Guide to BioRAFT
Research Management System

Biological Laboratories with Exempt Protocols

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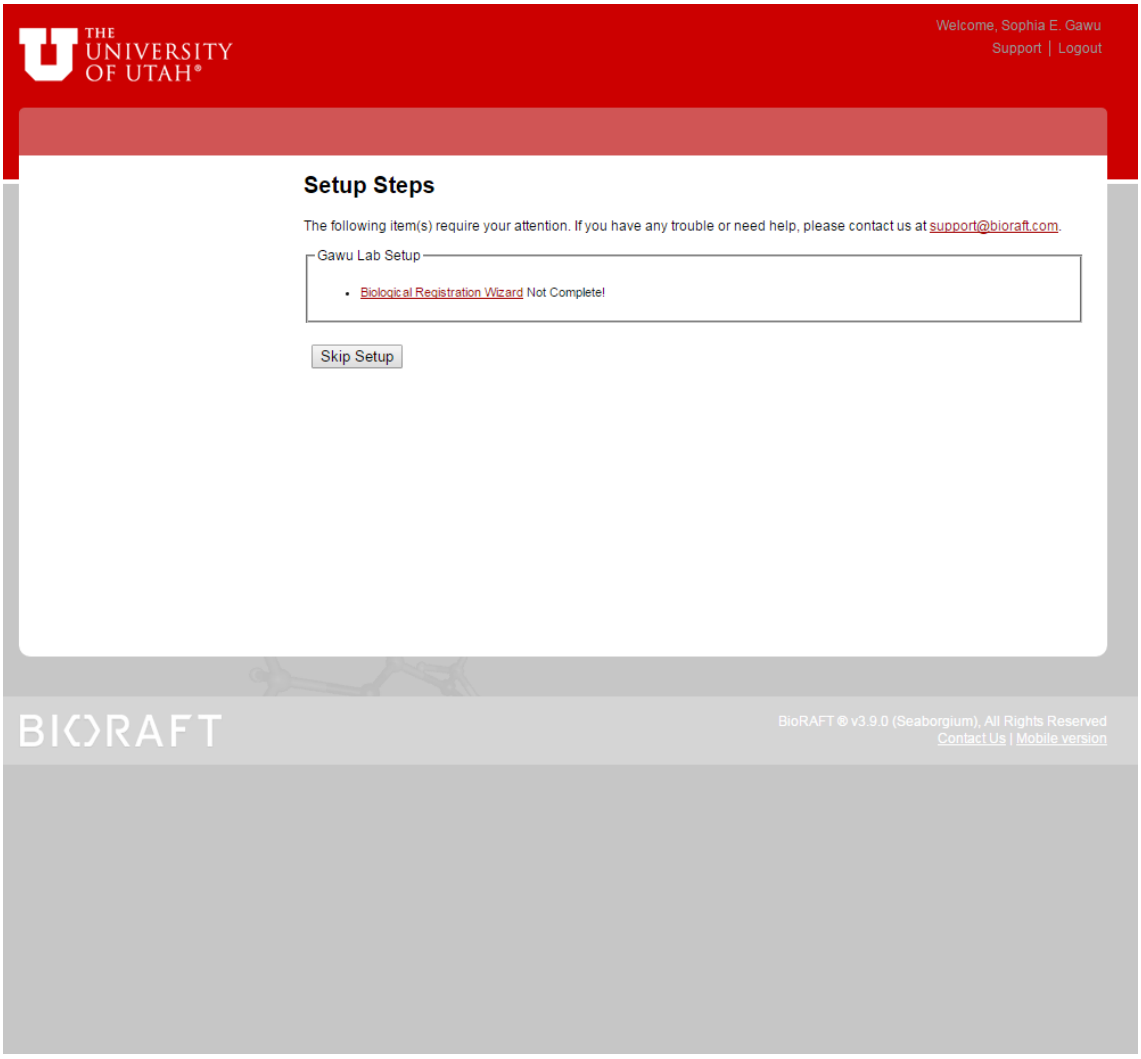
Biological labs with exempt protocols

1. Principal Investigators with a Biological lab and/or projects that are exempt from IBC review and approval are required to fill out a general Biological survey. If you are unsure whether your work needs to be registered with the IBC visit http://ehs.utah.edu/research-safety/biosafety/institutional-biosafety-committee-ibc for further information.

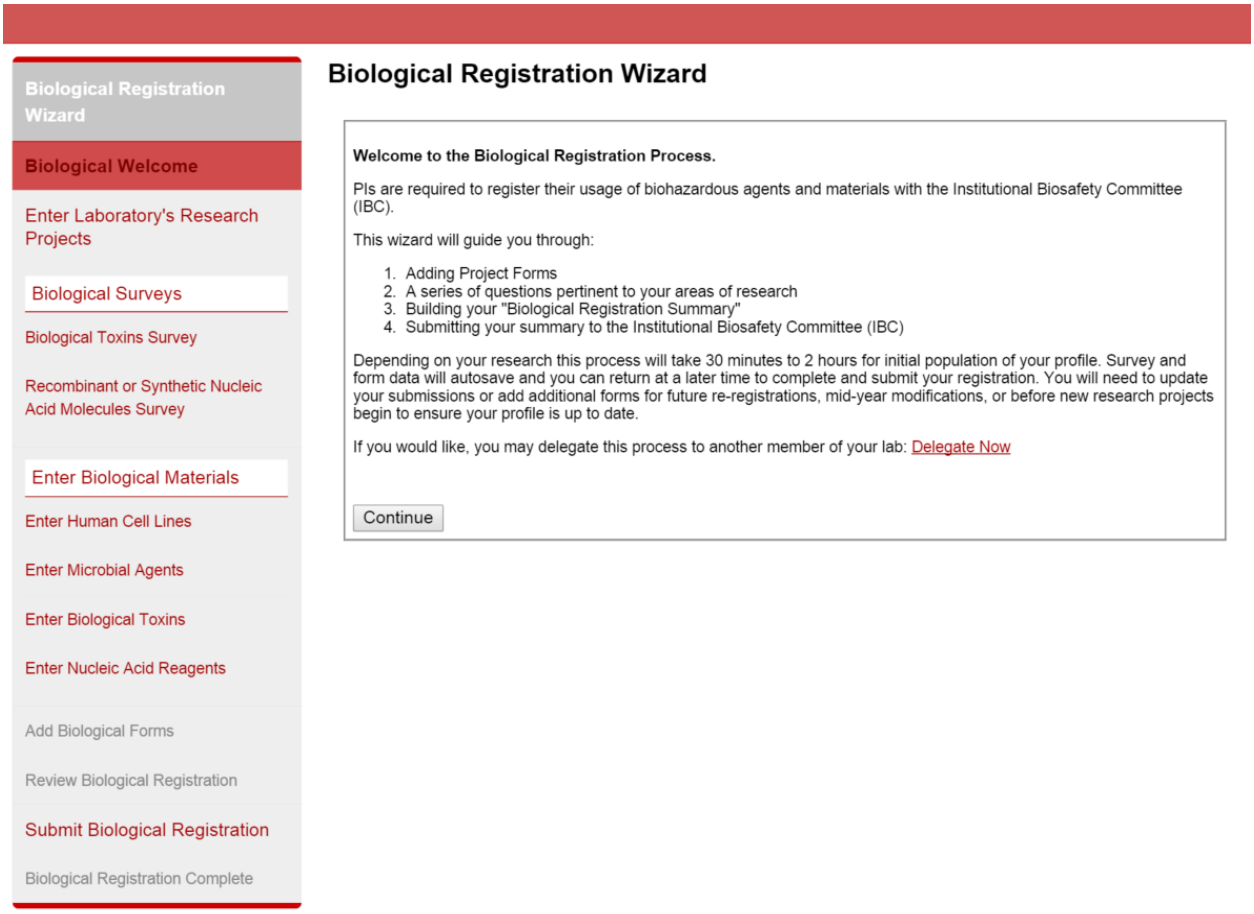
Biological Registration Wizard

1. To begin your Biological Registration Wizard, click the 'Biological Registration Wizard' link.



Note if you have already completed the registration wizard (only available the first time) you will see a screen shown on page 23. Follow the instructions for editing the Biological Registration beginning on page 24

