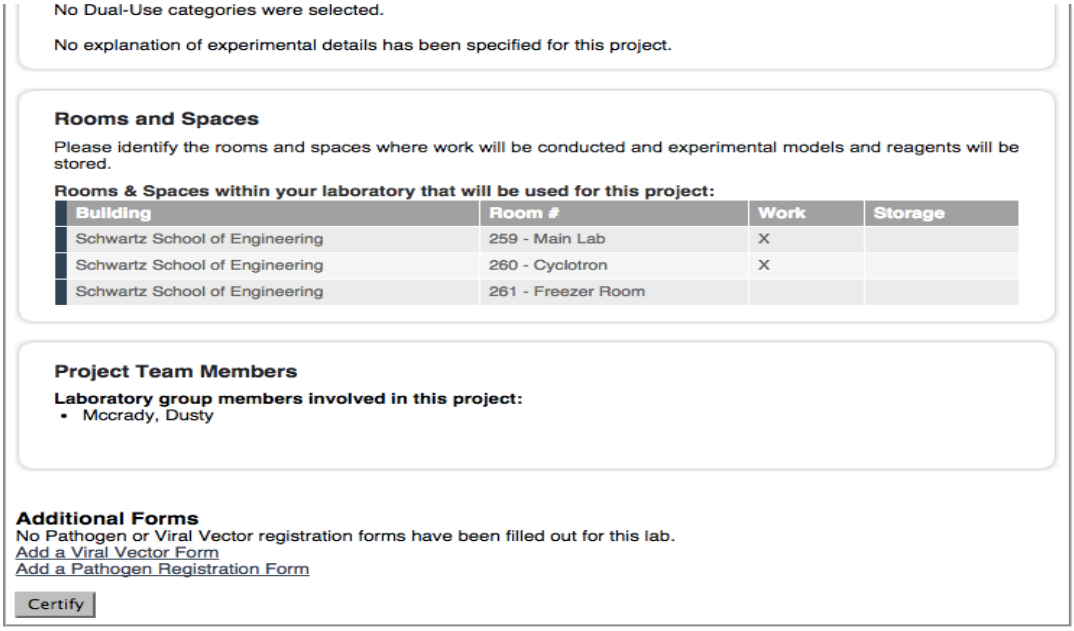
Indicate which of the following will be done in your lab with non-primate laboratory animal cell lines and/or tissues:
Introduce recombinant DNA or synthetic nucleic acids into cells/cell lines

Indicate which of the following will be done in your lab with non-primate laboratory animal cell lines and/or tissues:
N/A

Work in my lab will include injecting non-primate laboratory animal cell lines and/or tissues:

10b. Review and Certify

After a full review of the Biological Registration the PI will be asked to “Certify “their project.


No Dual-Use categories were selected.

No explanation of experimental details has been specified for this project.

Rooms and Spaces

Please identify the rooms and spaces where work will be conducted and experimental models and reagents will be stored.

Rooms & Spaces within your laboratory that will be used for this project:

Building	Room #	Work	Storage
Schwartz School of Engineering	259 - Main Lab	X	
Schwartz School of Engineering	260 - Cyclotron	X	
Schwartz School of Engineering	261 - Freezer Room		

Project Team Members

Laboratory group members involved in this project:

- Mccrady, Dusty

Additional Forms

No Pathogen or Viral Vector registration forms have been filled out for this lab.

