Guide to BioRAFT
Research Management System

Biological Laboratories with Non-Exempt Biological Protocols

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Biological labs with non-exempt protocols

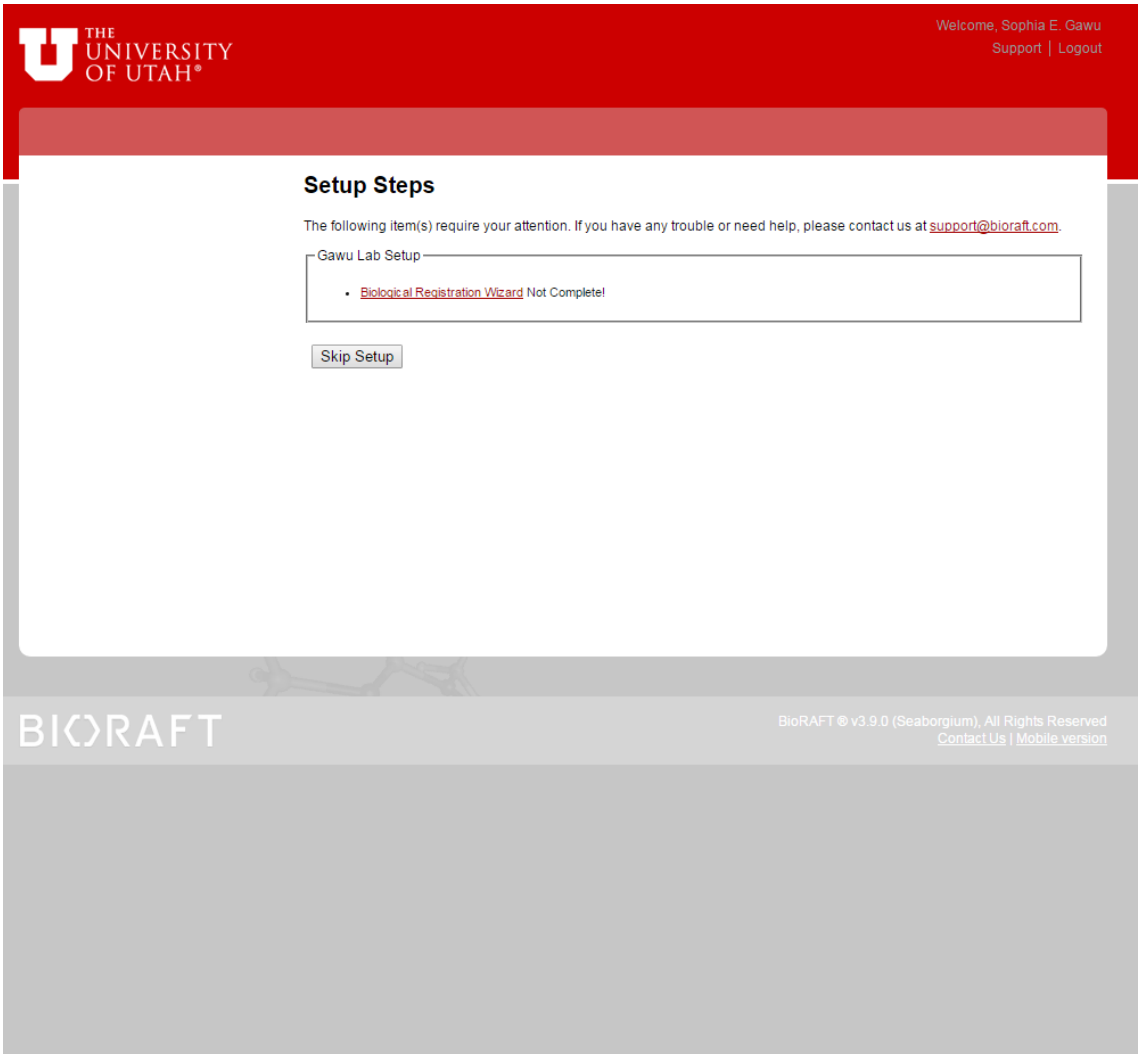
Principal Investigators with a Biological lab and projects that are **not** exempt from IBC review and approval (this includes work with human and animal pathogens (risk group 2 or higher), recombinant and synthetic DNA (as defined by the NIH Guidelines) and certain biological toxins) are required to fill out the Biological survey, research project forms (protocols) and supporting forms (Pathogen and Viral Vector forms) to be reviewed and approved by the IBC committee. 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 or contact the Biosafety Office.

After completing the General Lab Registration you will need to complete the Biological registration.

1. Proceed by clicking on the Biological Registration Wizard Link (see page 3).
2. Laboratories that are required to complete a biological registration will also be required to complete the following:
    a. The Biological registration wizard, including descriptions of projects and general biological usage survey.
    b. The following surveys, as applicable
        i. Human Source Materials Survey
        ii. Laboratory Animal Cell Lines (Non-Primate) Survey
        iii. Non-Human Primate Source Materials Survey
        iv. Arthropods Survey
        v. Plants Survey
        vi. Microbial Agents Survey
        vii. Biological Toxins Survey
        viii. Recombinant & Synthetic Nucleic Acids Survey
        ix. Research of Concern Survey
    c. Additional Forms for projects involving Human and Animal Pathogens and Recombinant and Synthetic DNA
        i. Pathogen form(s)
        ii. Viral Vector Form(s)

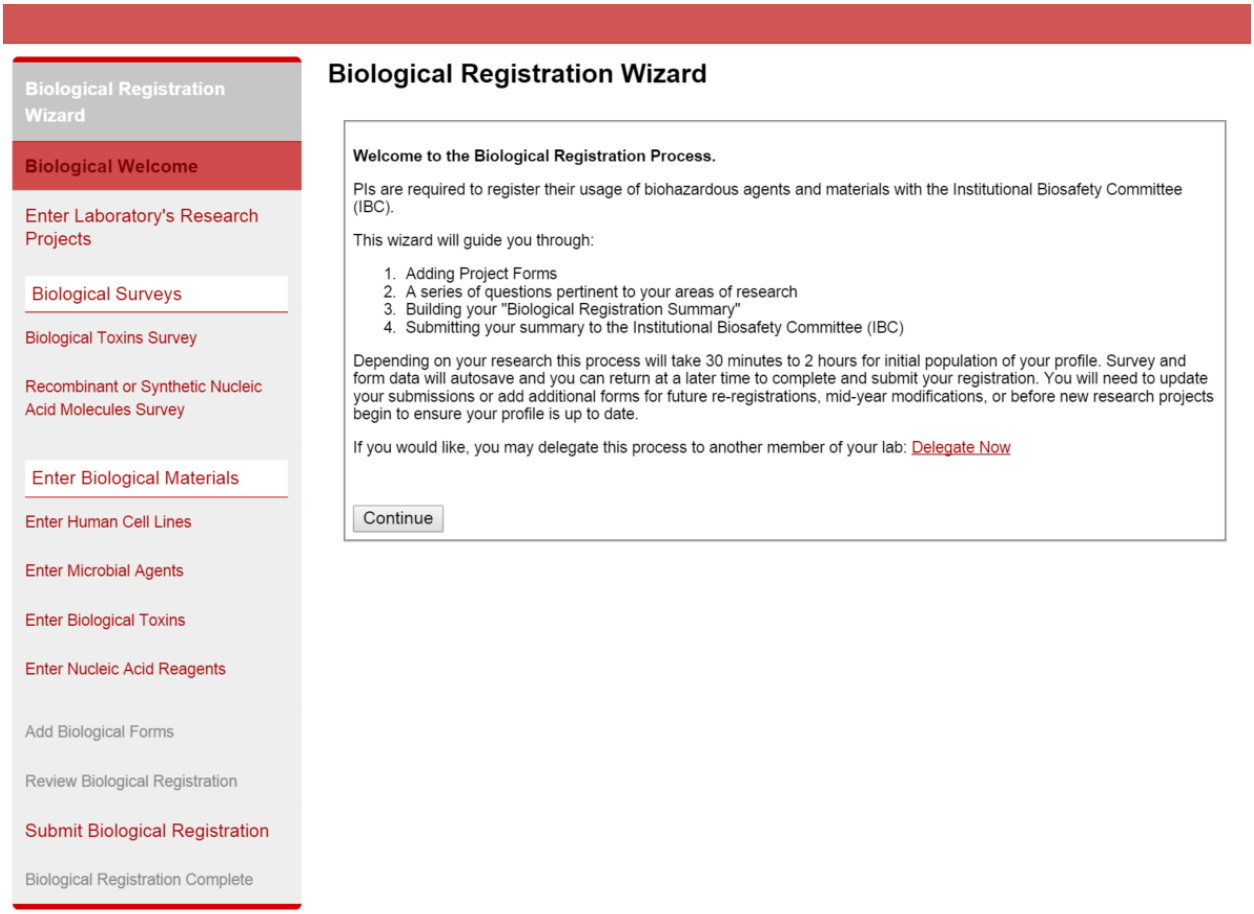
Biological Registration Wizard

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 37. Follow the instructions for editing the Biological Registration beginning on page 38

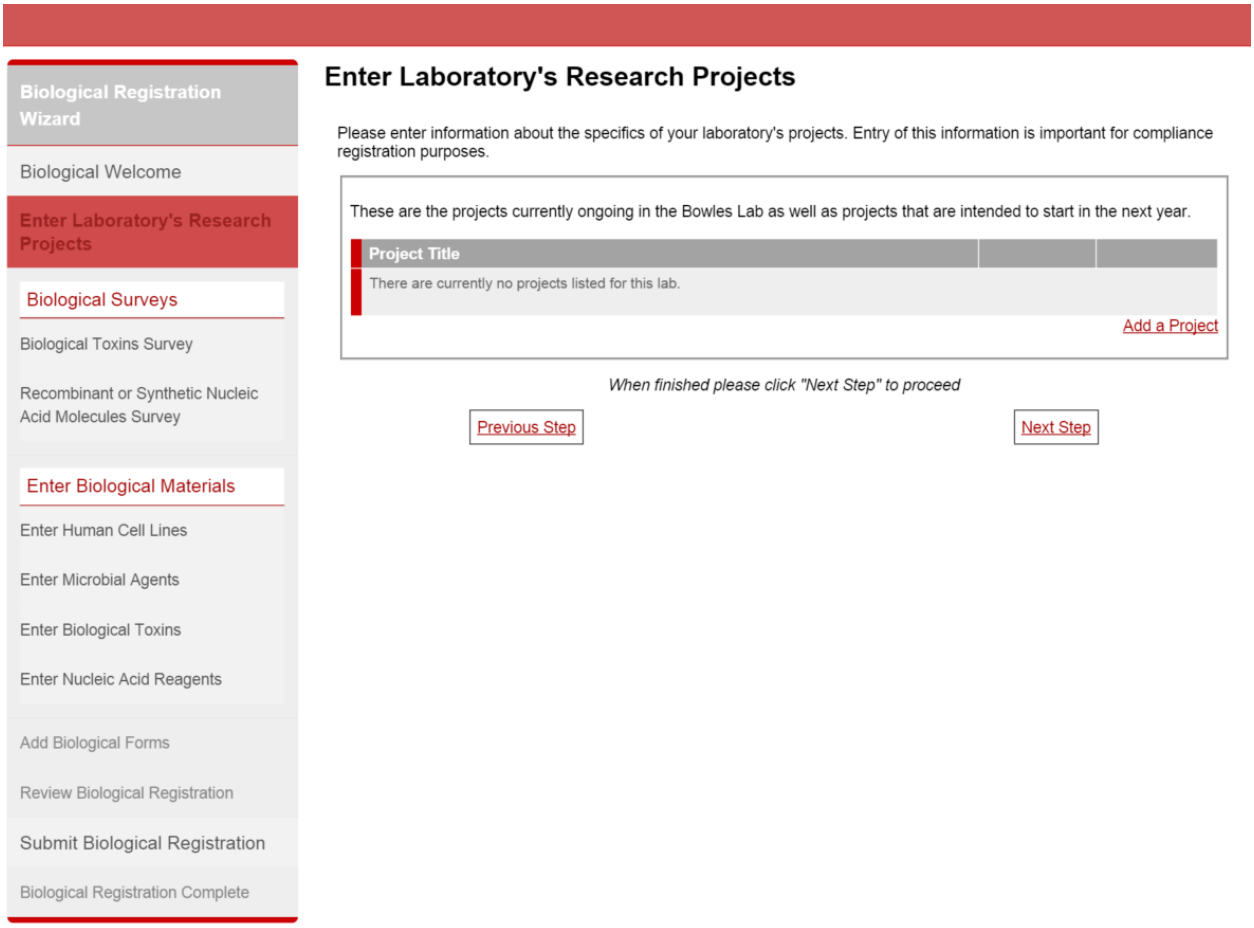
An introductory screen will appear. You have the opportunity to delegate a member of the laboratory to complete the registration. Otherwise Click “Continue.”