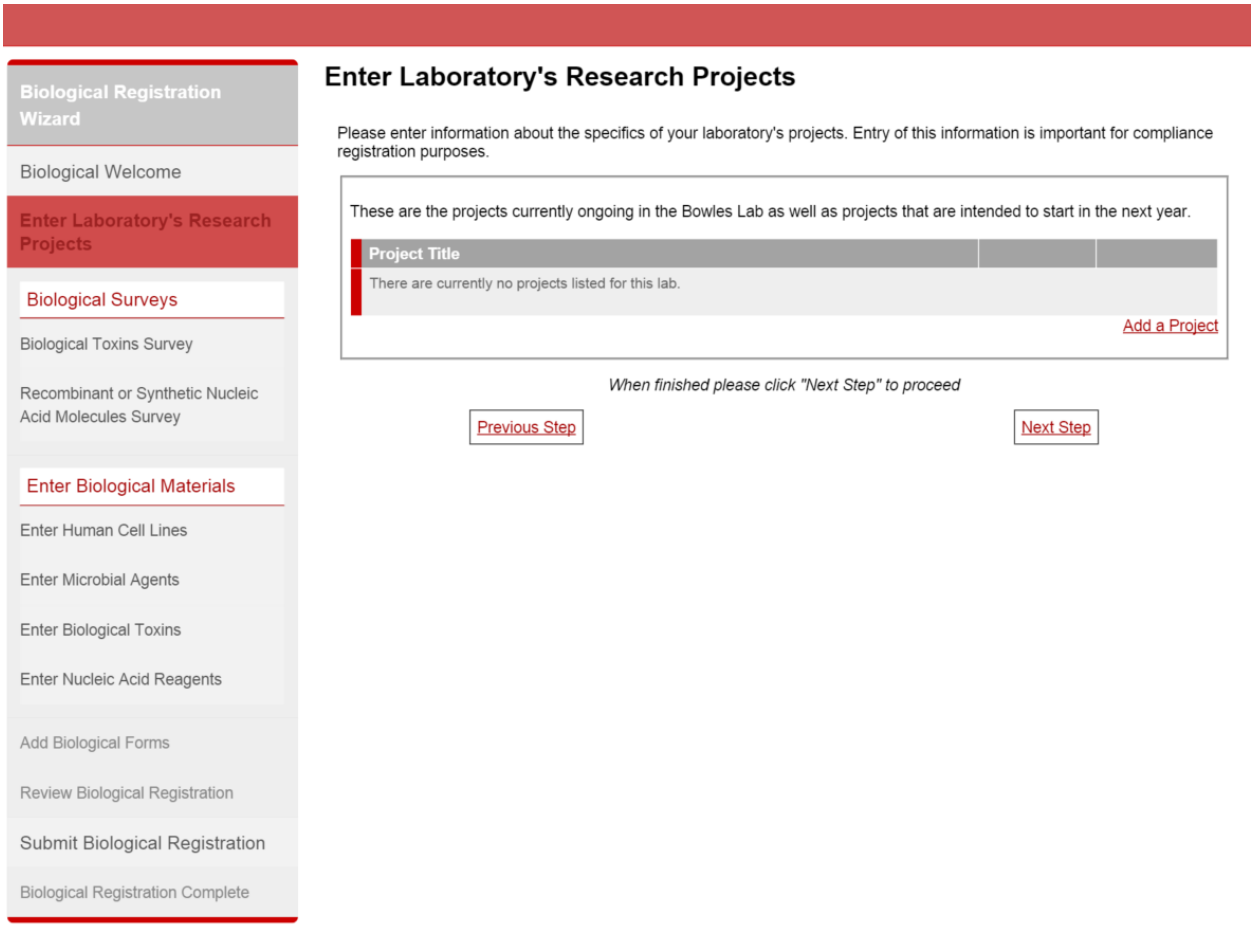
An introductory screen will appear. You have the opportunity to delegate a member of the laboratory to complete the registration. Otherwise Click “Continue.”



Entering Research Projects

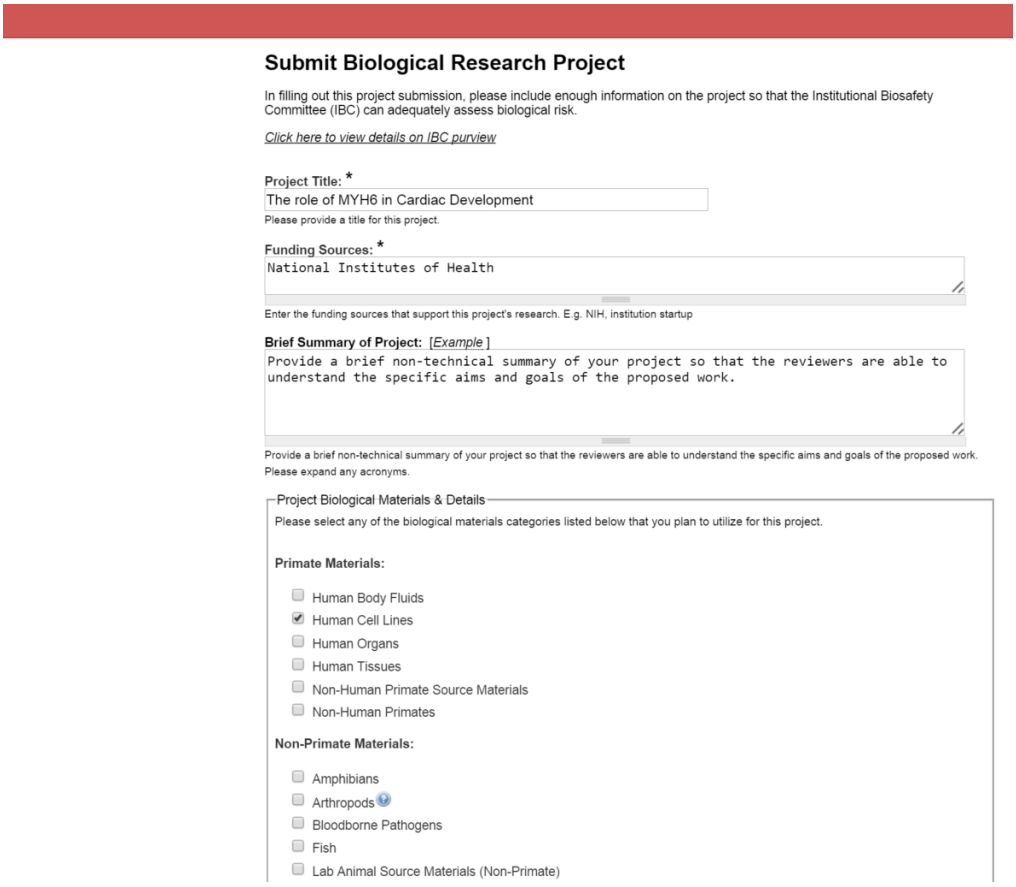
The first screen of the Biological Summary will appear. You will be prompted to enter some brief information about the research projects in your laboratory

A separate Project Form must be completed for each project conducted in the laboratory. Responses provided in the Project Form may require Specific Area Surveys and may trigger completion of Specific Material Entry.



Click on “Add a Project.”

This will open a survey. Please complete as appropriate.



Submit Biological Research Project

In filling out this project submission, please include enough information on the project so that the Institutional Biosafety Committee (IBC) can adequately assess biological risk.

Click here to view details on IBC purview

Project Title: *

The role of MYH6 in Cardiac Development

Please provide a title for this project.

Funding Sources: *

National Institutes of Health

Enter the funding sources that support this project's research. E.g. NIH, institution startup

Brief Summary of Project: [*Example*]

Provide a brief non-technical summary of your project so that the reviewers are able to understand the specific aims and goals of the proposed work.

Provide a brief non-technical summary of your project so that the reviewers are able to understand the specific aims and goals of the proposed work. Please expand any acronyms.

Project Biological Materials & Details

Please select any of the biological materials categories listed below that you plan to utilize for this project.

Primate Materials:

- [ ] Human Body Fluids
- [x] Human Cell Lines
- [ ] Human Organs
- [ ] Human Tissues
- [ ] Non-Human Primate Source Materials
- [ ] Non-Human Primates

Non-Primate Materials:

- [ ] Amphibians
- [ ] Arthropods
- [ ] Bloodborne Pathogens
- [ ] Fish
- [ ] Lab Animal Source Materials (Non-Primate)

- [ ] Lab Animal Tissues (Non-Primate)
- [ ] Lab Animals (Non-Primate)
- [x] Non-Pathogenic Microorganisms
- [ ] Pathogenic Microorganisms
- [ ] Plants
- [ ] Select Agent Pathogenic Microorganisms

Other Biological Source Materials:

- [ ] Biological Toxins
- [ ] Infectious Proteins
- [ ] Mutagenic Agents
- [x] Recombinant or Synthetic Nucleotides
- [ ] Select Agent Biological Toxins
- [ ] Viral Vectors

Other Hazards That May Be Present While Working with Biological Materials:

- [ ] Mixed Waste
- [ ] Physical Hazards
- [ ] Other Hazards

Additional Activities:

- [ ] Shipping Biological Materials

Dual-Use Research of Concern: [*Example*]

Select all that are applicable to this project.

- [ ] Enhances the harmful consequences of the agent or toxin
- [ ] Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- [ ] Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- [ ] Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- [ ] Alters the host range or tropism of the agent or toxin
- [ ] Enhances the susceptibility of a host population to the agent or toxin
- [ ] Generates or reconstitutes an eradicated or extinct agent or toxin *

* Where eradicated or extinct agents or toxins are any of the following: Avian influenza virus (highly pathogenic), Bacillus anthracis, Botulinum neurotoxin, Burkholderia mallei, Burkholderia pseudomallei, Ebola virus, Foot-and-mouth disease virus, Francisella tularensis, Marburg virus, Reconstructed 1918 Influenza virus, Rinderpest virus, Toxin-producing strains of Clostridium botulinum, Variola major virus, Variola minor virus, or Yersinia pestis.

Description of Experimental and Procedural Details: [*Example*]

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.

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.

Authorizations and Permits Applicable to this Project

Please include the applicable authorizations or permits involved with this Project. If authorization or permits are pending or depending on IBC approval please specify in additional information. Multiple permits of a type should be separated by commas.

IACUC Number:

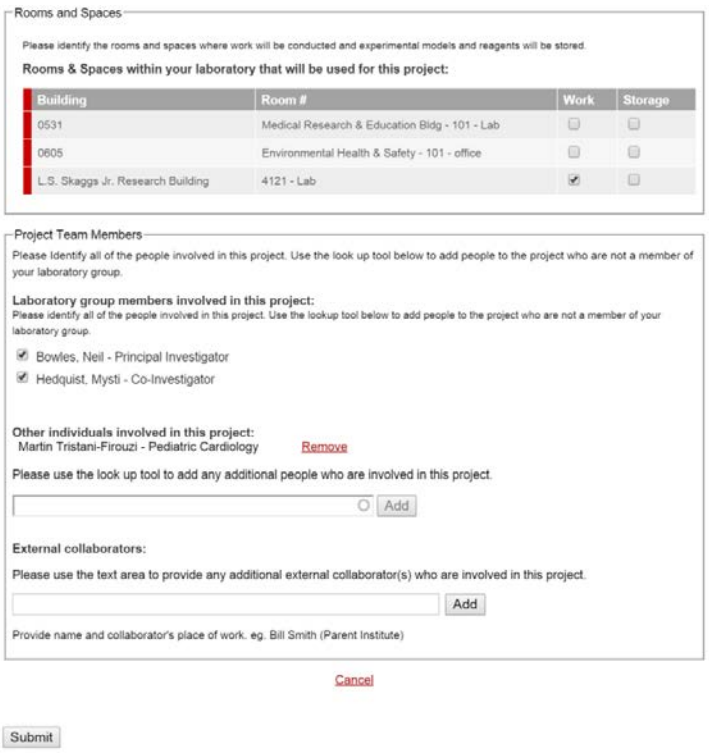
Additional Information:

IRB Number: 200086

Additional Information:

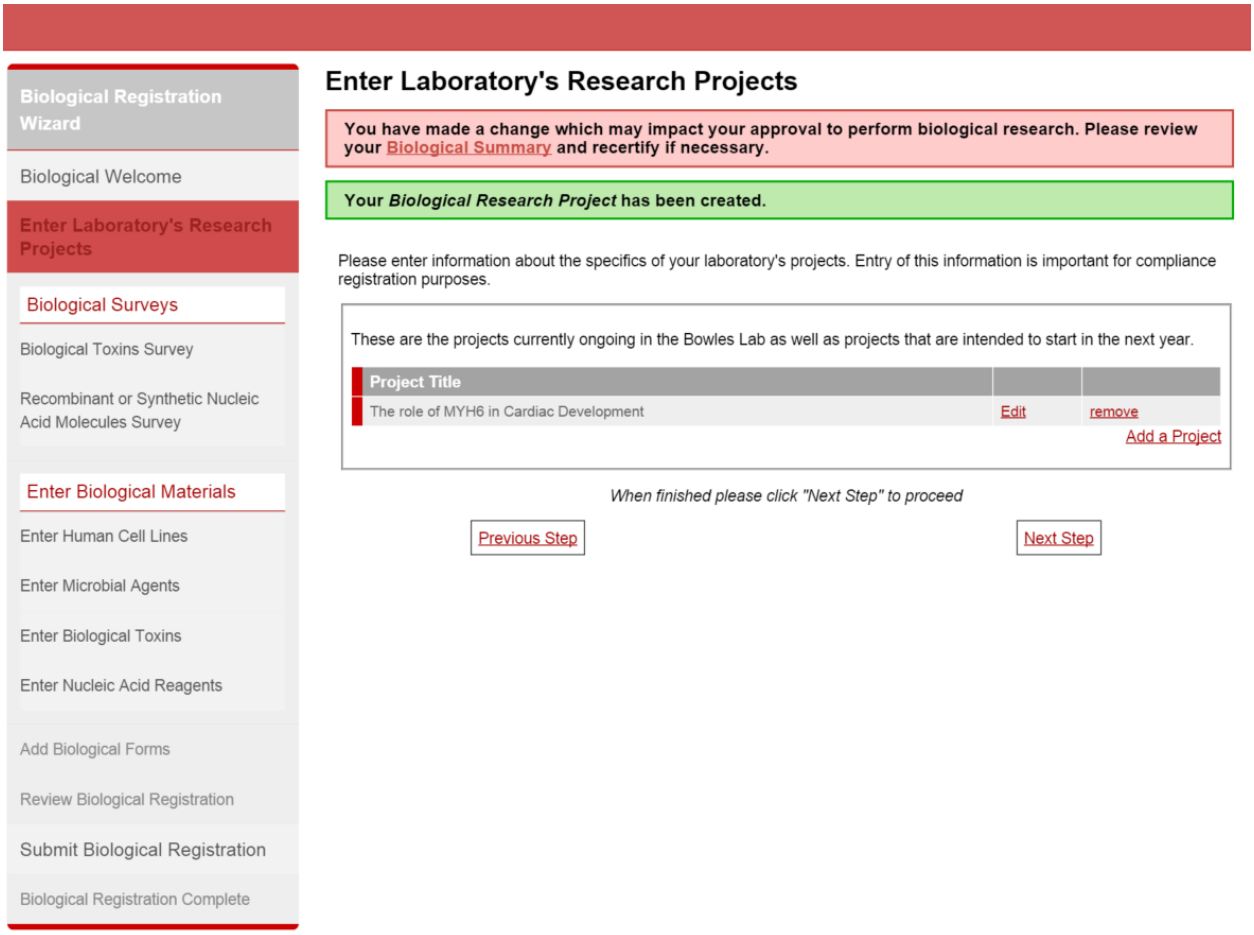
USDA/APHIS/PPQ Permits:

Additional Information:



In this example we are studying the effects of variants identified in patients on protein function. We will be expressing cDNAs, cloned into plasmids, in human cell lines (293s). The plasmids will be propagated in non-pathogenic E. coli. These boxes have been checked.

Click on “Submit”



Click “Add a Project” to add additional projects or click on “Next Step”

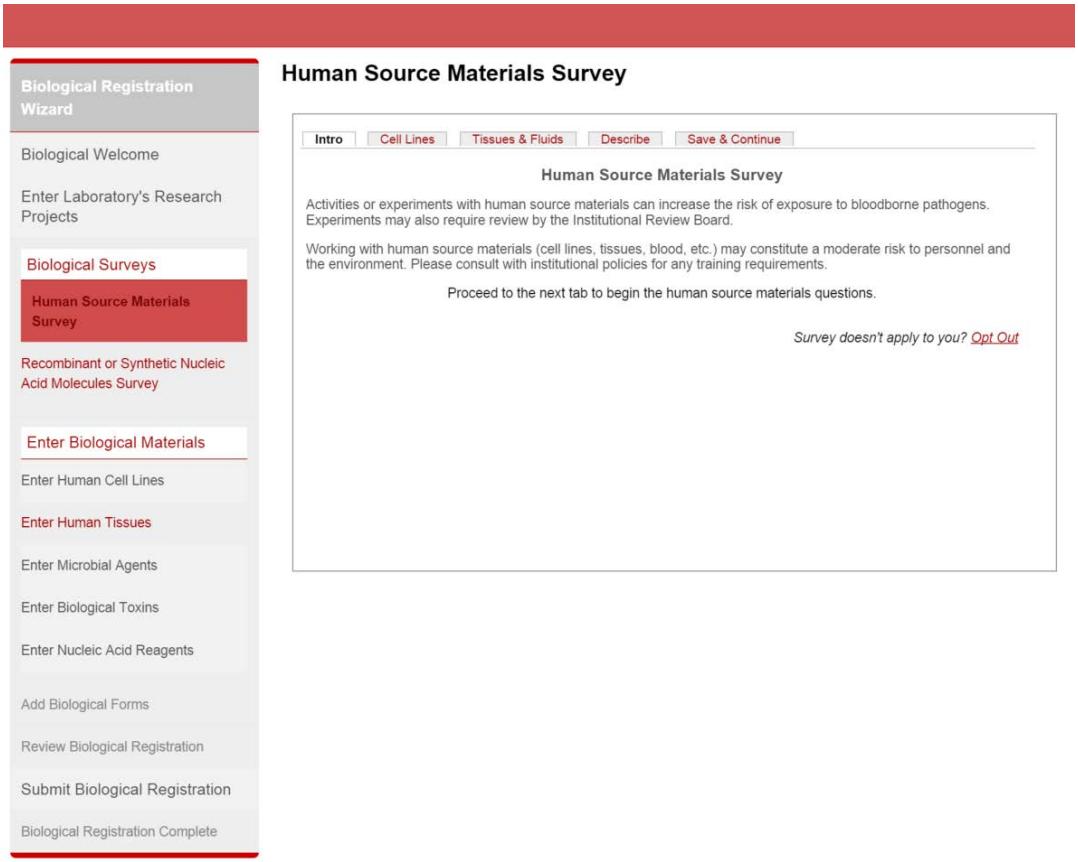
Completing Biological Surveys

This will initiate a series of Surveys, dependent on the answers in the registration.

Potential Surveys that may be triggered:

- Human Source Materials Survey
- Laboratory Animal Cell Lines (Non---Primate) Survey
- Non---Human Primate Source Materials Survey
- Plants Survey
- Microbial Agents Survey
- Biological Toxins Survey
- Recombinant & Synthetic Nucleic Acids Survey
- Research of Concern Survey

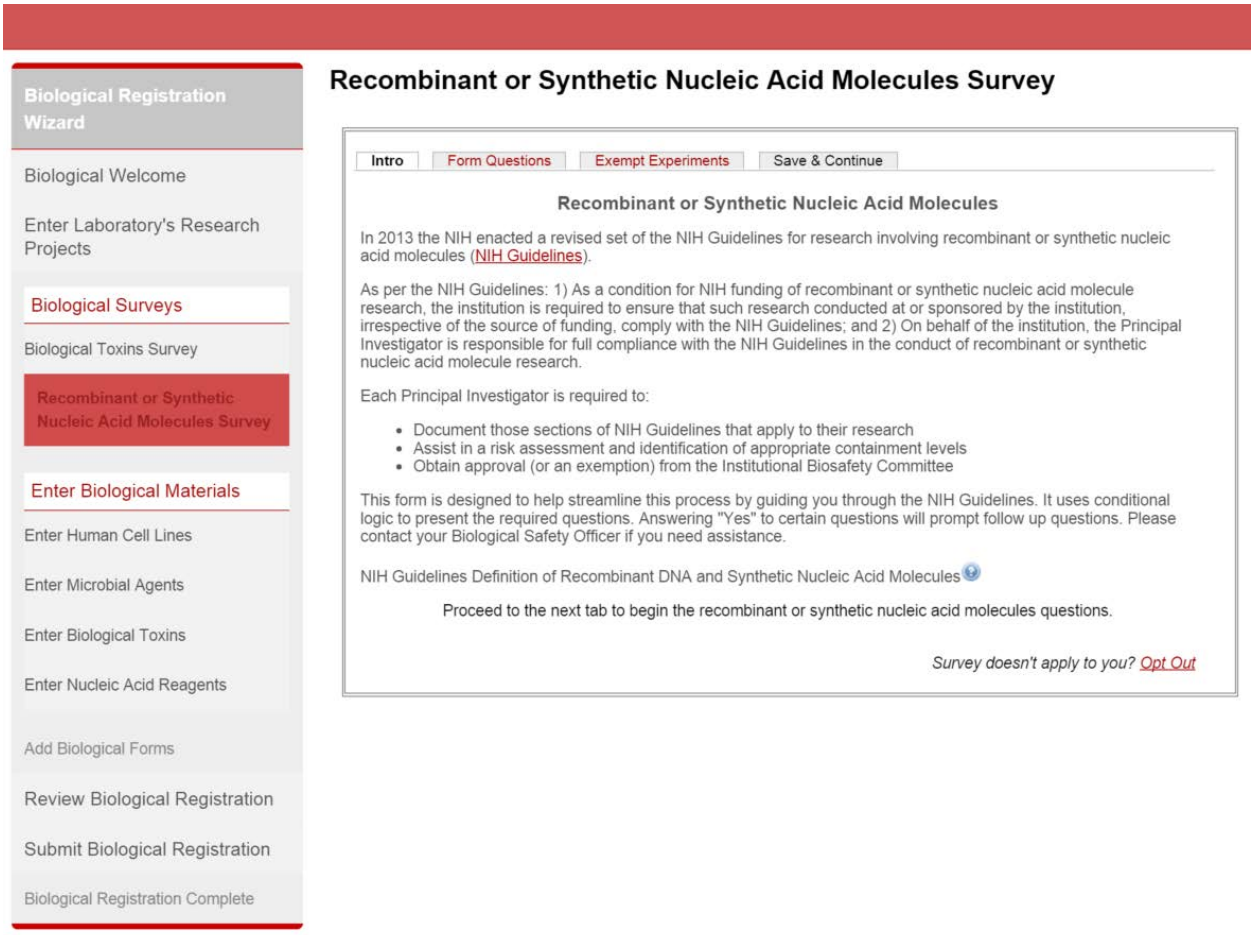
Answer the questions under each tab and click “Save”