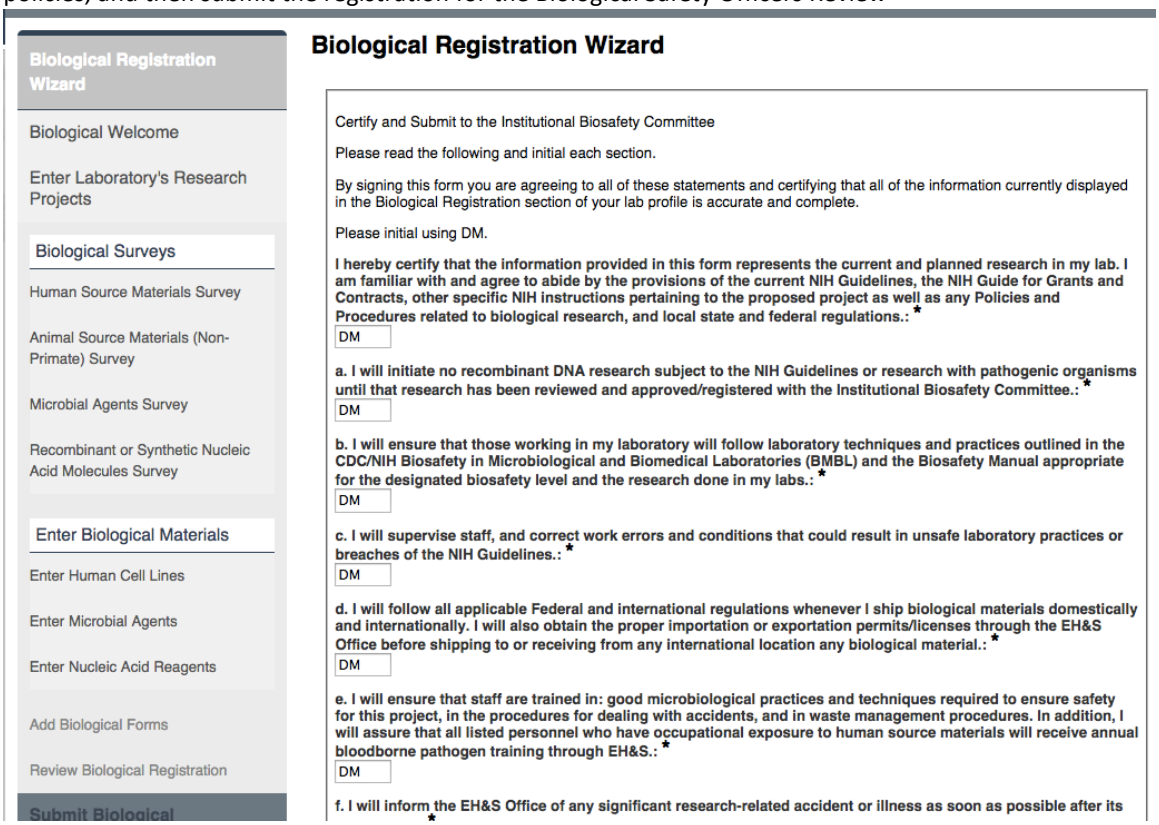
Add a Viral Vector Form

Add a Pathogen Registration Form

Certify

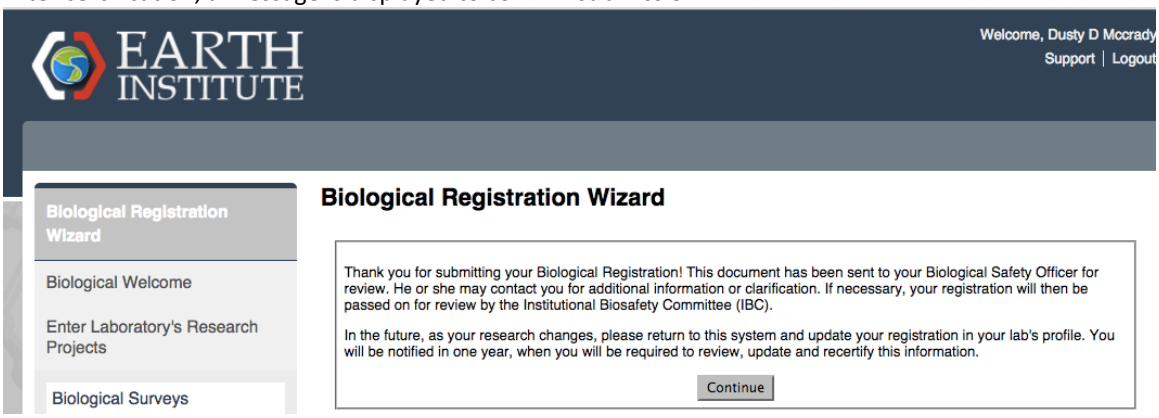
10c. Certify and Submit

The PI will be prompted to initial each statement to indicate that they will comply with institutional policies, and then submit the registration for the Biological Safety Officers Review