Entering Research Projects

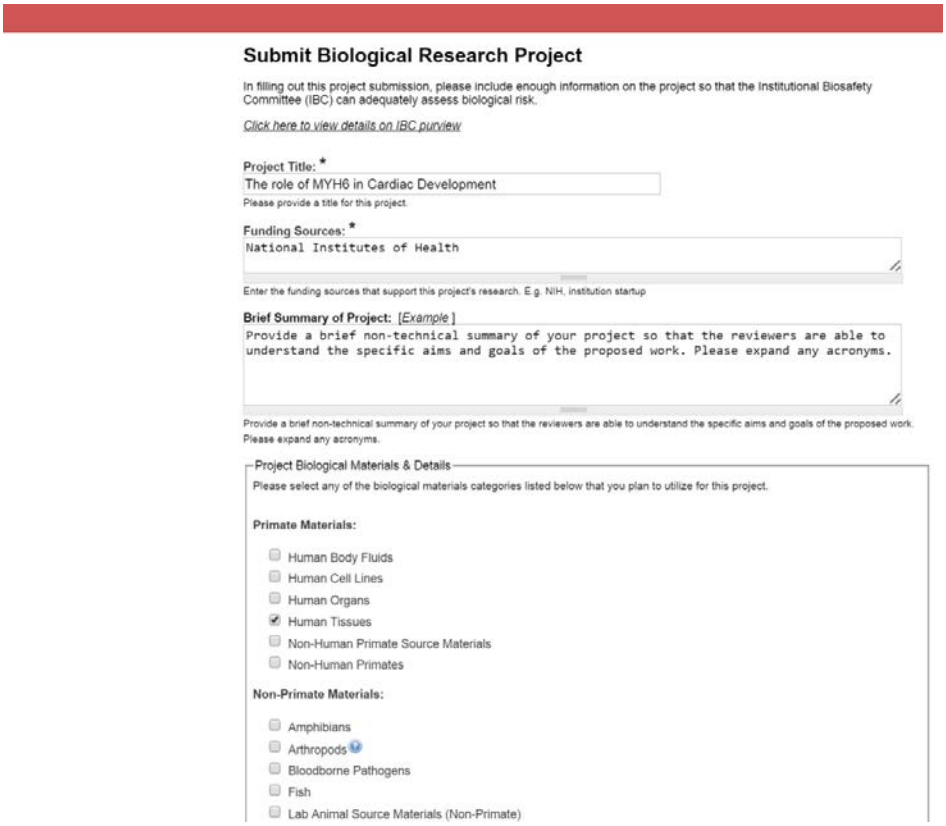
The first screen of the Biological Summary will appear. You will be prompted to enter some brief information about the research projects in your laboratory

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. Please expand any acronyms.

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
- ☐ 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)
- [ ] 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
- [x] 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*]

lentiviral vectors expressing OCT4, SOX2, Kfl4 and c-Myc
2) Characterize differences in cellular structure and gene expression between cells from patients and controls
3) Determine if transduction with rADV5_MYH6 rescues the phenotype in patient iPS cardiomyocytes

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: 1000202

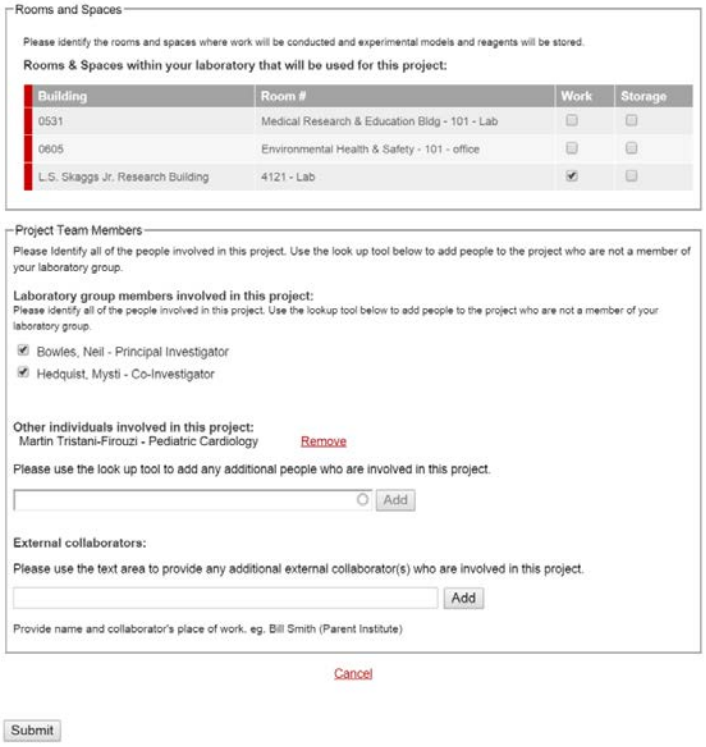
Additional Information:
Allows for the collection of blood and tissue samples from patients with congenital heart defects

USDA/APHIS/PPQ Permits:

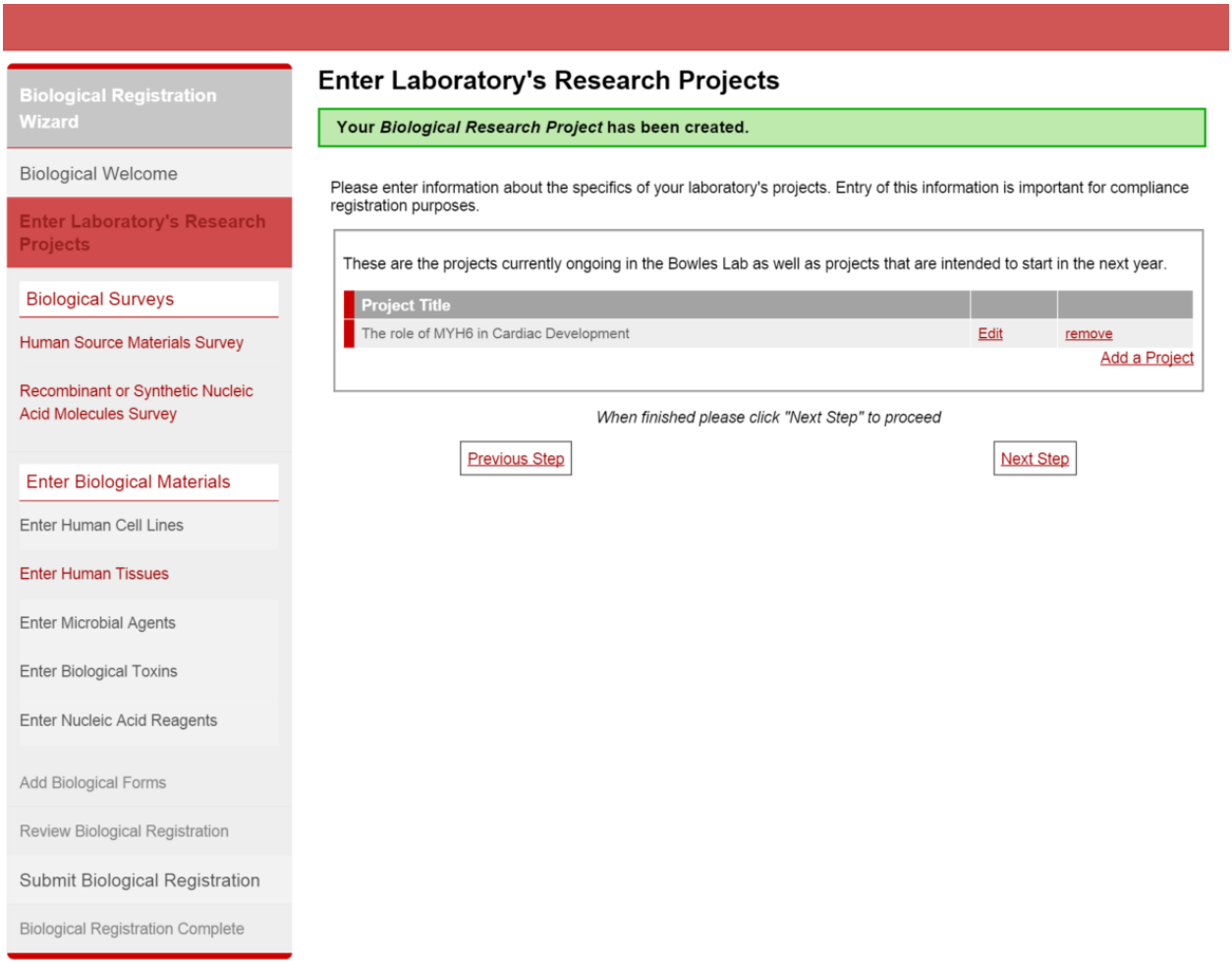
Additional Information:

CDC Import/Export Permits:

Additional Information:



Click on Submit



Repeat for all research projects on-going in your laboratory.

When complete, Click “Next Step”

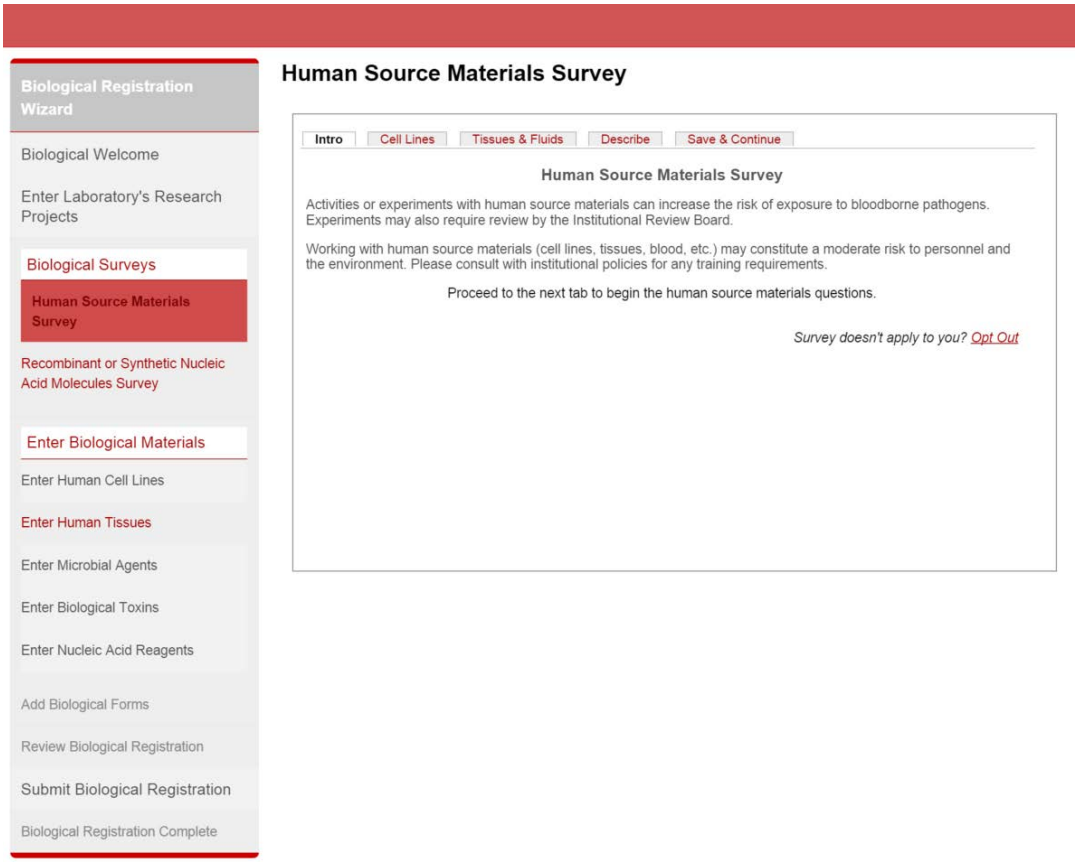
Completing Biological Surveys

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”

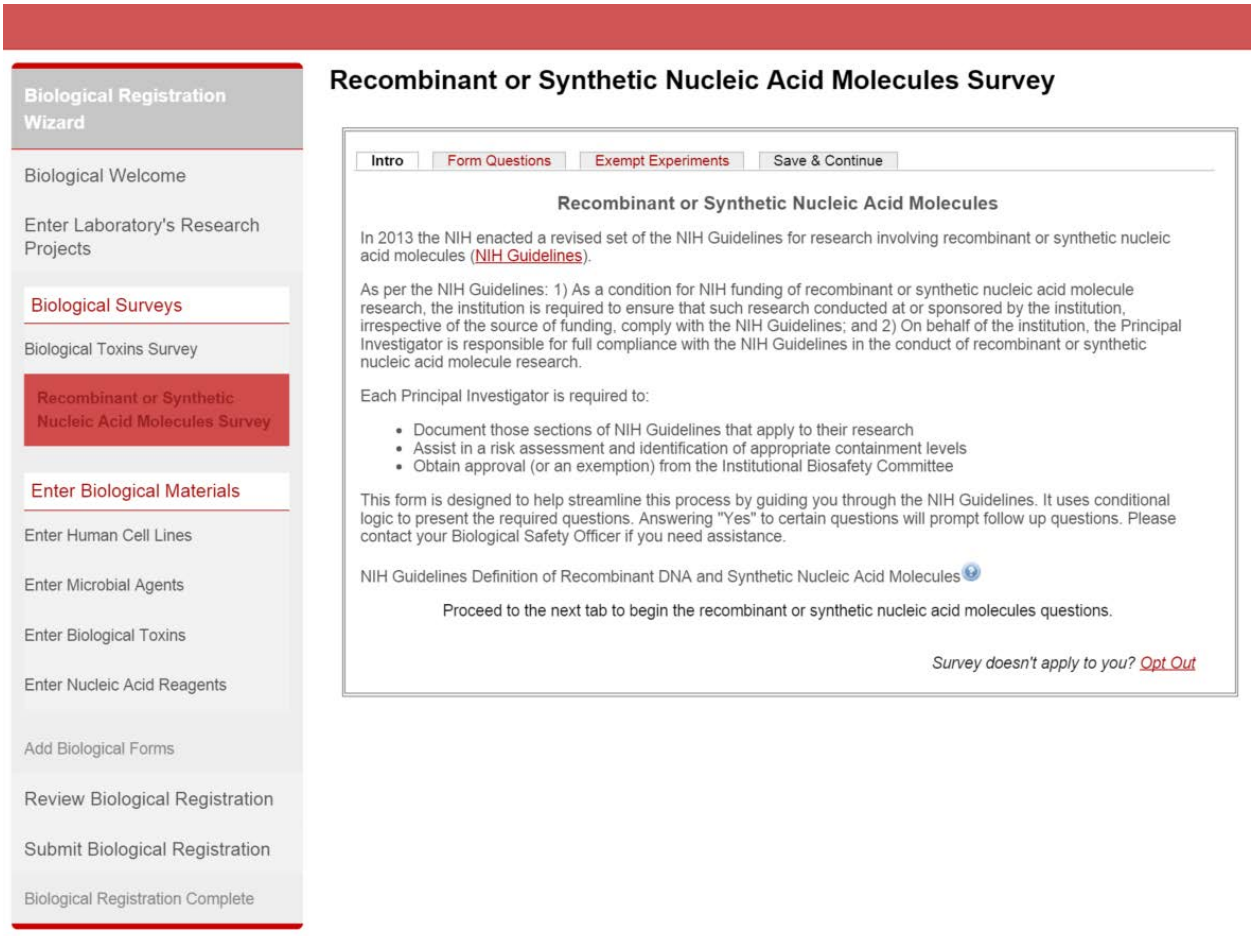


If you believe the survey does not apply, click on “Opt Out.”