If you believe the survey does not apply, click on “Opt Out.”

In this example the next step is the Recombinant or Synthetic Nucleic Acid Molecules Survey, which will confirm whether the work you are doing is exempt under the NIH guidelines. Click on each tab and answer each of the questions.

Under the second tab (Form questions), if you check yes to any of the questions your work is NOT exempt from IBC review.
Under the third tab (Exempt experiments), answer yes to any of the exemptions that apply. If you answer yes to at least one category of exemption then the work is likely exempt from IBC review. Note the expression of genes/cDNAs in a plasmid (non-viral) vector in eukaryotic cells would typically be exempt under Section III-F-8. However, if the plasmid is expressing an oncogene or biological toxin, Q8 should be answered "No."

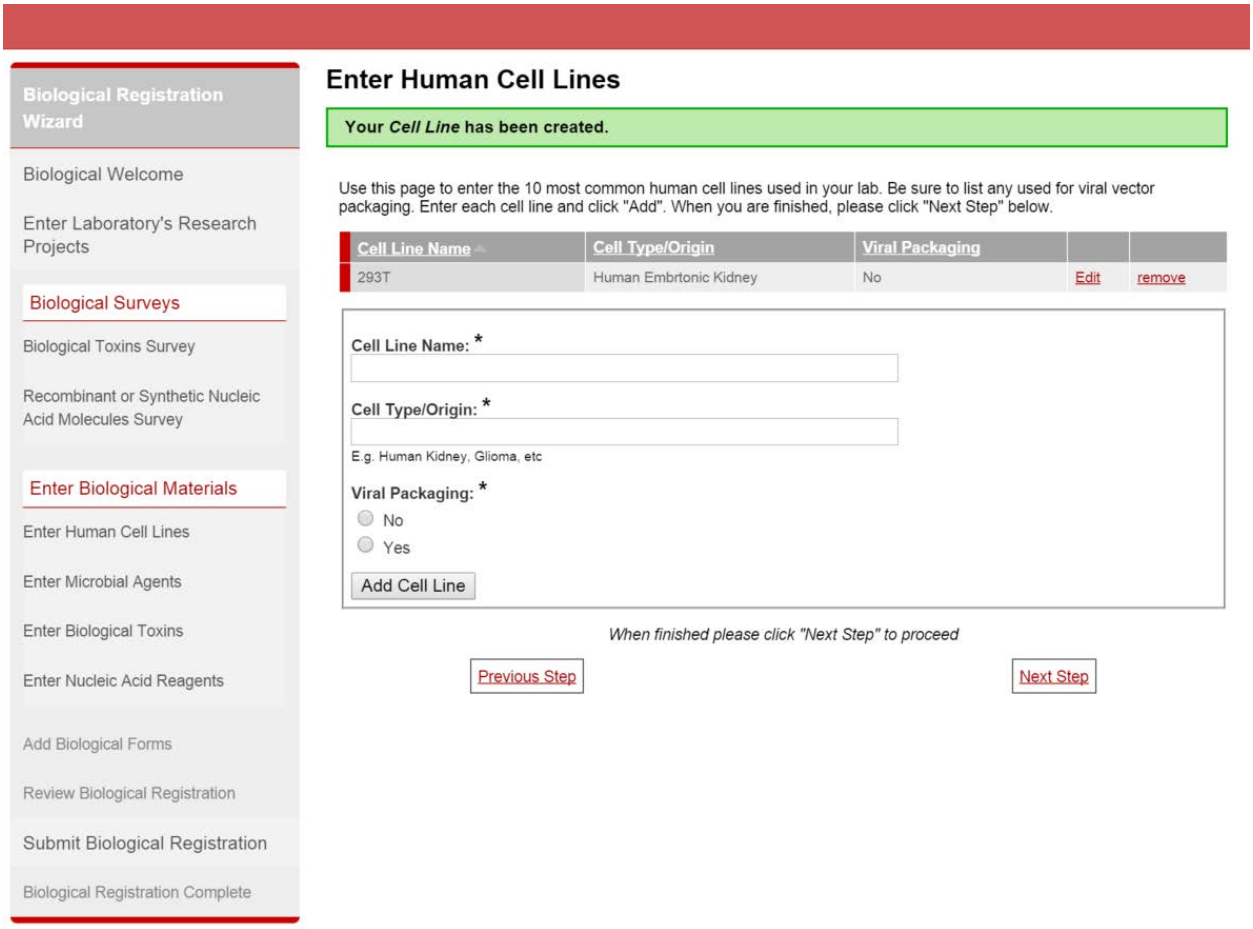


On the last tab, click "Save"

Entering Biological Materials

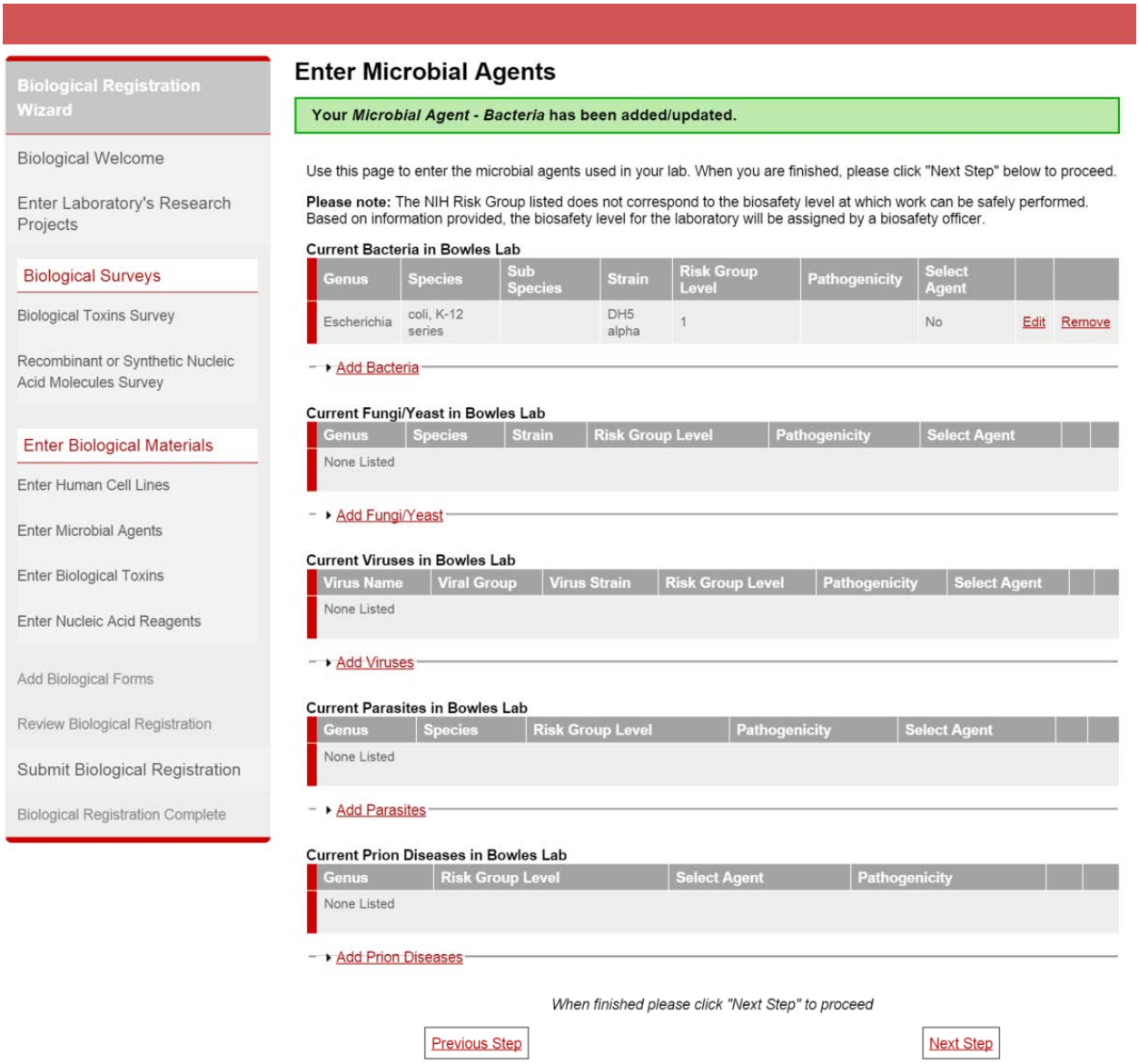
Depending on the earlier responses you will be prompted to answer questions on specific biological materials, including:

- Human Cell Lines
- Human Tissues
- Plants
- Microbial Agents
  - Bacteria, Viruses, Fungi, Parasites
- Biological Toxins
- Nucleic Acid Reagents
  - Plasmids and Inserts
  - Recombinant Animals



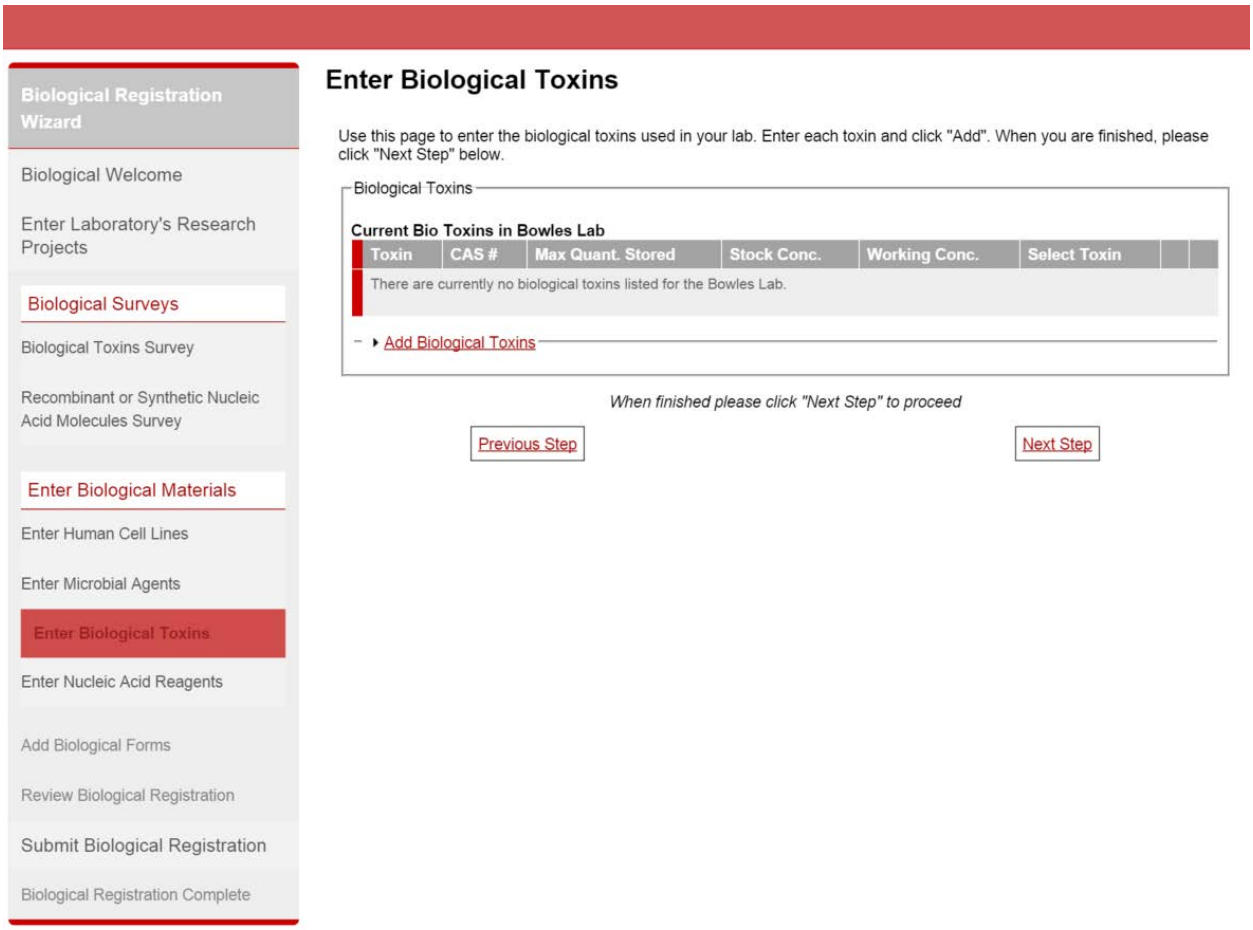
After adding all cell lines, click on “Next Step”.

On the next screen add Microbial Agents



In this case we have added DH5-alpha bacteria which we use to propagate plasmids.

Click on “Next Step”



Enter information on Biological Toxins. In this example we are not using any toxins.

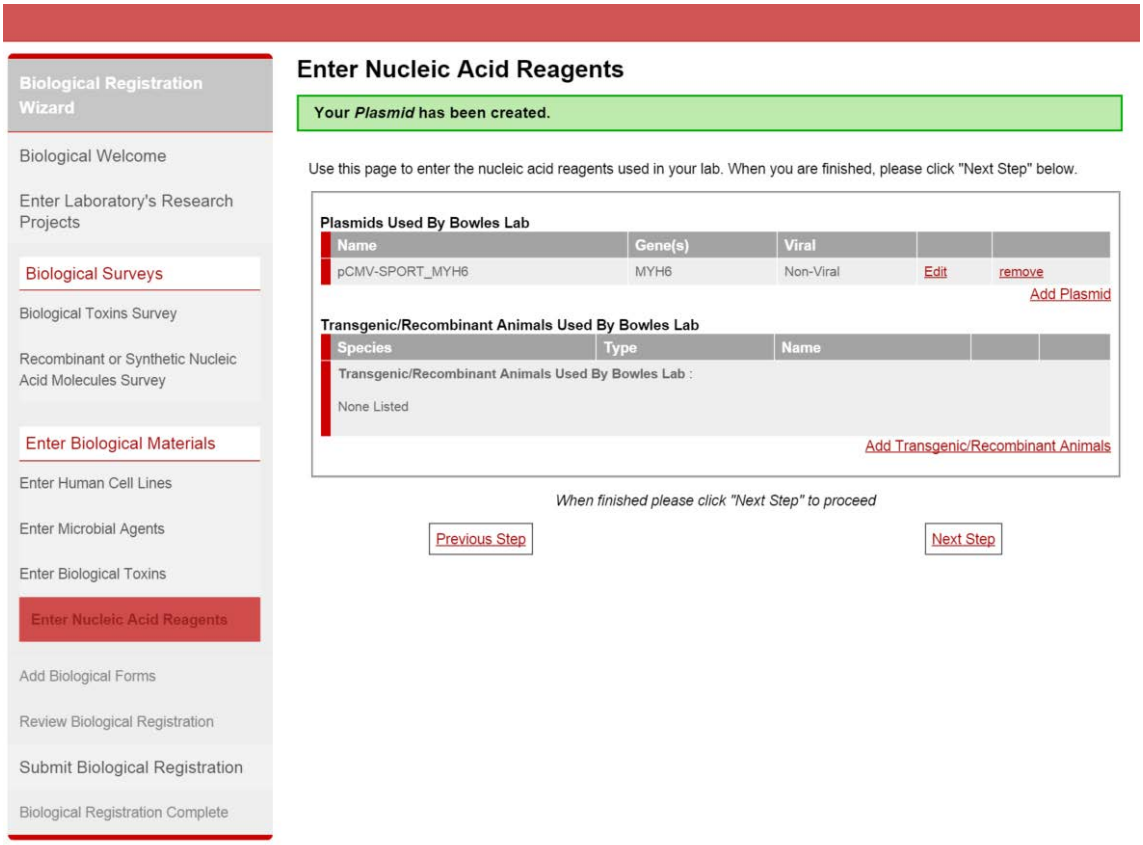
Click on “Next Step”

Add the names of plasmids commonly used in your laboratory by clicking the “Add Plasmid” button. Please note that EHS is not necessarily expecting all plasmids that are used in your lab, just the major ones. However, please include all plasmids that:

1) Can replicate in eukaryotic cells, or
2) Encode DNA elements that can integrate into DNA, or
3) Express an oncogene or biological toxin that is lethal for vertebrates at an LD50 of less than 100ng/kg body weight, or
4) Express genes of human pathogens (viruses, bacteria, etc).

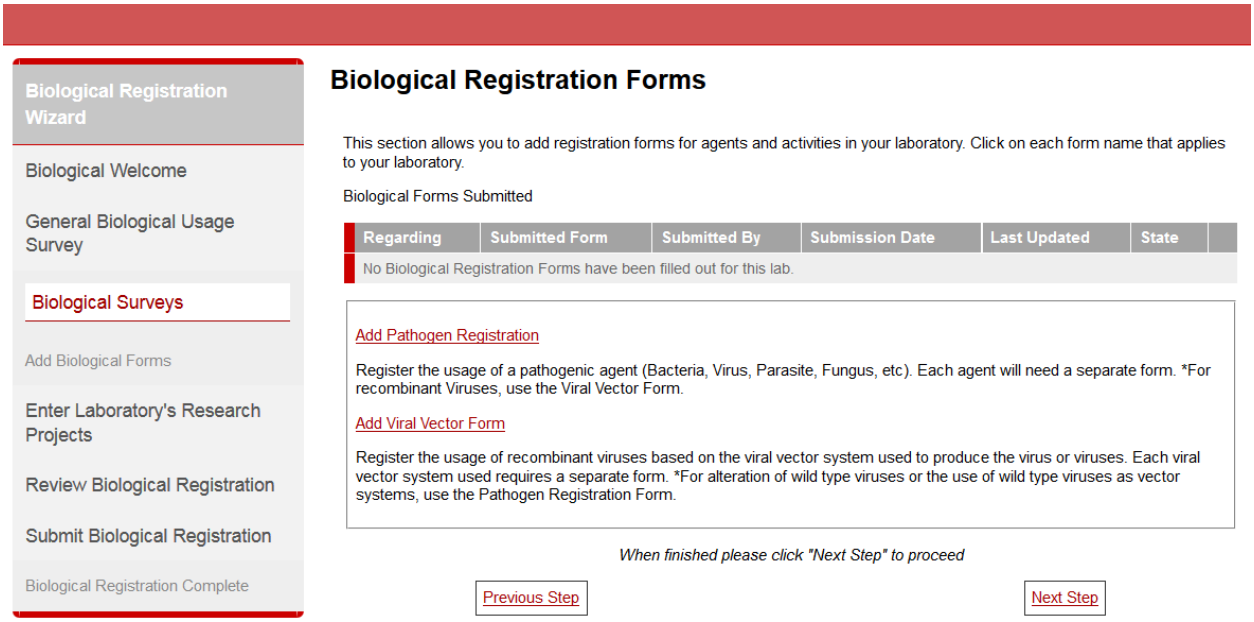
Only add transgenic/recombinant animals if you are creating them in your laboratory (i.e. do not enter commercially purchased animals or generated in the University of Utah Core).