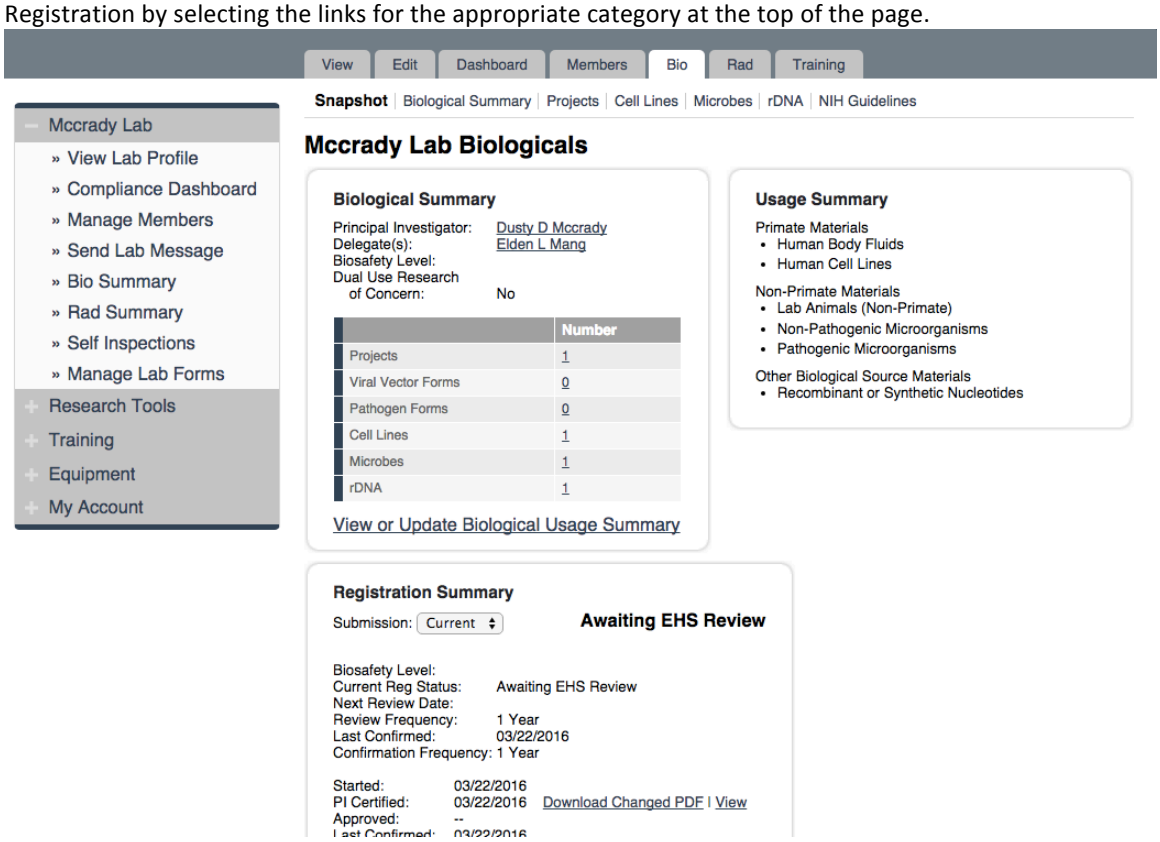
10d. Confirmation screen

After certification, a message is displayed to confirm submission.