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."



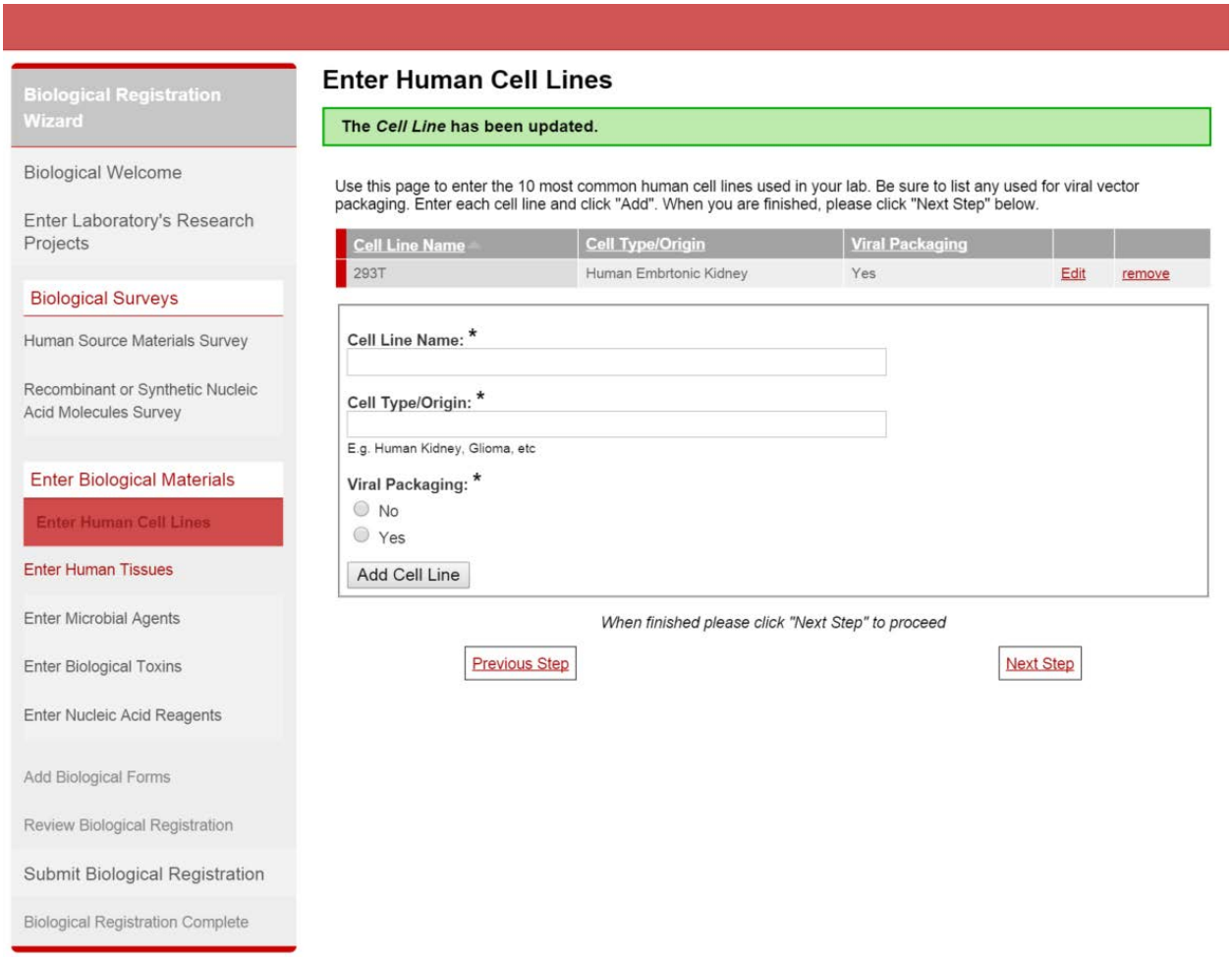
On the last tab, click "Save"

Entering Biological Materials

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

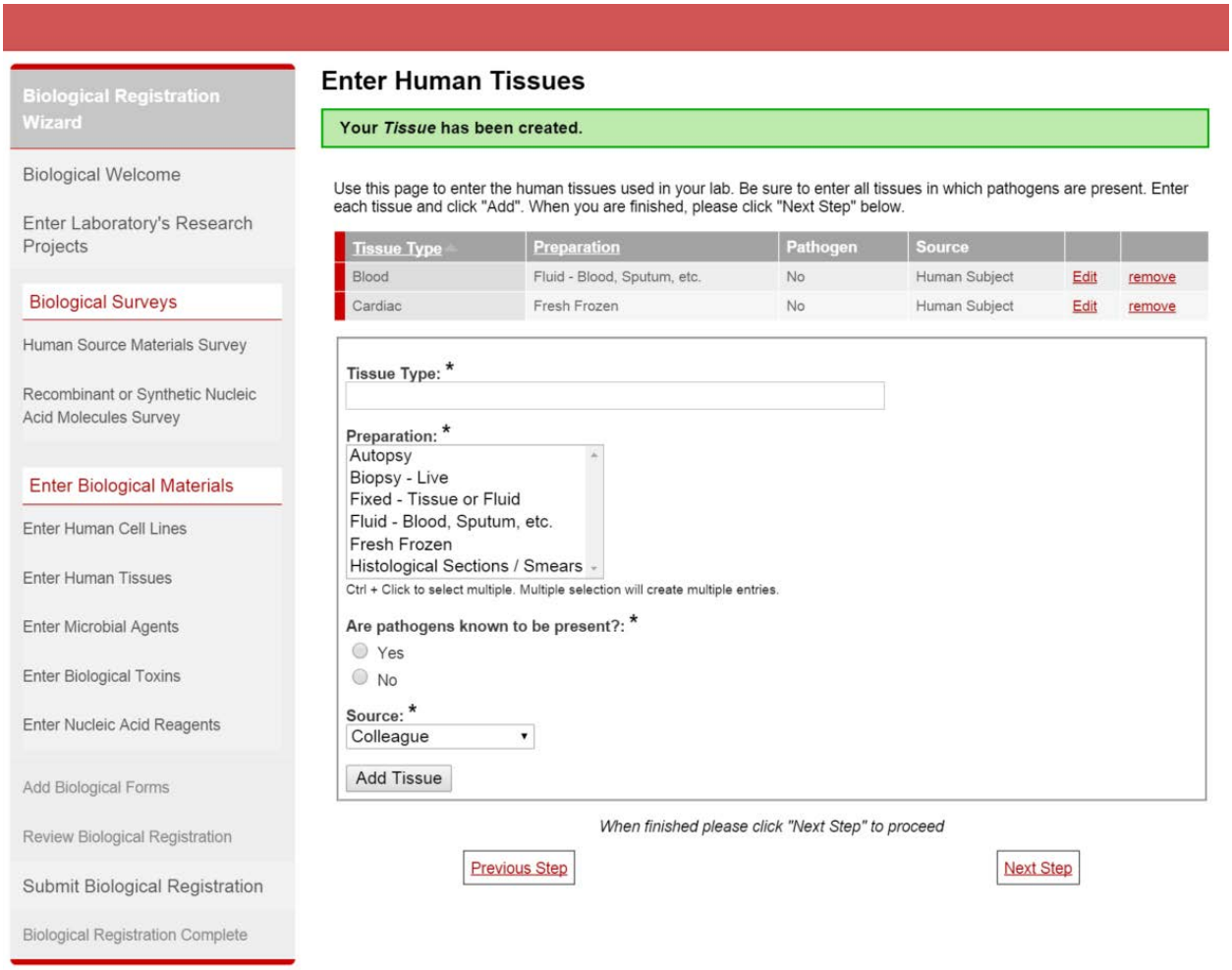
- Human Cell Lines
- Human Tissues
- Plants
- Microbial Agents
  - Bacteria, Viruses, Fungi, Parasites
- Biological Toxins
- Nucleic Acid Reagents
  - Plasmids and Inserts
  - Recombinant Animals

In this example the first screen asks you to enter cell lines that are used in your lab.



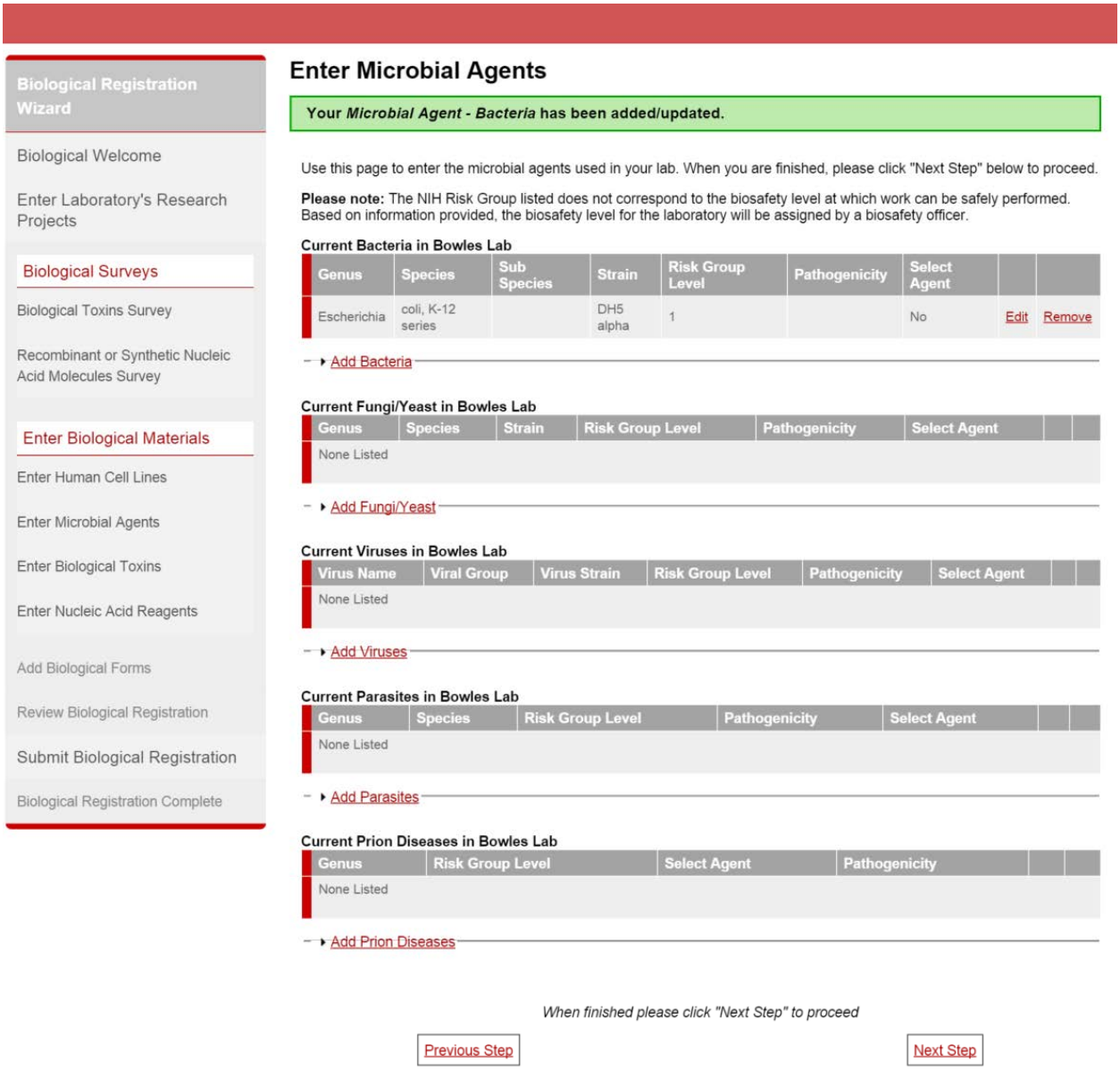
After adding all cell lines, click on “Next Step”.

In this example we have indicated that we use human tissue (blood and cardiac tissue collected during surgery).