Click “Next Step”.



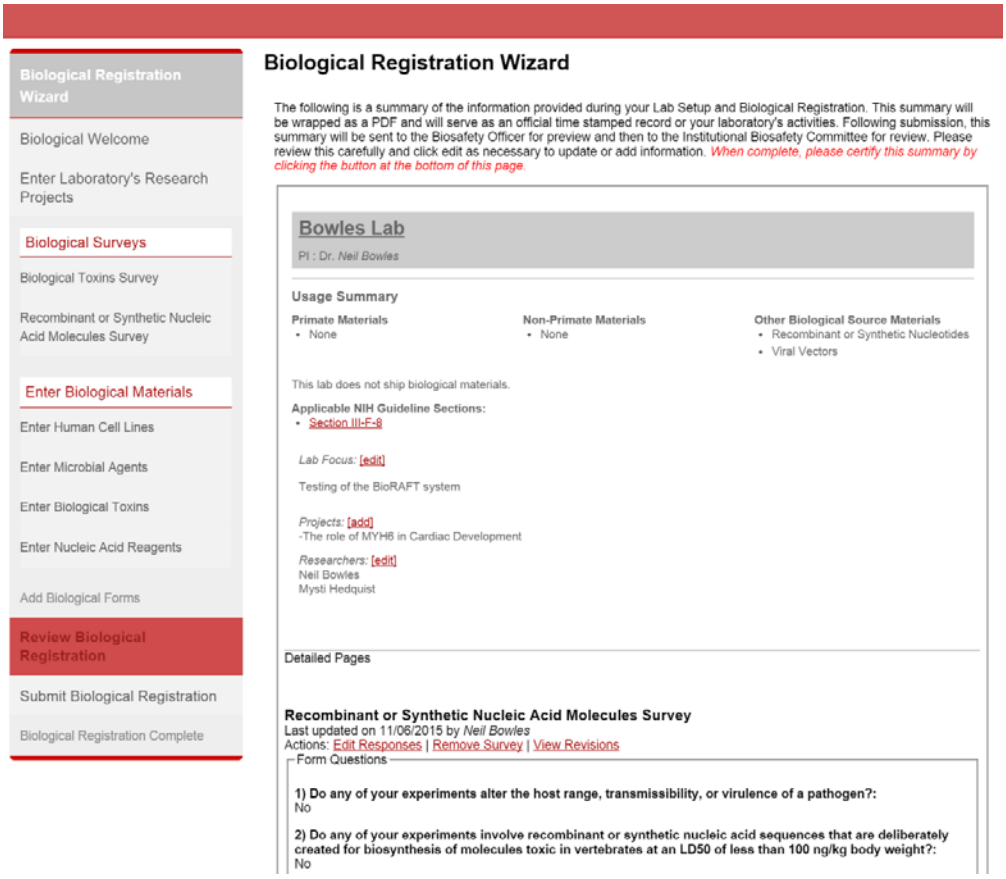
If your registration is exempt from IBC review and you will not need to complete any additional forms or surveys. However, please complete the final few steps of the Registration.

After clicking “Next Step” you should see the page illustrated below. There is no need to add any forms. Click “Next Step”.



Biological Registration Summary

On the next screen you will see a summary of your Registration. If everything is correct, click “Certify” at the bottom of the screen. If there are errors they can be edited by clicking on the “edit” or “edit responses” buttons



3) Do you conduct experiments in which recombinant or synthetic nucleic acids are transferred into human subjects? (E.g. Gene therapy studies, vaccination studies):
No

4) Does your research involve the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2, 3, 4 or Restricted Agents?:
No

5) Does your research involve the cloning of recombinant or synthetic nucleic acids from risk group 2, 3, 4 or restricted agents cloned into a nonpathogenic prokaryotic or lower eukaryotic host vector system?:
No

6) Do your experiments involve the use of infectious or defective DNA or RNA Viruses in tissue culture systems? (This includes the use of a packaging cell line(s) to generate viral particles for transduction):
No

7) Do your experiments involve whole animals?:
No

8) Do your experiments involve plants containing recombinant or synthetic nucleic acid molecules?:
No

9) Do your experiments involve growing cultures of organisms containing recombinant, synthetic recombinant, or synthetic nucleic acid molecules in excess of 10 liters in a single growth vessel?:
No

10) Do you perform experiments with influenza viruses generated by recombinant or synthetic methods?:
No

Exempt Experiments

1) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-1?:
No

2) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-2?:
No

3) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-3?:
No

4) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-4?:
No

5) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-5?:
No

6) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-6?:
No

7) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-7?:
No

8) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-8?:
Not a toxin or oncogene

Transgenic/Recombinant Animals Used in Lab:

Species	Type	Name		
None Listed				

Add Transgenic/Recombinant Animals

Plasmids Used in Lab:

Name	Gene(s)	Viral		
pCMV-SPORT_MYH6	MYH6	Non-Viral	Edit	Remove

Add Plasmid

Research Projects

Project Title:
The role of MYH6 in Cardiac Development [edit project] [remove]

Project Number: 21

Funding Sources:
National Institutes of Health

Laboratory:
Bowles Lab

Principal Investigator:
Neil Bowles

Department:

Building:
0605 - Environmental Health & Safety

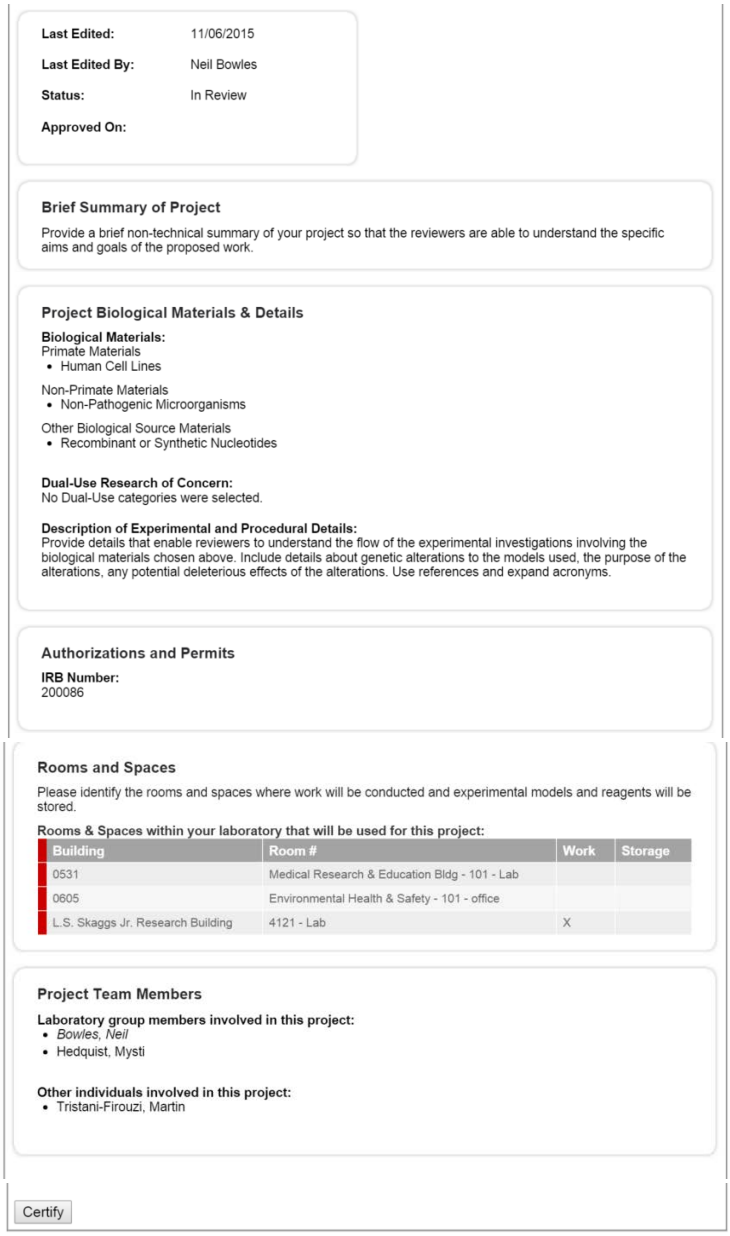
Room Number:
1

Mail Code:

Phone Number:
585-9325

Phone 2:

Dual-Use Research: No



Last Edited: 11/06/2015

Last Edited By: Neil Bowles

Status: In Review

Approved On:

Brief Summary of Project

Provide a brief non-technical summary of your project so that the reviewers are able to understand the specific aims and goals of the proposed work.

Project Biological Materials & Details

Biological Materials:
Primate Materials
- Human Cell Lines

Non-Primate Materials
- Non-Pathogenic Microorganisms

Other Biological Source Materials
- Recombinant or Synthetic Nucleotides

Dual-Use Research of Concern:
No Dual-Use categories were selected.

Description of Experimental and Procedural Details:
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.

Authorizations and Permits

IRB Number:
200086

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
0531	Medical Research & Education Bldg - 101 - Lab		
0605	Environmental Health & Safety - 101 - office		
L.S. Skaggs Jr. Research Building	4121 - Lab	X	

Project Team Members

Laboratory group members involved in this project:
- *Bowles, Neil*
- Hedquist, Mysti

Other individuals involved in this project:
- Tristani-Firouzi, Martin

Certify

Once you have finished reviewing your summary, click the 'Certify' button at the bottom of the page. Go to page 21.