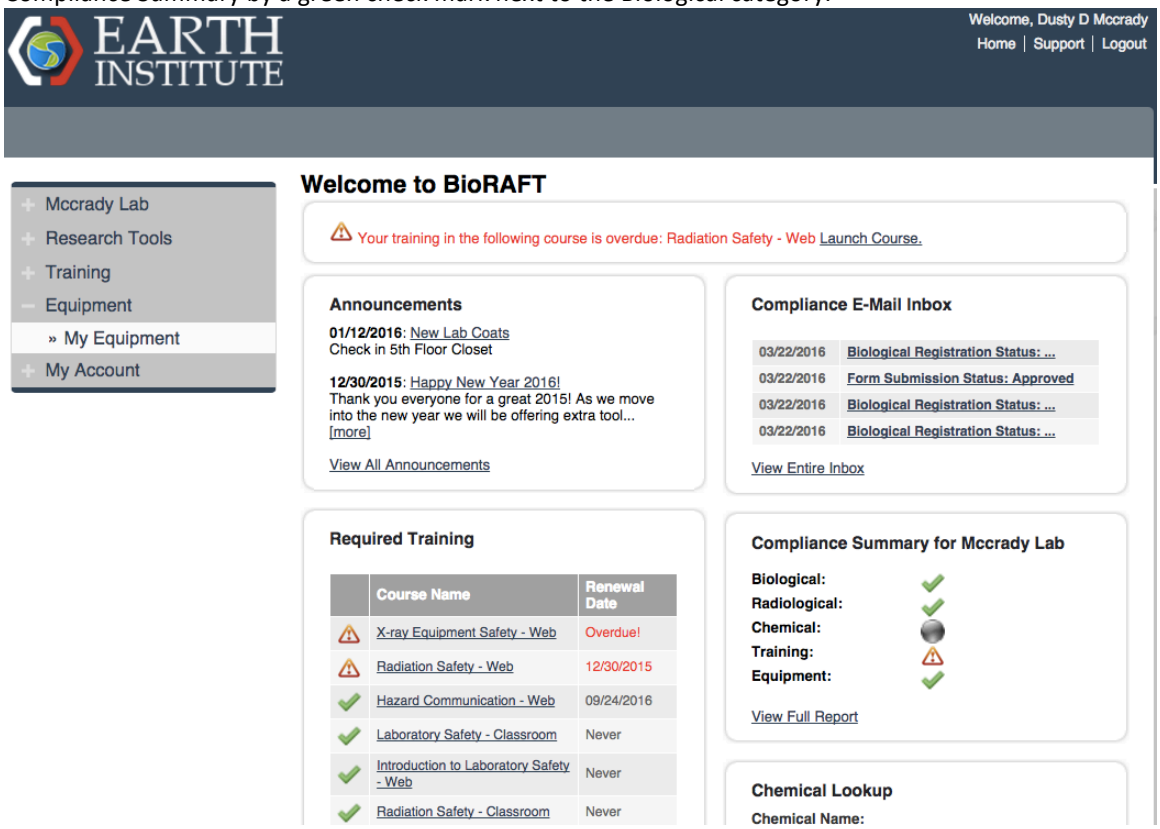
11. Awaiting Approval

After submission, this Biological Registration is now awaiting EHS Review. This screen is available in the "Biological Snapshot" page. We have quick access to detailed information about the Biological Registration by selecting the links for the appropriate category at the top of the page.



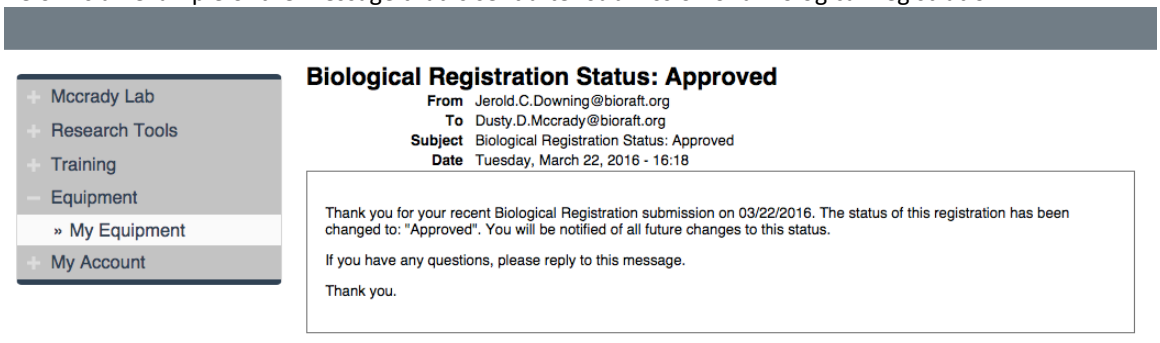
12. Health and Safety / Bio Safety Officer Approval Process

The Biological Safety Officer will get a notice to review the submitted Biological Registration. Once the Biological Safety Officer has reviewed the documentation, it may be slated for IBC. The PI will be notified of his biological registration status change via the Compliance Mailbox. This will also be reflected in the Compliance Summary by a green check mark next to the Biological category.