Click on “Next Step”

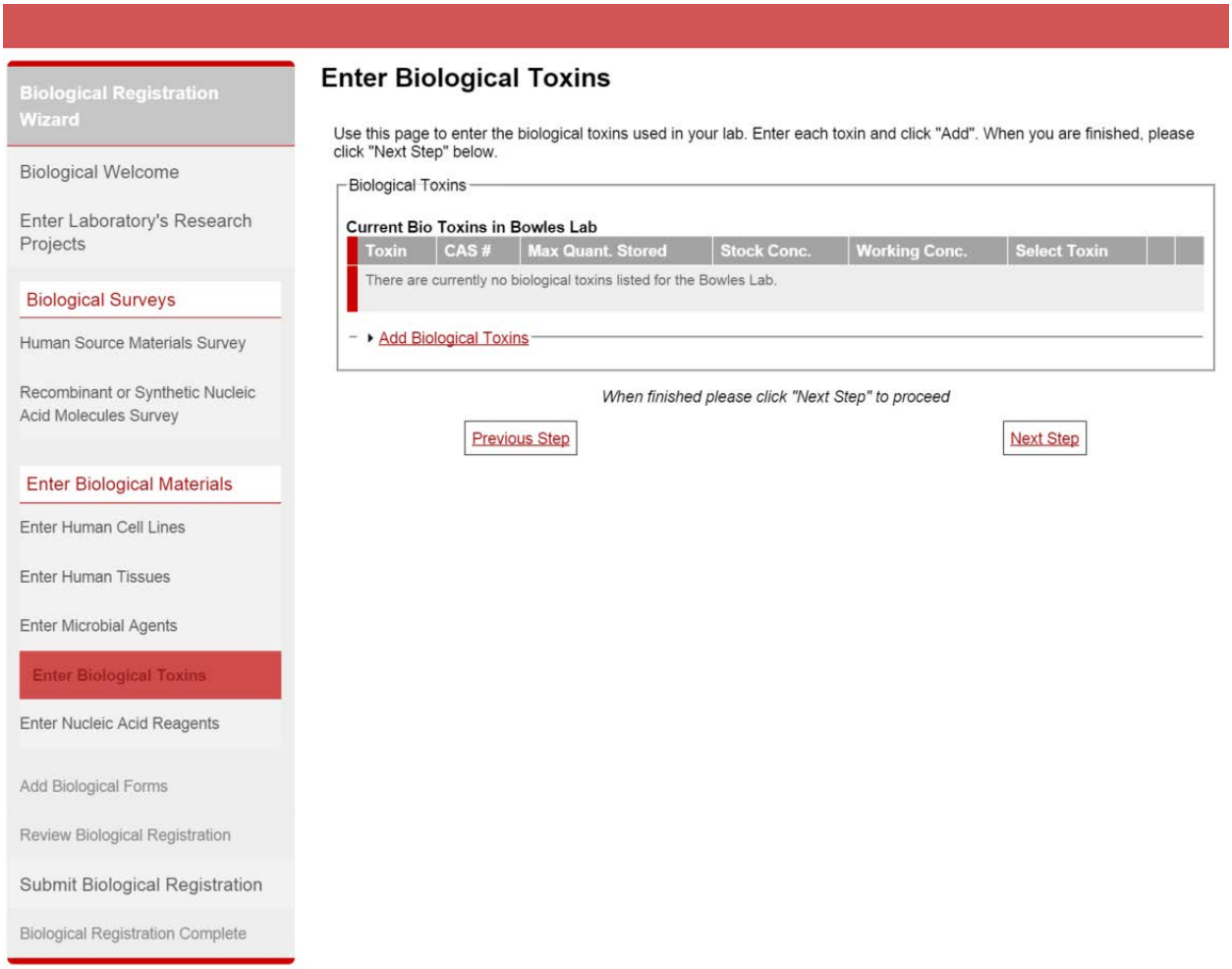
On the next screen add Microbial Agents



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

Note the viral vectors are not added here (they are not viruses). If helper viruses are used for vector propagation they would need to be added here.

We are not using any toxins



Click “Next Step”

Plasmids

Add the names of plasmids commonly used in your laboratory by clicking the "Add Plasmid" button. Please note that EHS is not expecting all plasmids that are used in your lab, just the ones relevant to the registration. 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).
5) Viral vectors

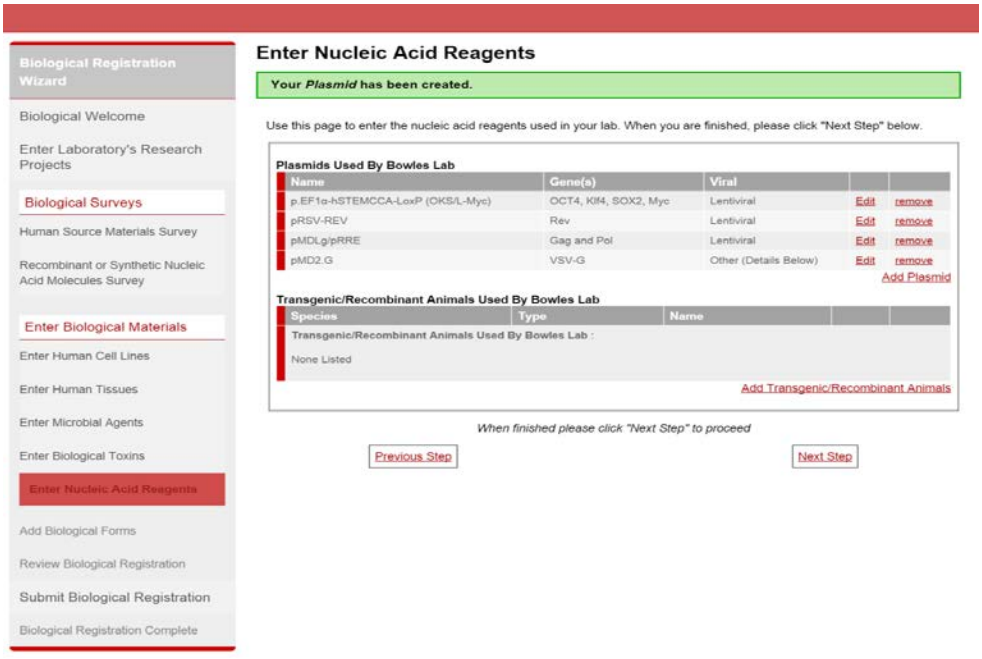
Transgenic/Recombinant Animals

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). However, if you are using a recombinant vector to introduce mutations/genes or knockout genes please list the animals here.

In the section entitled "Additional Details, please address the following:

Identify and describe any ecological advantages/disadvantages that transgenic animals might acquire through the proposed genetic recombination.

Describe the containment procedures that will be followed to prevent the escape of transgenic animals from the laboratory.



Click "Next Step".

Add Biological Registration Forms

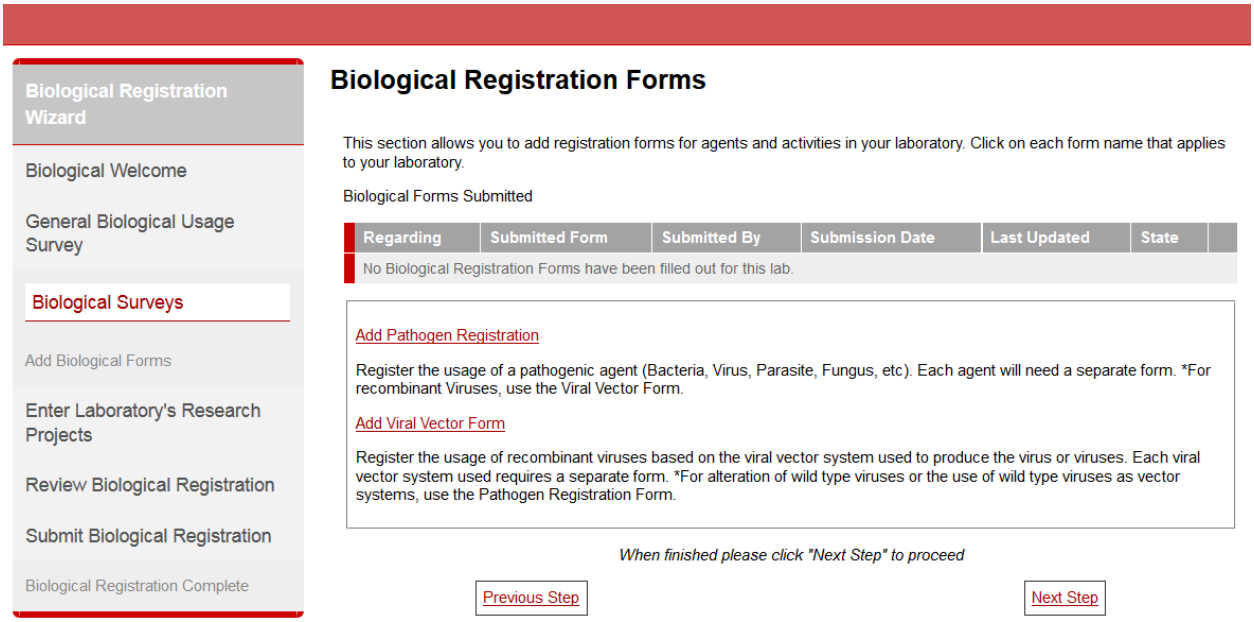
Once you have completed all of the surveys and questionnaires you will be prompted to complete forms describing pathogens or recombinant viral vectors. If neither of these applies to your work click “Next Step”.

a. If you are working with human or animal pathogens you will need to register the use of these pathogenic agents. Click on the ‘Add Pathogen Registration’ link. Please complete a separate form for each agent.

b. If you are working with recombinant viral vectors (e.g., lentiviral vectors, adenoviral vectors, recombinant AAV) you will need to register the use of these vectors. Click on the ‘Add Viral Vector Form’. . Please complete a separate form for each vector system you are proposing to use.

Note: Pathogen and viral vector forms will auto save every 75 seconds. A bar will appear at the bottom of the page to alert you when the form has been saved. You may only work on one form at a time.

c. If you have nor forms to add or are finished adding forms, click ‘Next Step’. **Goto page 25 of the guide.**



Pathogen Registration

The Pathogen registration form replaces the Biological Materials Registration (BMR) currently used by the IBC. This form will auto save every 75 seconds. A bar will appear at the bottom of the page to alert you when the form has been saved.

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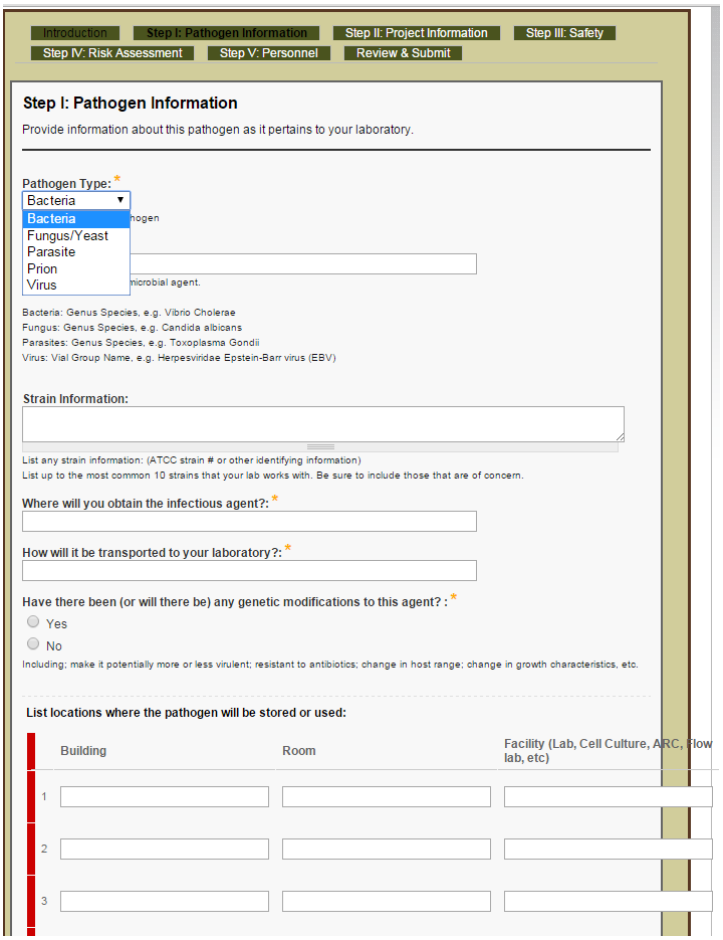


Notes

The information provided on these forms contain the primary information required by the IBC to ensure that work practices are appropriate and provide adequate protection. The practices described in these sections should be described in detail in the PIs laboratory-specific Standard Operating Procedures (SOPs). In order to provide this information clearly to the IBC, we require one of two options:

1) The laboratory-specific SOPs can be attached to the Registration (see page 33). All questions should be answered but description can be brief or refer to the SOPs. In order to assist the PI the IBC has developed model SOPs for BSL2 and BSL2 enhanced laboratories, which can be

downloaded from the IB website (http://ehs.utah.edu/research-safety/biosafety/protocol-review/recombinant-dna-registration). **This is the preferred option for the IBC** because:

a. It ensures that the laboratory has SOPs in place that will provide information on all aspects of safe operating procedures to personnel
b. NIH and the Institution expect comprehensive SOPs to be available to all personnel
c. It will be incorporated into training
d. If the SOPs are complete, it reduces the likelihood that registrations will require prolonged IBC review

2. Complete descriptions of laboratory procedures can be provided on these forms. For PIs renewing IBC approved protocols much of the narrative can be copied from their current SOPs. For Step II: Project Information, in the box entitled "Provide a brief description of project(s) involving this agent', provide SOPs including, as applicable, but not limited to:
    e. Methods of production
    f. Methods of titering
    g. What happens to infected cells
    h. Decontamination procedures

    However, separate "Spill Procedures" and "Post-Exposure Procedures" documents will need to be generated and added as an attachment (see page 33): templates are available on the Biosafety website (http://ehs.utah.edu/research-safety/biosafety/protocol-review/recombinant-dna-registration).