NOTE: If you are the delegate rather than the PI the button will say "**Notify PI**". It will state "Click below to notify the PI that changes have been made to the Live Biological Survey." Click "**Notify PI**"

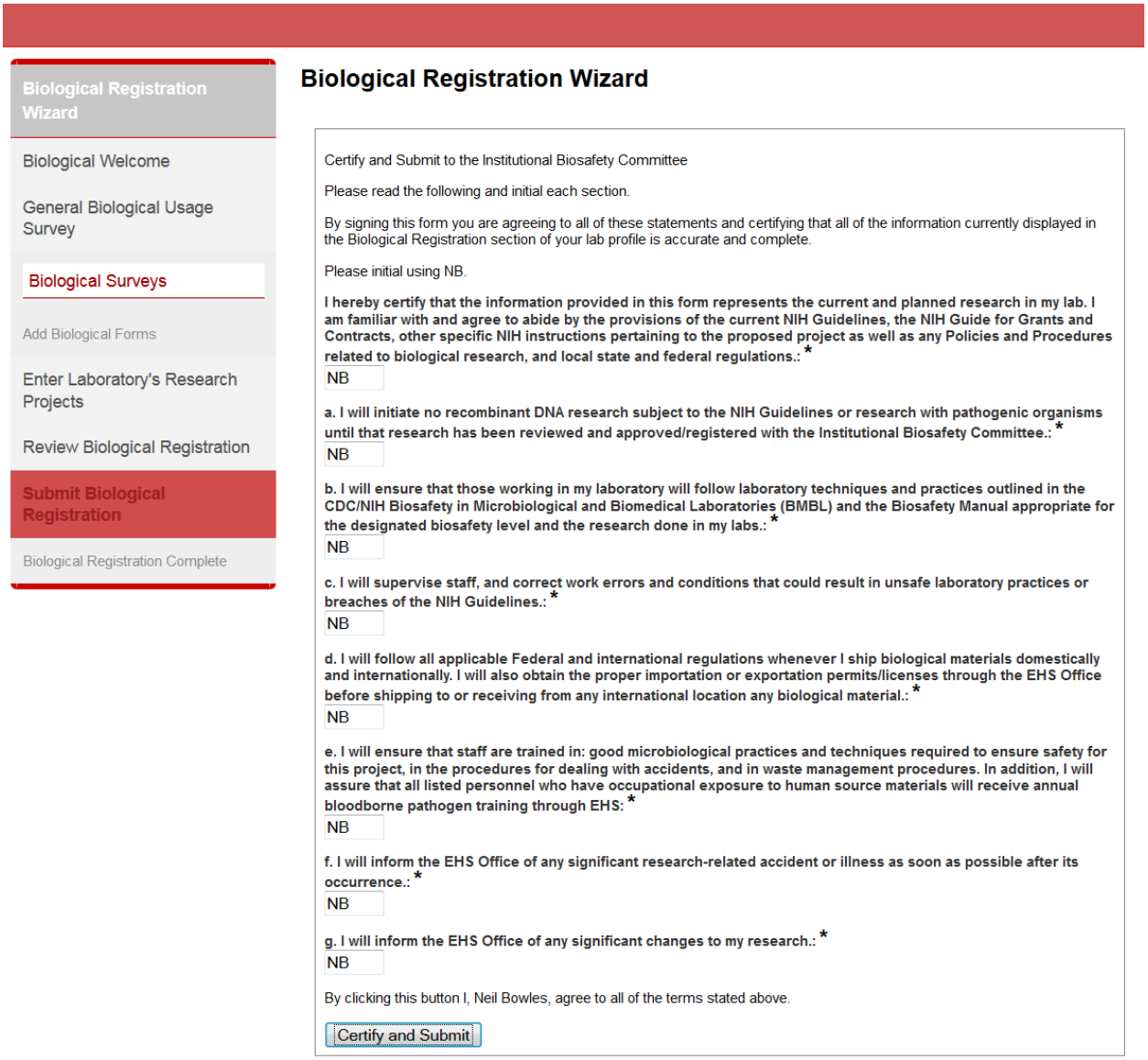
You should receive the message:

- **Email successfully sent to *PI name*, view message.**

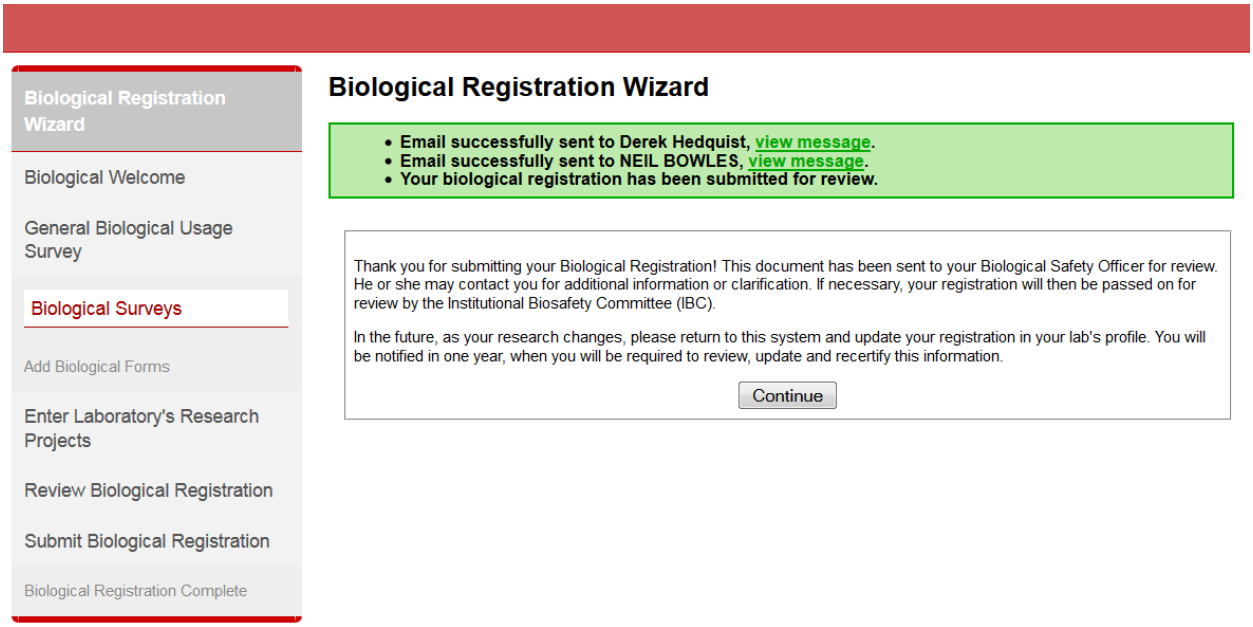
- ***PI name*** **has been notified via email that the registration is ready for submission**
  The PI should be prompted to complete the registration as described on the next page.

Biological Registration Certification

On the next screen you will need to certify that the registration is accurate and complete by typing in your initials in the boxes (you can use “Tab” to jump to the next box). Then click “Certify and Submit”.



The Registration is submitted to the Biosafety Program. The screen will show:



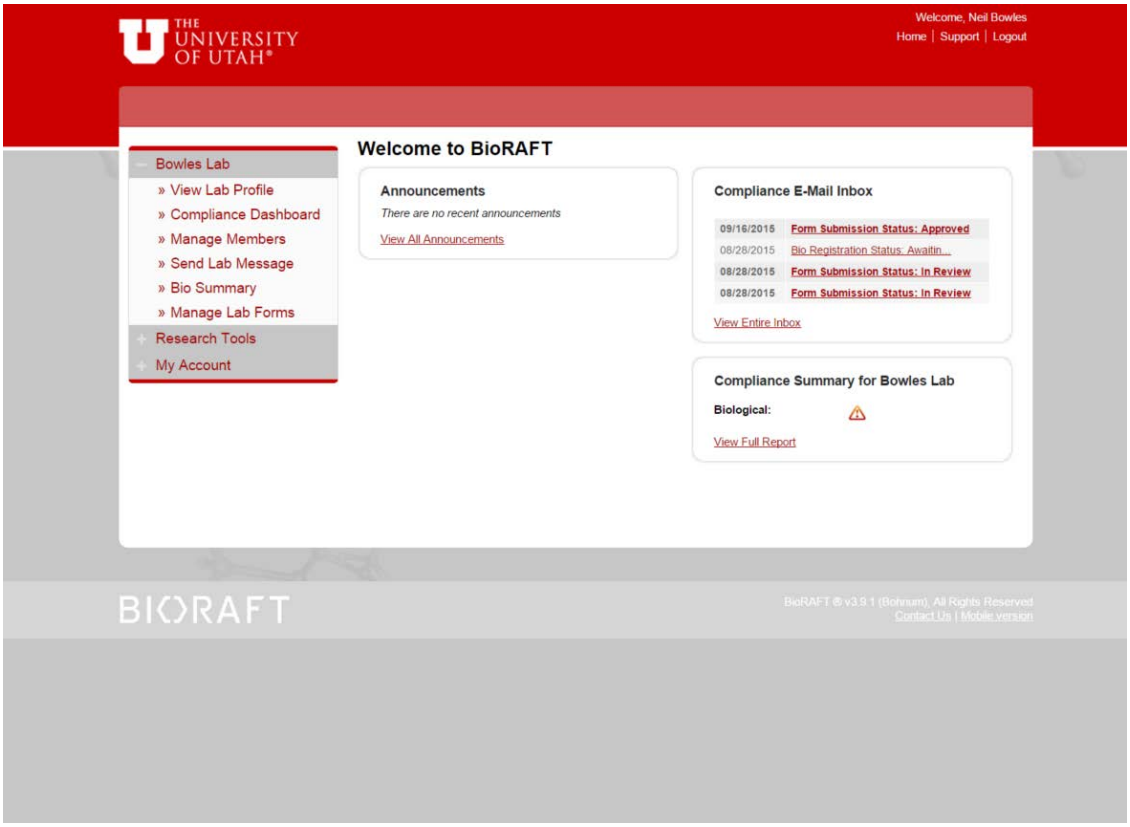
Click on “Continue.” This will take you back to BioRAFT Dashboard.

The Biosafety Officers will review your Registration and either contact you for further information or approve your Registration. The Registration will be approved for 5 years.