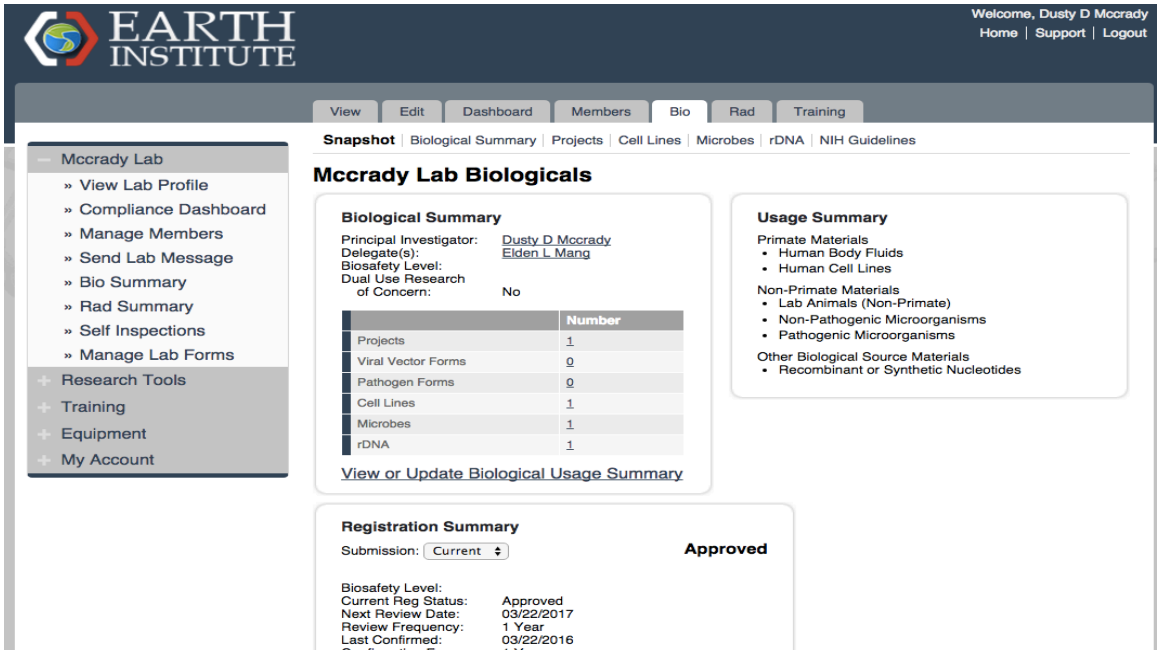
13. Message Received

Below is an example of the message that is sent after submission of a Biological Registration.



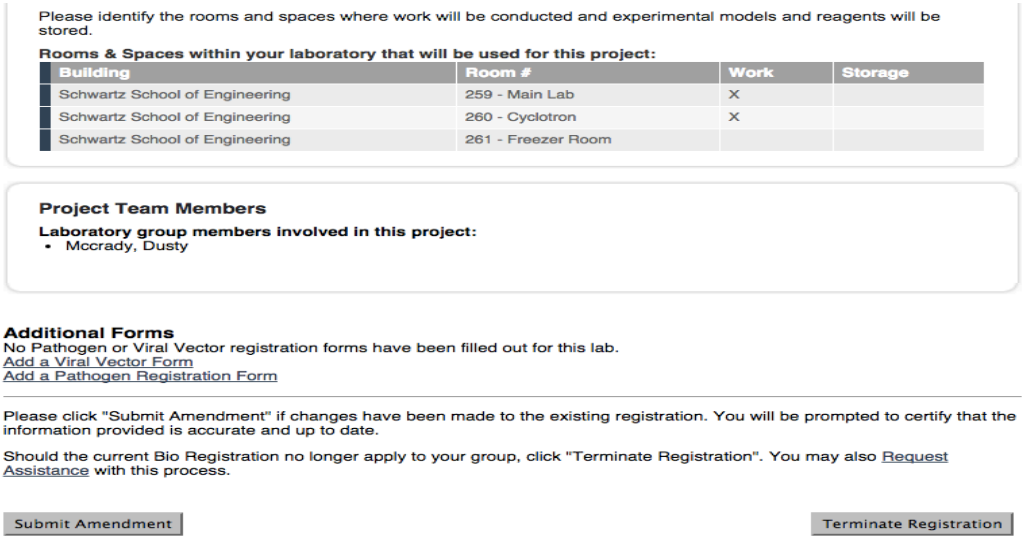
14. Amendments

After the Biological 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 to the appropriate category next to the Biological **Snapshot** (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.



14a. Amendment Submission

After any changes are made, the PI will be asked to review the Biological Usage Summary and select "Submit Amendment."



14b. Amendment Review

After you submit the amendment, the status of the Biological Registration will then change to "Amendment Awaiting Review," at which time the process of the Bio Safety Officer review/IBC approval will be repeated as needed.