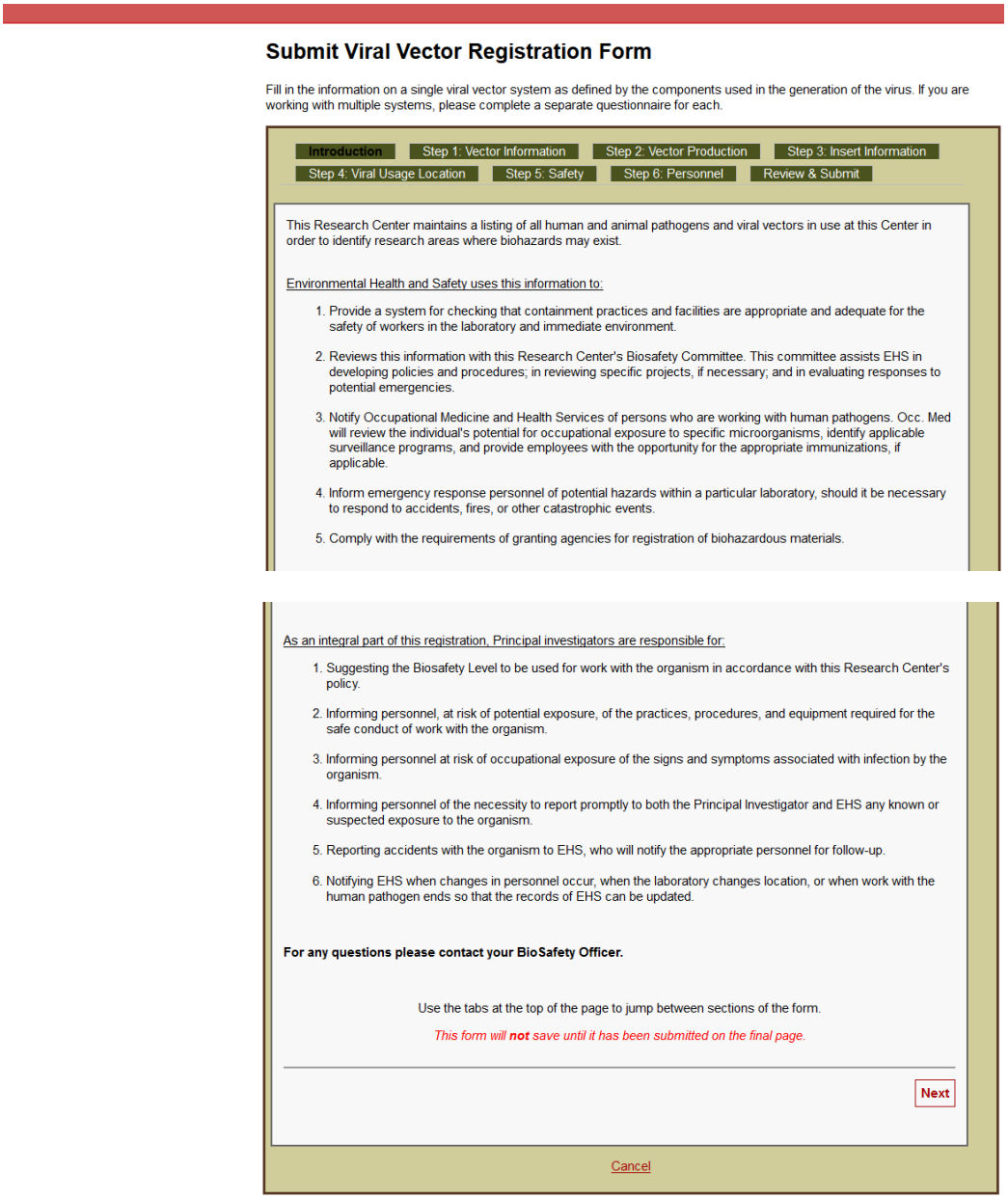
    These forms cannot be cloned or copied at present. Therefore, if you need to submit multiple Pathogen Registration forms with similar narratives we recommend that you prepare the text in Word (or other word processing software) and copy into the text boxes.

NOTE: If you are using pathogens with similar properties/containment requirements/SOPs you can list multiple agents on one form, as long as all checkboxes require the same response.

Viral Vector Registration Form

The Viral Vector replaces the recombinant and synthetic nucleic acid registration forms currently used by the IBC. This form will auto save every 75 seconds. A bar will appear at the bottom of the page to alert you when the form has been saved.

Note: If you have an auto saved form, you may choose to use it or discard the form. Discarding auto save from will delete all previously saved items.



Notes

The information provided on these forms contain the primary information required by the IBC to ensure that work practices are appropriate and provide adequate protection. The practices described in these sections should be described in detail in the PIs laboratory-specific Standard Operating Procedures. In order to provide this information clearly to the IBC, we require one of two options:

1. The laboratory-specific SOPs can be attached to the Registration (see page 33). All questions should be answered but description can be brief or refer to the SOPs. In order to assist the PI the IBC has developed model SOPs for BSL2 and BSL2 enhanced laboratories, which can be downloaded from the IB website (http://ehs.utah.edu/research-safety/biosafety/protocol-review/recombinant-dna-registration). **This is the preferred option for the IBC** because:
   a. It ensures that the laboratory has SOPs in place that will provide information on all aspects of safe operating procedures to personnel
   b. NIH and the Institution expect comprehensive SOPs to be available to all personnel
   c. It will be incorporated into training
   d. If the SOPs are complete, it reduces the likelihood that registrations will require prolonged IBC review

2. Complete descriptions of laboratory procedures can be provided on these forms. For PIs renewing IBC approved protocols much of the narrative can be copied from their current SOPs.

   In the section entitled "Describe your viral vector production methods" please include information related to viral purification and the measurement of viral titers (as applicable).
   In the section entitled "Provide a brief description of project(s) involving this viral system" please include (as applicable):
   a. Descriptions of experiments using the recombinant vectors, including methods of transducing cells in culture and administration into animals
   b. Describe methods of decontamination of potentially infected materials (cell lines, animal tissues, etc.)

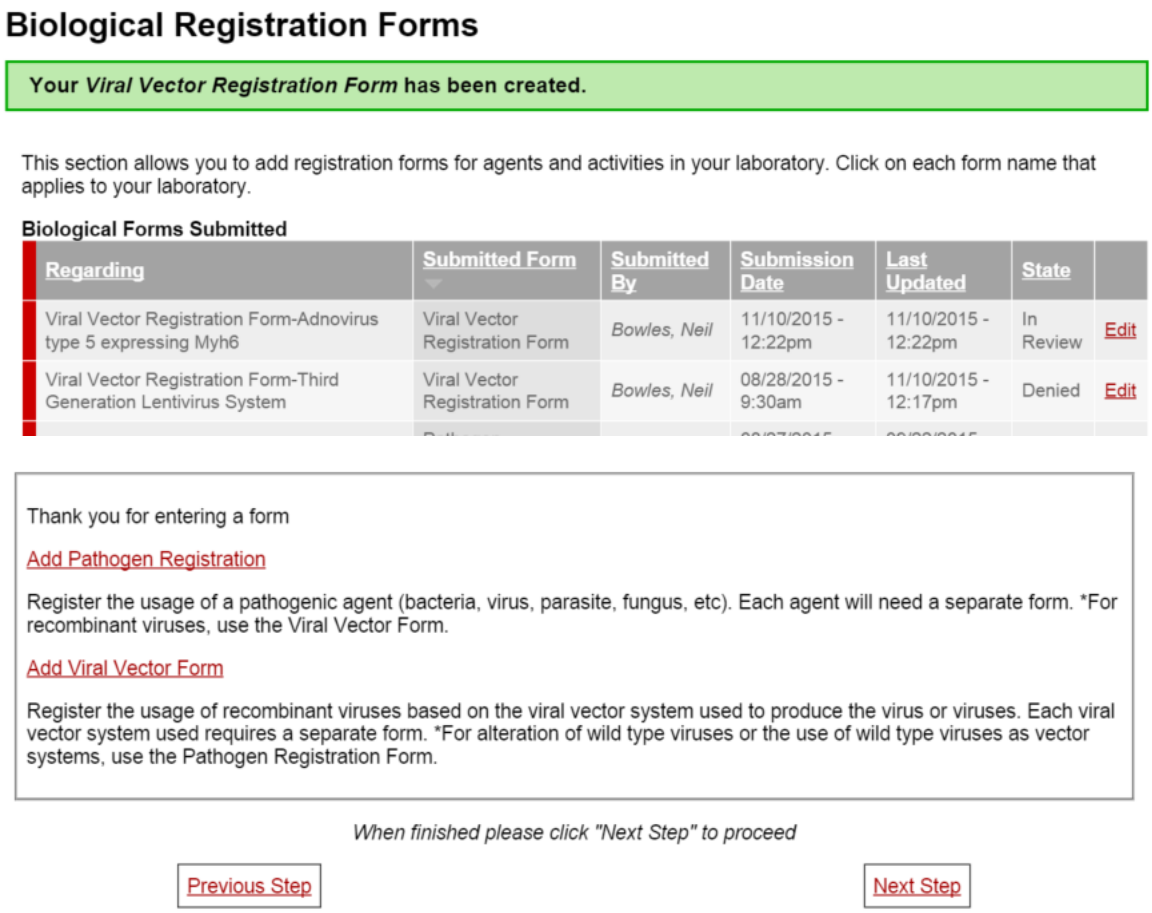
   However, separate "Spill Procedures" and "Post-Exposure Procedures" documents will need to be generated and added as an attachment (see page 33): templates are available on the Biosafety website (http://ehs.utah.edu/research-safety/biosafety/protocol-review/recombinant-dna-registration).

   These forms cannot be cloned or copied at present. Therefore, if you need to submit multiple Viral Vector Registration forms with similar narratives we recommend that you prepare the text in Word (or other word processing software) and copy into the text boxes.

NOTE: If you are using vectors with similar properties/containment requirements/SOPs you can list multiple agents on one form, as long as all checkboxes require the same response. For example using vectors expressing different transgenes could be on a single form.

Attach vector maps (PDF format) in the documents section of the Laboratory Registration: see page 33 for instructions.

Once you have completed the Pathogen or Viral Vector forms click on “Next Step”



Biological Registration Forms

Your *Viral Vector Registration Form* has been created.

This section allows you to add registration forms for agents and activities in your laboratory. Click on each form name that applies to your laboratory.

Biological Forms Submitted

Regarding	Submitted Form	Submitted By	Submission Date	Last Updated	State	
Viral Vector Registration Form-Adnovirus type 5 expressing Myh6	Viral Vector Registration Form	*Bowles, Neil*	11/10/2015 - 12:22pm	11/10/2015 - 12:22pm	In Review	Edit
Viral Vector Registration Form-Third Generation Lentivirus System	Viral Vector Registration Form	*Bowles, Neil*	08/28/2015 - 9:30am	11/10/2015 - 12:17pm	Denied	Edit

Thank you for entering a form

Add Pathogen Registration

Register the usage of a pathogenic agent (bacteria, virus, parasite, fungus, etc). Each agent will need a separate form. *For recombinant viruses, use the Viral Vector Form.

Add Viral Vector Form

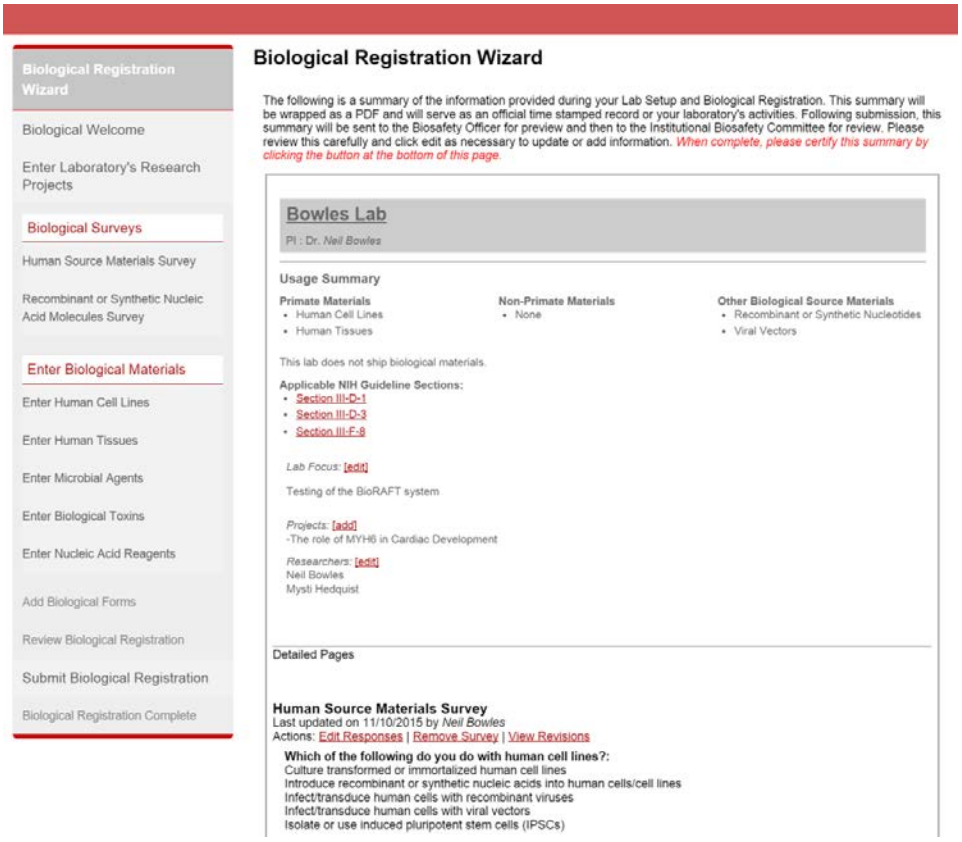
Register the usage of recombinant viruses based on the viral vector system used to produce the virus or viruses. Each viral vector system used requires a separate form. *For alteration of wild type viruses or the use of wild type viruses as vector systems, use the Pathogen Registration Form.