Amendments/Editing Registrations

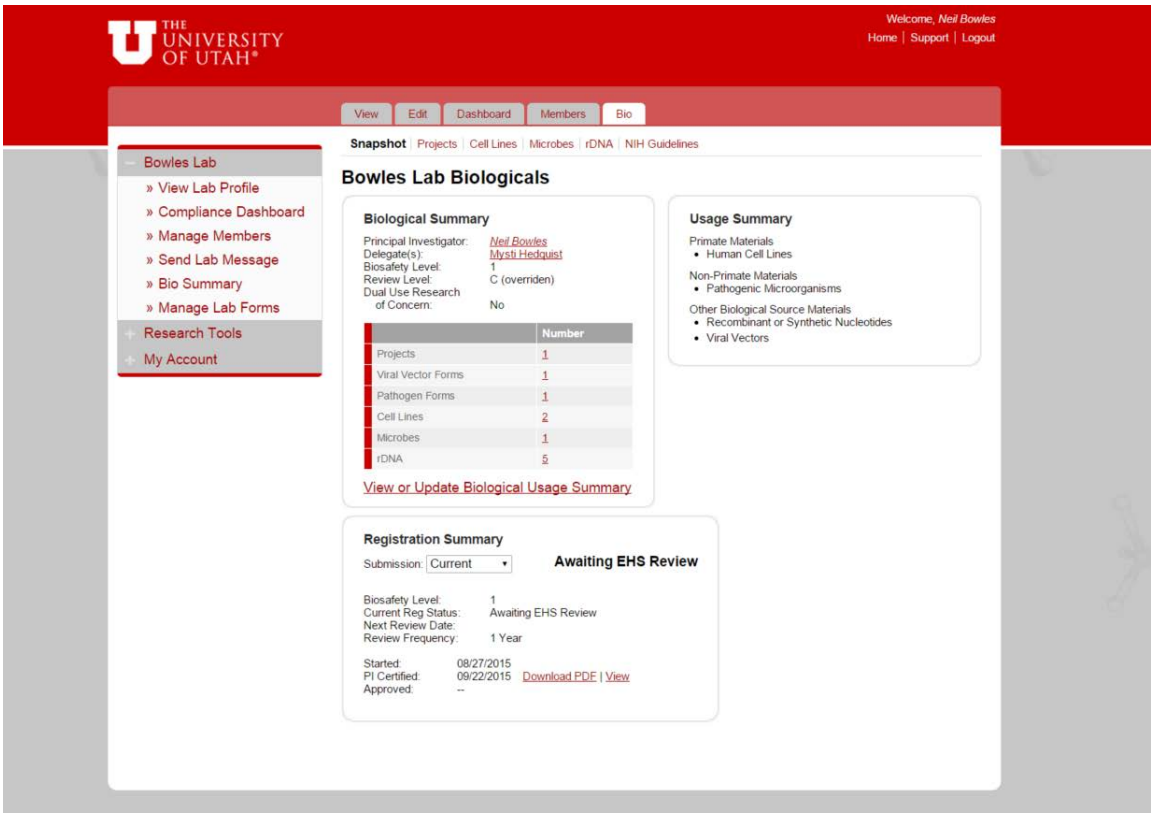
If you need to make an amendment to your registration either because you have made changes to the protocol (e.g. new staff/employees/students, changes in vectors/pathogens, etc) or in response to the IBC review follow the following steps;

Log in to BioRAFT.



To add or remove new personnel, click on "**Manage members**" and follow the instruction in the General Laboratory Guide.

To make changes to your Biological Registration, Click on "**Bio Summary"**



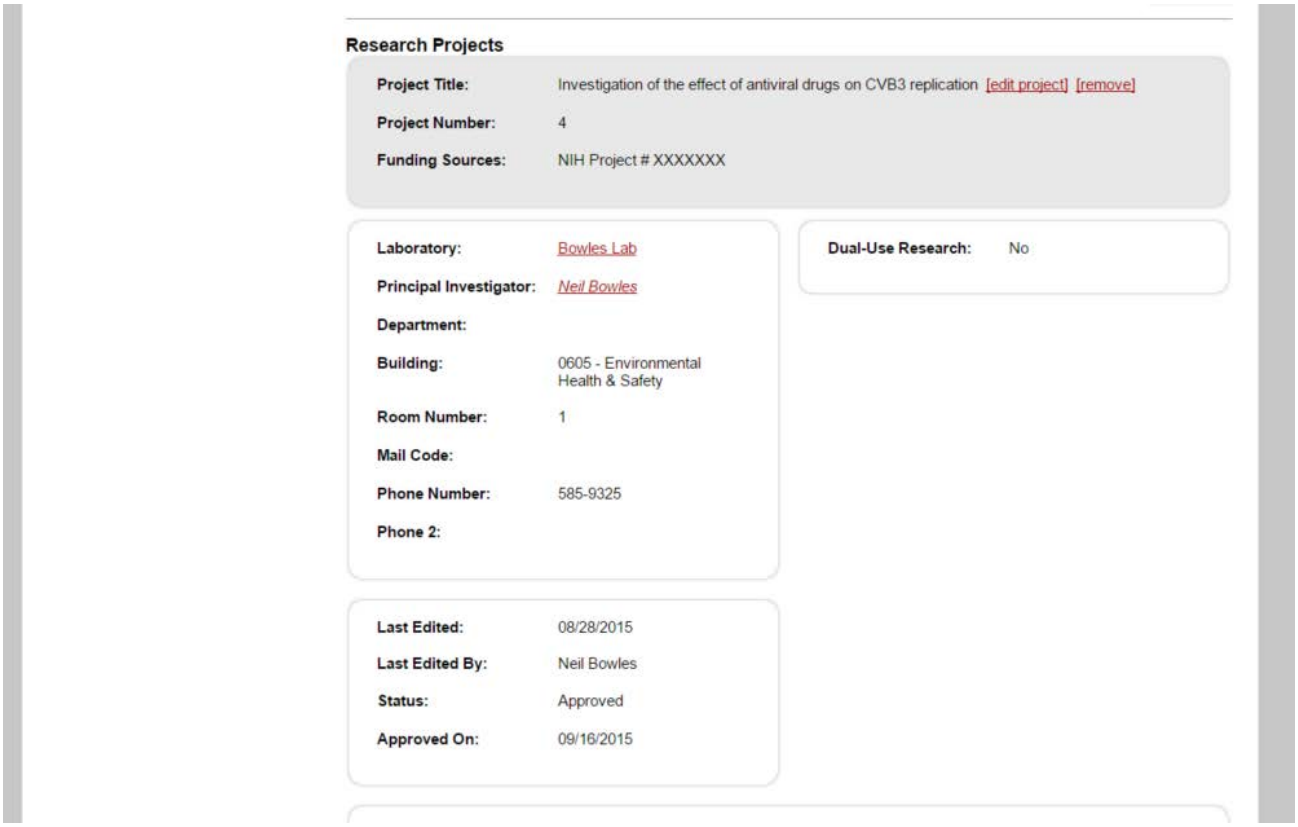
Click on "**View or Update Biological Usage Summary**"

This will open the Biological Usage summary page.

If there are no additional changes follow the instructions beginning on page 17 to recertify the registration.. Note that if the new personnel are using viral vectors or pathogens they will need to be added to the project form as described below.

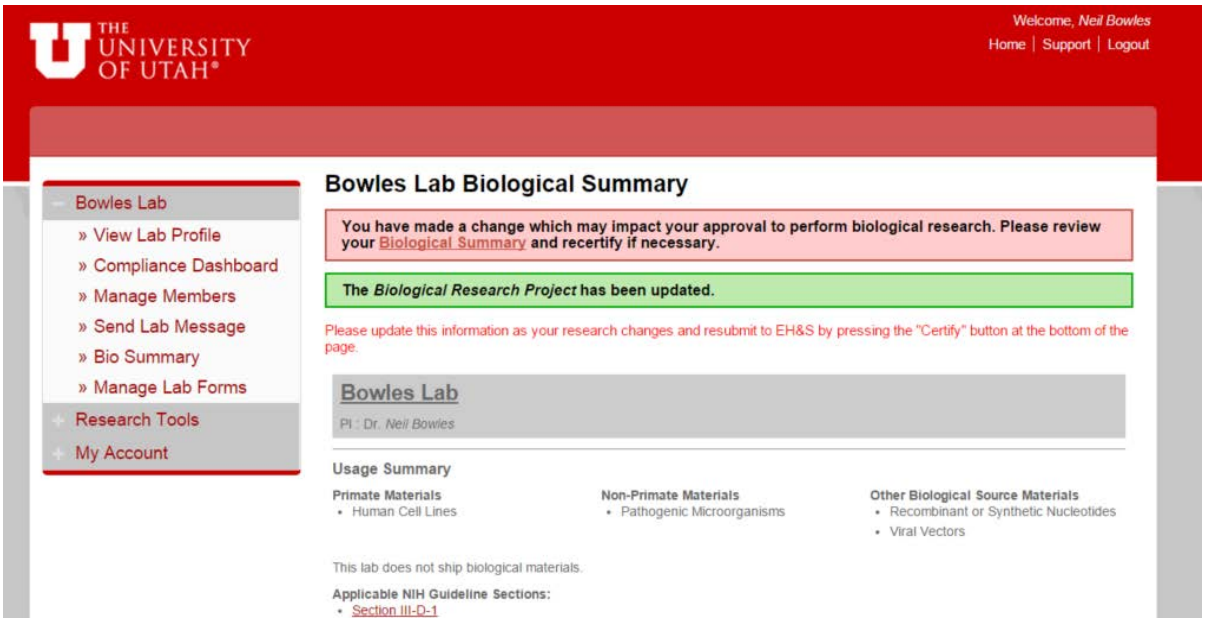
If you need to make an amendment to a form or research project, go to next page.

Editing Projects



Click on the "**edit project"** button to the right of the project title.

Make the necessary changes and click the "**Submit**" at the bottom of the page. This will take you back to the Biological Summary page.



If there are no additional changes follow the instructions beginning on page 17 to recertify the registration.