When finished please click "Next Step" to proceed

Previous Step Next Step

Review Biological Registration

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



Upon initial receipt, human tissues and/or fluids used by my laboratory are:
Fresh
Do you plan to obtain human tissues or fluids that carry pathogenic organisms?:
No

Describe:
Generate iPS cardiomyocytes from blood samples from patients with CHD. Transduce iPS cardiomyocytes with recombinant adenoviral vectors expressing MYH6.

Cell Lines Used in Lab:

Cell Line Name	Cell Type/Origin	Viral Packaging		
293T	Human Embrtonic Kidney	Yes	Edit	Remove

Add Cell Line

Tissues Used in Lab:

Tissue Type	Preparation	Pathogen	Source		
Blood	Fluid - Blood, Sputum, etc.	No	Human Subject	Edit	Remove
Cardiac	Fresh Frozen	No	Human Subject	Edit	Remove

Add Tissues

Recombinant or Synthetic Nucleic Acid Molecules Survey

Last updated on 11/10/2015 by *Neil Bowles*
Actions: Edit Responses | Remove Survey | View Revisions

Form Questions

1) Do any of your experiments alter the host range, transmissibility, or virulence of a pathogen?:
No

2) Do any of your experiments involve recombinant or synthetic nucleic acid sequences that are deliberately created for biosynthesis of molecules toxic in vertebrates at an LD50 of less than 100 ng/kg body weight?:
No

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?:
Yes

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):
Yes

6-A) Do your experiments involve the formation of DNA molecules containing no more than 2/3 of the genome of any eukaryotic virus?:
No

6-B) Do your experiments involve the use of defective DNA or RNA viruses in the presence of a helper virus in tissue culture?:
No

6-C) Do your experiments involve the use of infectious DNA or RNA viruses in tissue culture?:
Yes

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		
p.EF1α-hSTEMCCA-LoxP (OKS/L-Myc)	OCT4, Klf4, SOX2, Myc	Lentiviral	Edit	Remove
pRSV-REV	Rev	Lentiviral	Edit	Remove
pMDLg/pRRE	Gag and Pol	Lentiviral	Edit	Remove
pMD2.G	VSV-G	Other (Details Below)	Edit	Remove

Add Plasmid

Research Projects

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

Project Number: 22

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: 11/10/2015

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. Please expand any acronyms.

Project Biological Materials & Details

Biological Materials:
Primate Materials
- Human Tissues

Other Biological Source Materials
- Recombinant or Synthetic Nucleotides
- Viral Vectors

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

Description of Experimental and Procedural Details:
We are developing iPS cardiomyocytes from blood samples obtained from patients with congenital heart defects. A subset of patients with MYH6 variants will be studied to investigate the role of this gene in pathogenesis:
1) Develop iPS cardiomyocytes from patients and unaffected relatives using lentiviral vectors expressing OCT4, SOX2, Klf4 and c-Myc
2) Characterize differences in cellular structure and gene expression between cells from patients and controls
3) Determine if transduction with rADV5_MYH6 rescues the phenotype in patient iPS cardiomyocytes

Authorizations and Permits

IRB Number:
1000202

Additional Information:
Allows for the collection of blood and tissue samples from patients with congenital heart defects

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

Additional Forms

Viral Vector Registration Form-Adnovirus type 5 expressing Myh6

Edit Form

Form Status: In Review
Laboratory: Bowles Lab
Researcher: *Neil Bowles*

First Submission: Nov 10, 2015 - 2:22 pm
Current Revision: Nov 10, 2015 - 2:22 pm

Viral Vector Registration Form
Viral Vector Registration Form-Adnovirus type 5 expressing Myh6

Step 1: Vector Information

Information on the viral vector system.

Viral Vector System name:
Adnovirus type 5 expressing Myh6

Virus Type:
Adenovirus

Supplier name:
Addgene

Does your vector system include a helper virus?:
No

Have any changes been made to the natural host range or tropism?:
No

What is the host range or tropism?:
Human only

Will you be testing for replication competence of your viral vector preps?:
No

Step 2: Vector Production

Viral vector production methods

Will another laboratory or a commercial supplier be involved in the production of the vector preparation?:
Yes

(Off-site/Outsourced Production Details):
Produced by Addgene. No helper virus. They test for replication competent virus

In which buildings and cell culture rooms will this virus will be produced?:
7250 EIHG

Step 3: Insert Information

Information about the inserts to be used with this viral vector system.

Identify the sequences/genes to be inserted into this viral vector system.:

	Gene/Insert Name	Source/Species	Type (e.g. cDNA)	Gene Function
1	Myh6	Human	cDNA	Structural
2	-	-	-	-
3	-	-	-	-
4	-	-	-	-
5	-	-	-	-

Is the product of the gene you are working with secreted?:
No

Will there be deliberate formation of rDNAs containing genes for biosynthesis of toxic molecules?:
No

Are any of your genes/sequences of interest involved in cell growth control (i.e., oncogene, tumor suppressor, cytokine)?:
No

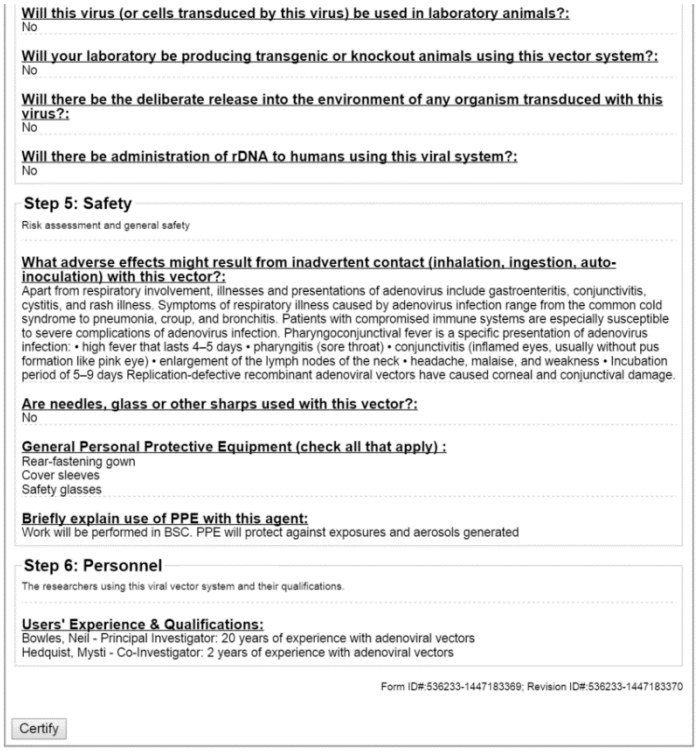
Step 4: Viral Usage Location

Information on the specific usage of viruses produced with this viral vector system.

Provide a brief description of project(s) involving this viral system:
We will use this vector to transduce iPS cardiomyocytes

List locations where the viral stock will be stored or used:;

	Building	Room	Facility (Lab, Cell Culture, ARC, Flow lab, etc)
1	EIHG	7250	Lab
2	-	-	-
3	-	-	-
4	-	-	-
5	-	-	-



Will this virus (or cells transduced by this virus) be used in laboratory animals?:
No

Will your laboratory be producing transgenic or knockout animals using this vector system?:
No

Will there be the deliberate release into the environment of any organism transduced with this virus?:
No

Will there be administration of rDNA to humans using this viral system?:
No

Step 5: Safety

Risk assessment and general safety

What adverse effects might result from inadvertent contact (inhalation, ingestion, auto-inoculation) with this vector?:
Apart from respiratory involvement, illnesses and presentations of adenovirus include gastroenteritis, conjunctivitis, cystitis, and rash illness. Symptoms of respiratory illness caused by adenovirus infection range from the common cold syndrome to pneumonia, croup, and bronchitis. Patients with compromised immune systems are especially susceptible to severe complications of adenovirus infection. Pharyngoconjunctival fever is a specific presentation of adenovirus infection: • high fever that lasts 4–5 days • pharyngitis (sore throat) • conjunctivitis (inflamed eyes, usually without pus formation like pink eye) • enlargement of the lymph nodes of the neck • headache, malaise, and weakness • Incubation period of 5–9 days Replication-defective recombinant adenoviral vectors have caused corneal and conjunctival damage.

Are needles, glass or other sharps used with this vector?:
No

General Personal Protective Equipment (check all that apply) :
Rear-fastening gown
Cover sleeves
Safety glasses

Briefly explain use of PPE with this agent:
Work will be performed in BSC. PPE will protect against exposures and aerosols generated

Step 6: Personnel

The researchers using this viral vector system and their qualifications.

Users' Experience & Qualifications:
Bowles, Neil - Principal Investigator: 20 years of experience with adenoviral vectors
Hedquist, Mysti - Co-Investigator: 2 years of experience with adenoviral vectors

Form ID#:536233-1447183369; Revision ID#:536233-1447183370

Certify

Once you have finished reviewing your summary, click the 'Certify' button at the bottom of the page. Go to page 30.

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**"

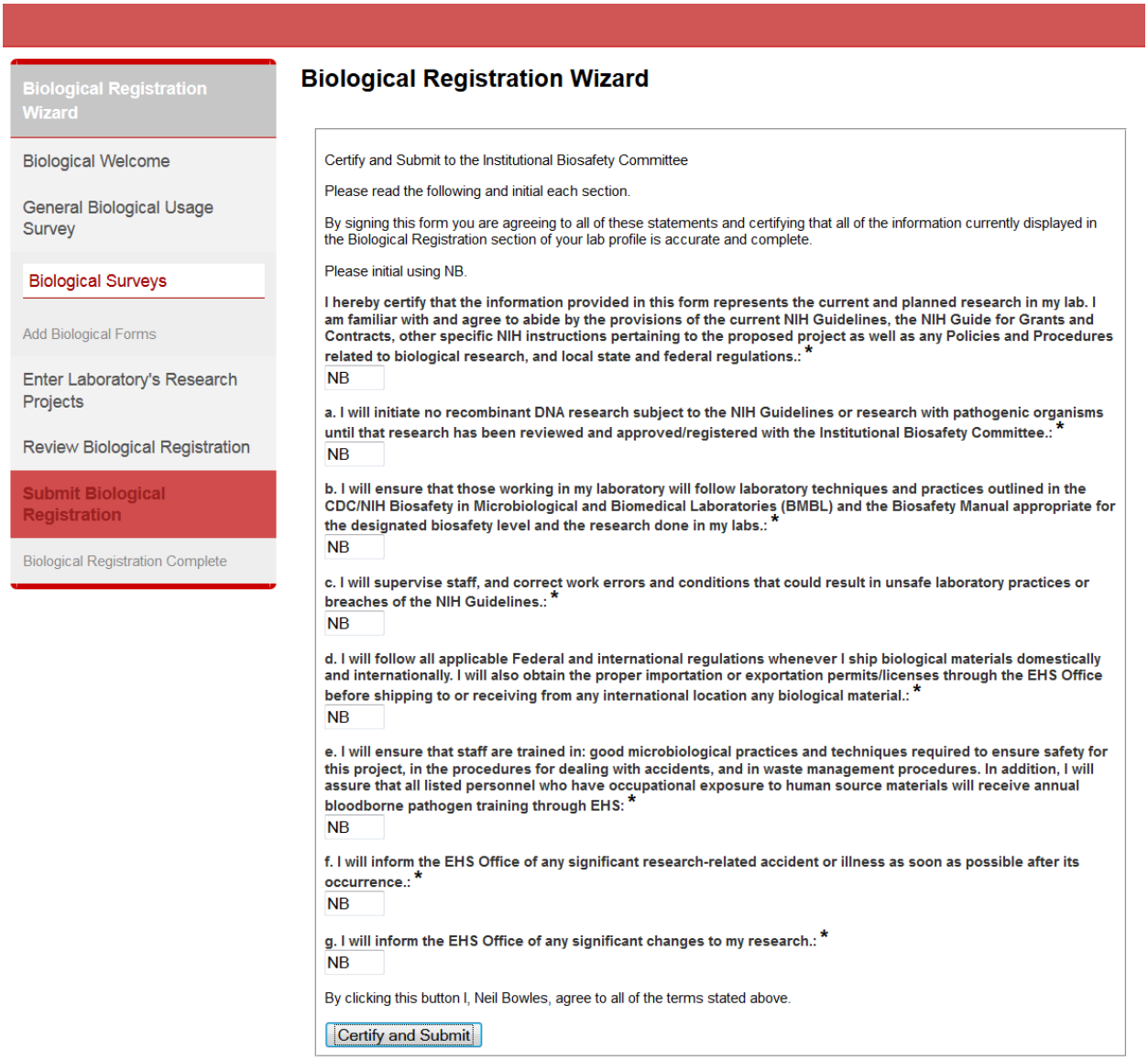
You should receive the message:

- **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.

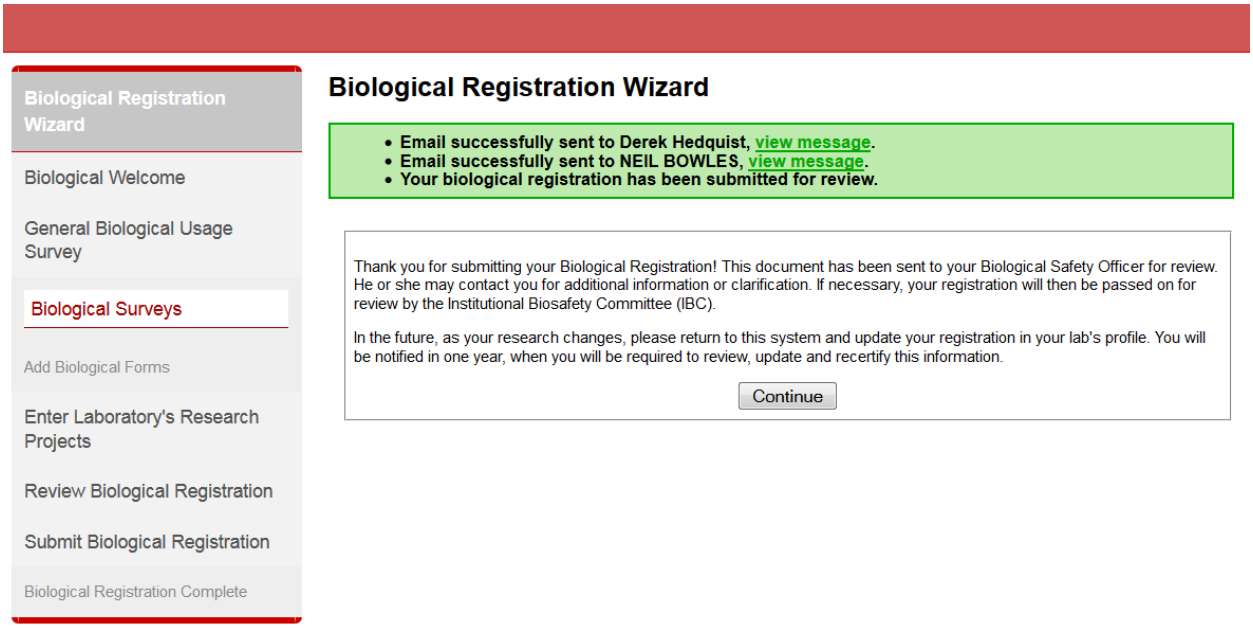
Submit Registration

To certify and submit your Biological Registration to the Biosafety Officers, read the following sections and initial in each box.

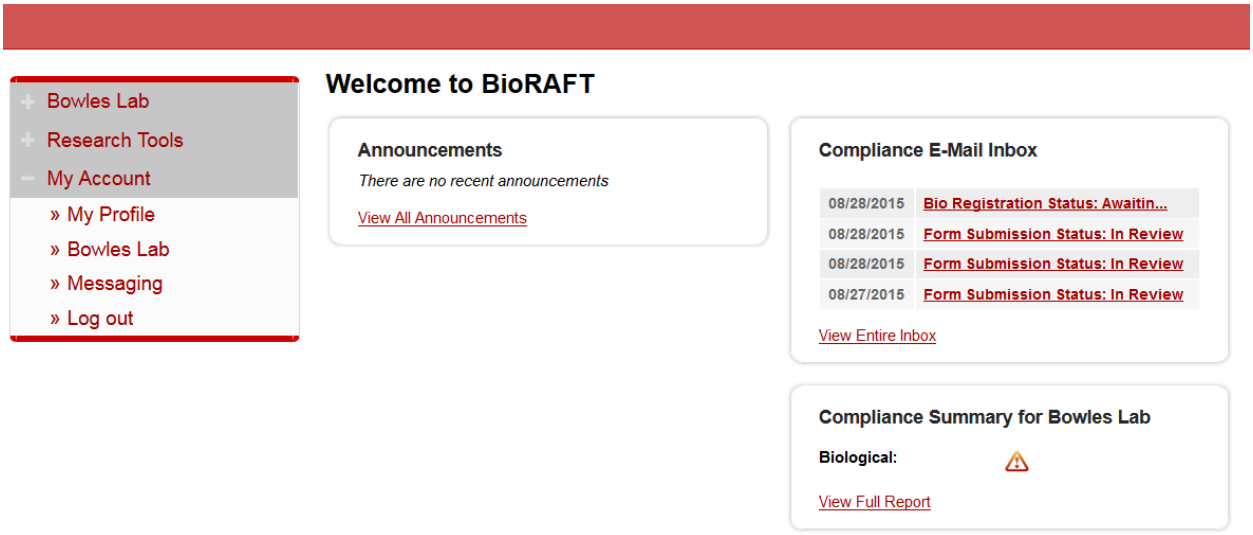


Once you are ready to submit your Biological Registration, click the 'Certify and Submit' button at the bottom of the page.

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



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

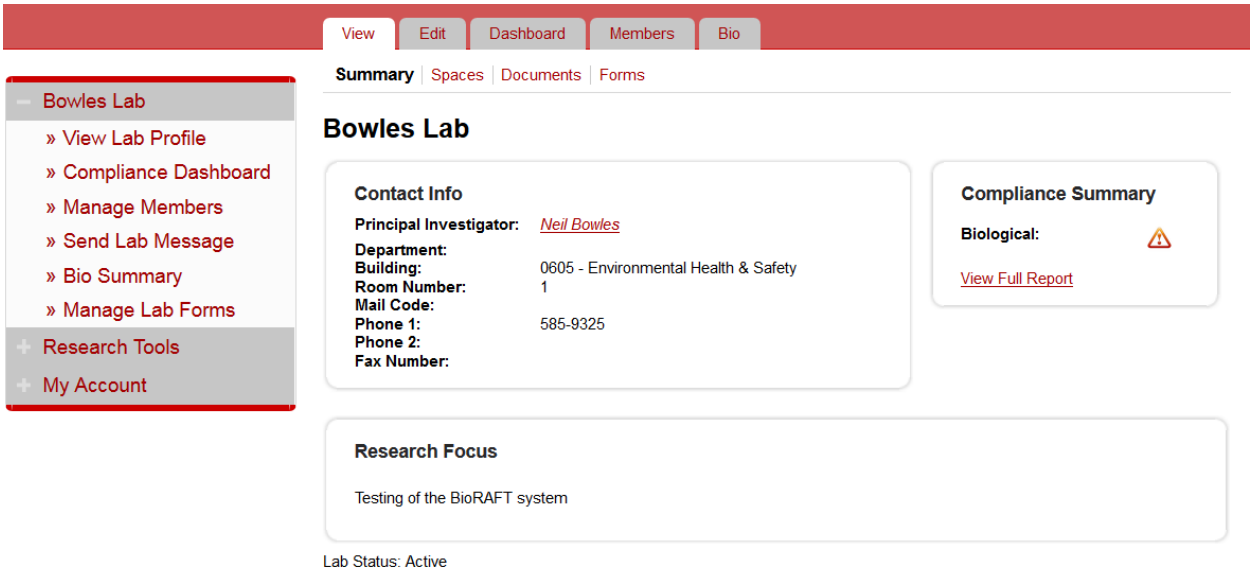


If you do not have documents to download go to page 33.

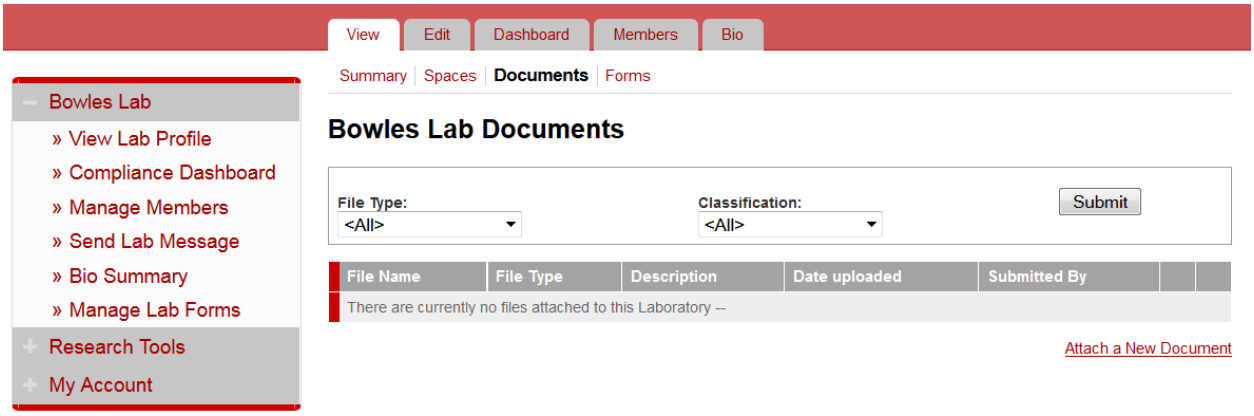
If you need to amend your registration, go to page 37.

Adding Documents

To add documents to the Registration, click on the name of the lab in the left margin and then click on "View Lab Profile"



Click on “Documents”



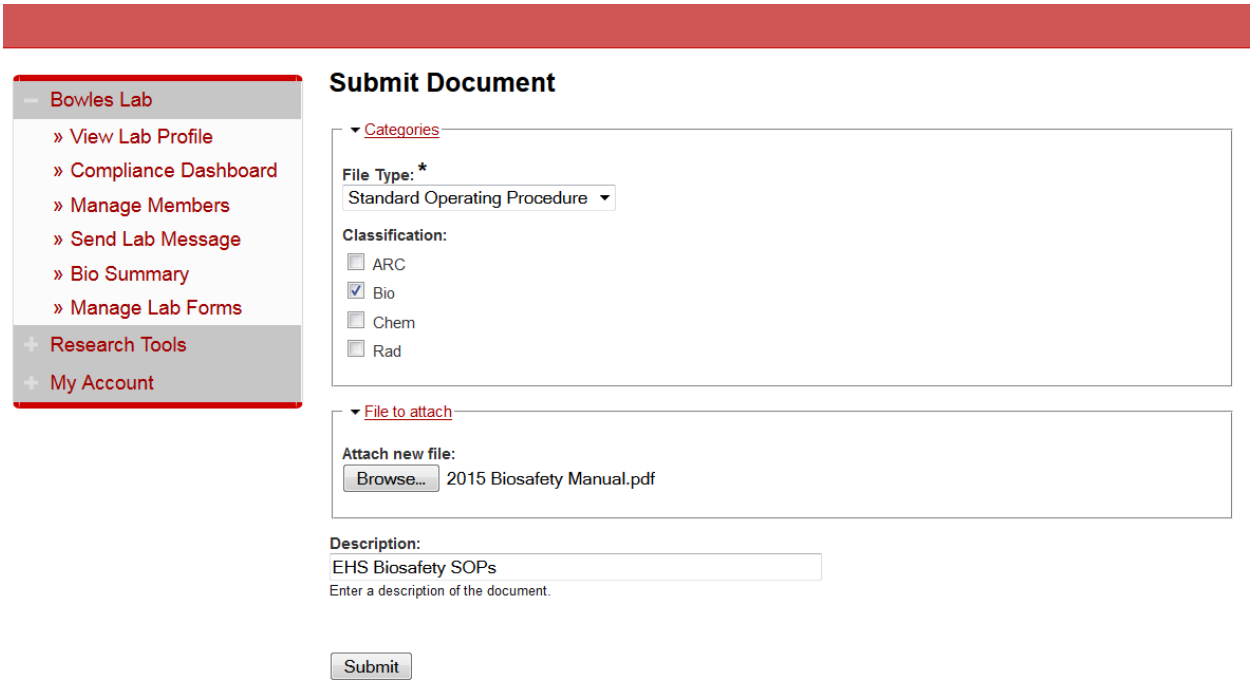
Click “Attach a New Document” (bottom right) and add any documentation supporting your registration. Please submit as PDFs, if possible. Additional documents could include, for example:

Viral Vector maps

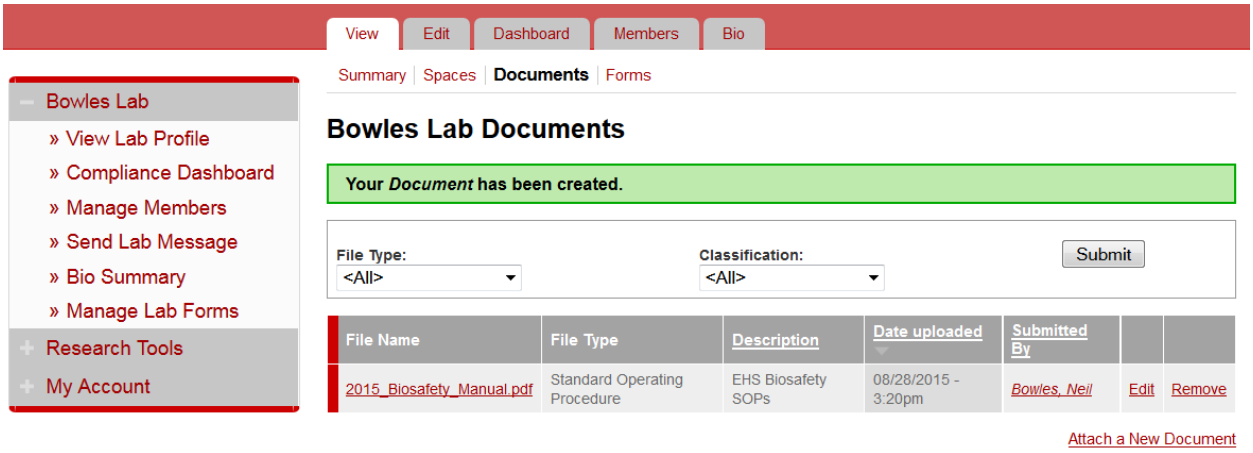
Spills and Exposure Procedures

Lab specific SOPs (if additional information or detail needs to be added to the Registration narrative). The IBC has generated model SOPs for BSL2 and BSL2 enhanced laboratories (*link to model documents*). These can be modified for BSL1 laboratories.

Select the File type. Put a check in the “Bio” box. Browse for the file and add a description. Click “Submit”



Once submitted the screen will show:



At this point your Registration is complete. If an initial review by the Biosafety Officers does not identify problems or issues they will submit it for IBC review. If the Biosafety Officers or IBC request changes to the registration please complete the process outlined on the following page.

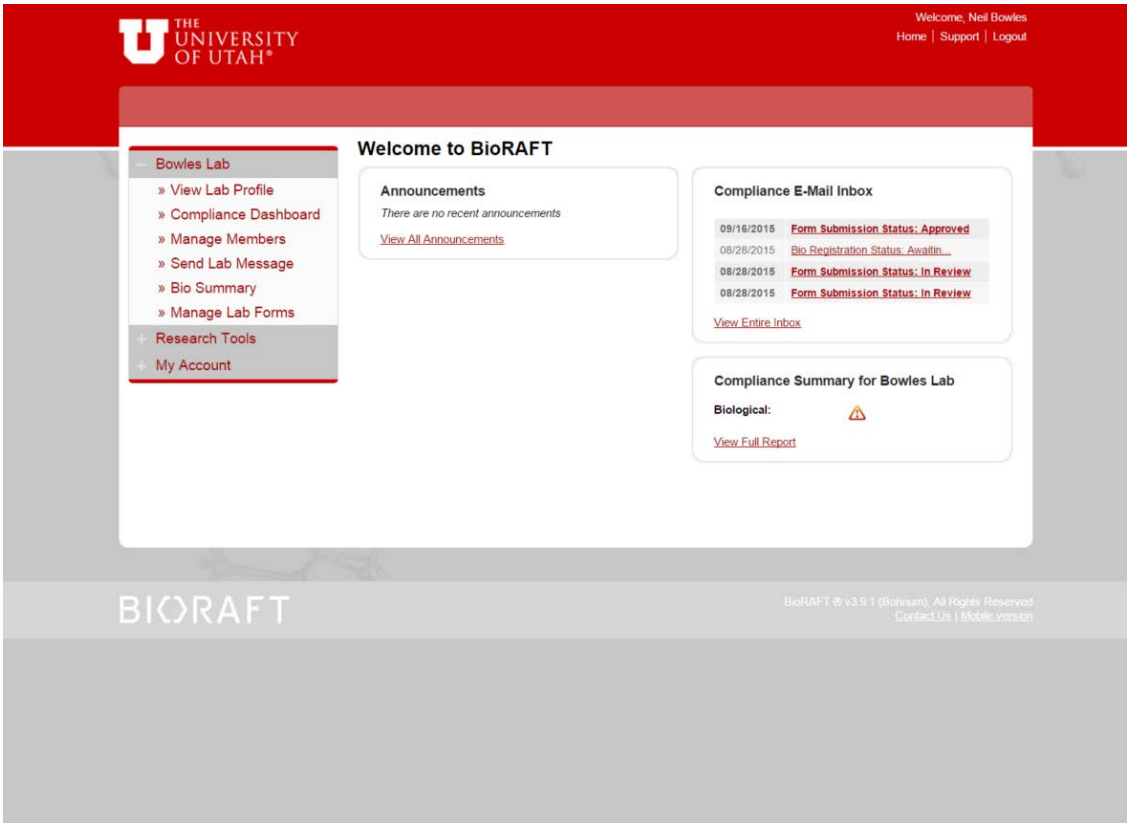
Once approved by the IBC the registration will be valid for up to 3 years. Note that if the laboratory adds new viral vectors/pathogens/projects they will need to be submitted as an amendment to this Registration through BioRAFT, as described below. This will not alter the renewal date.

BioRAFT will send annual reminders for PIs to review their registration and confirm that it is still accurate.

Amendments/Editing Registrations

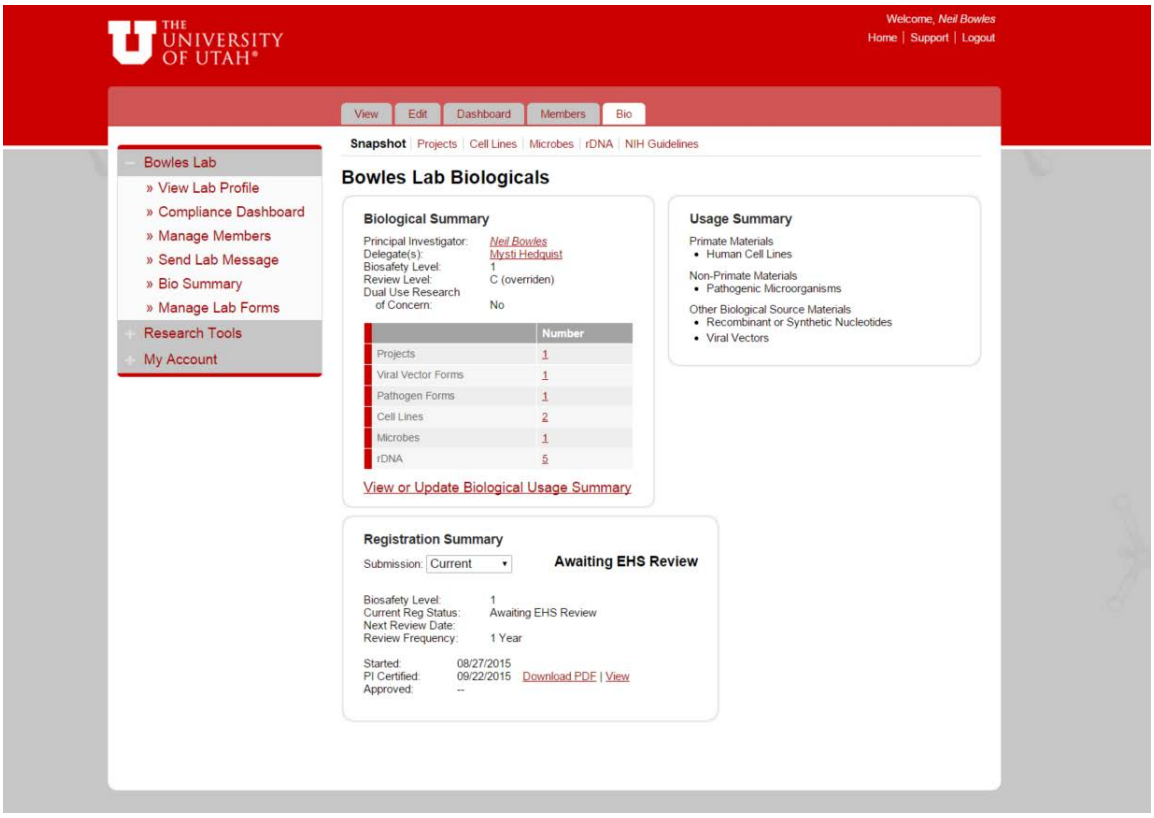
If you need to make an amendment to your registration either because you have made changes to the protocol (e.g. new staff/employees/students, changes in vectors/pathogens, etc) or in response to the IBC review follow the following steps;

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"**



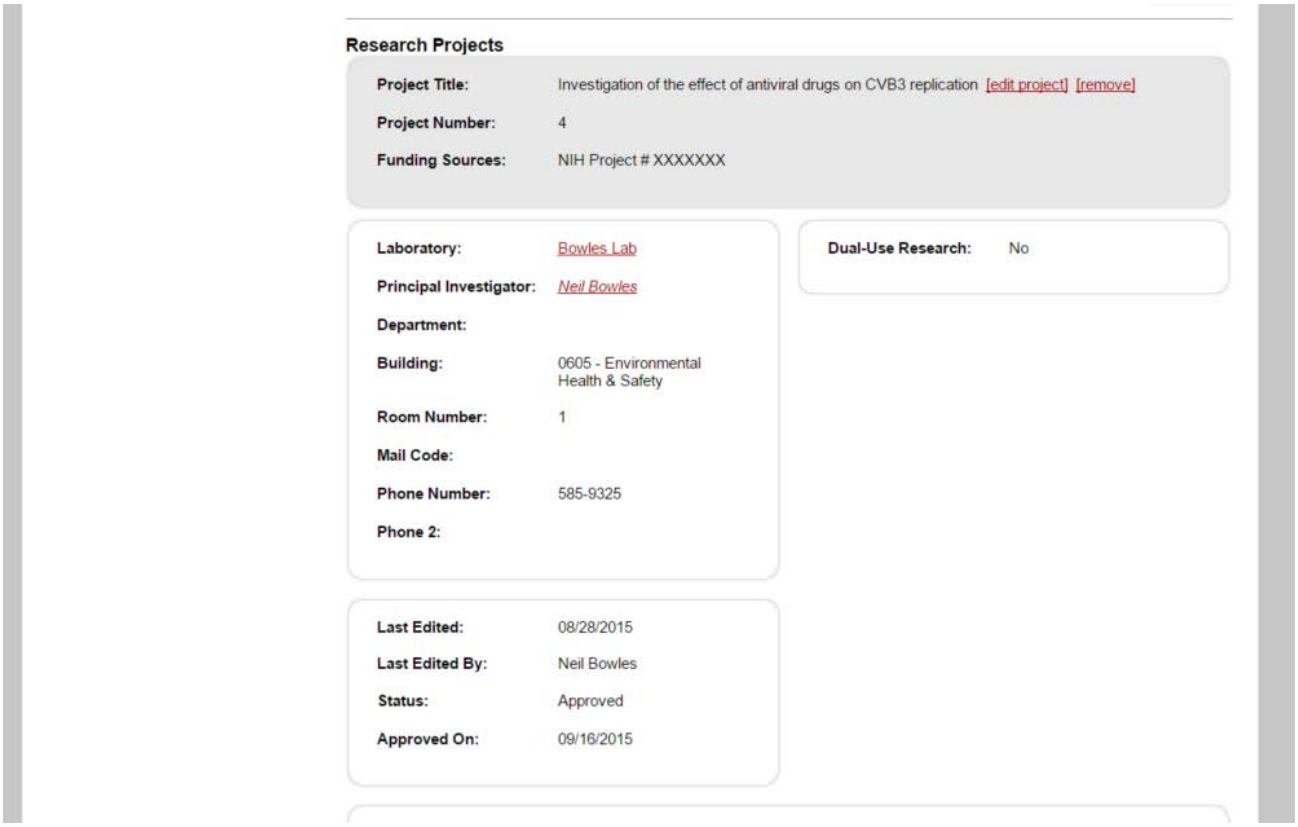
Click on "**View or Update Biological Usage Summary**"

This will open the Biological Usage summary page.

If there are no additional changes follow the instructions beginning on page 30. 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.

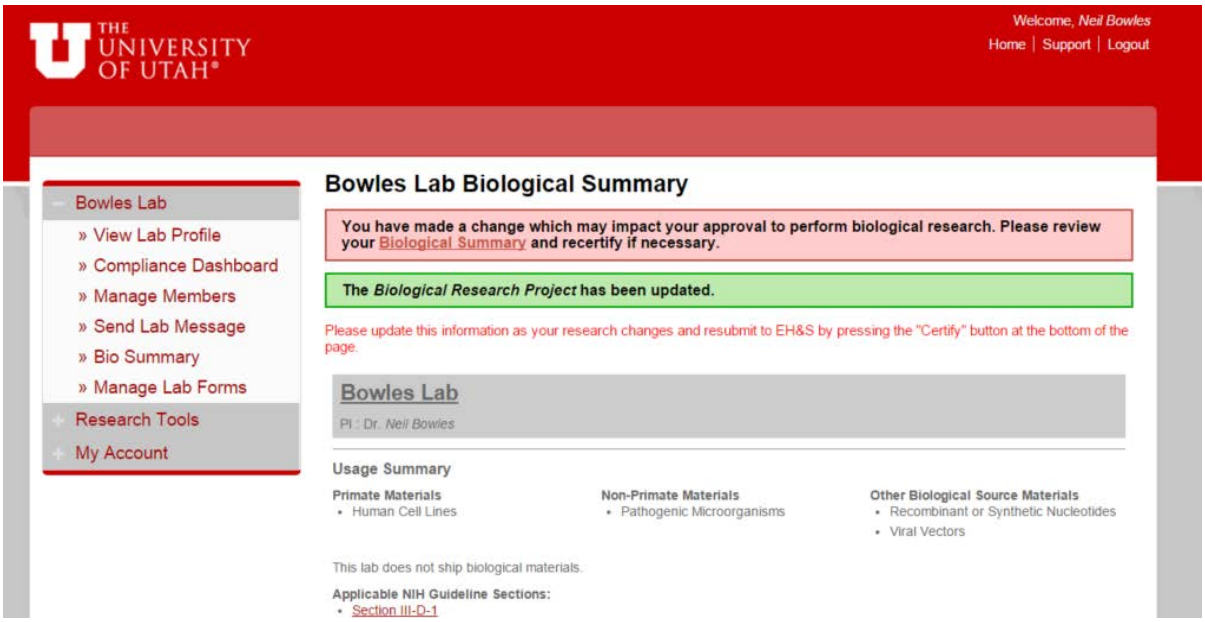
If you need to make an amendment to a form or research project, go to next page.

Editing Projects



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

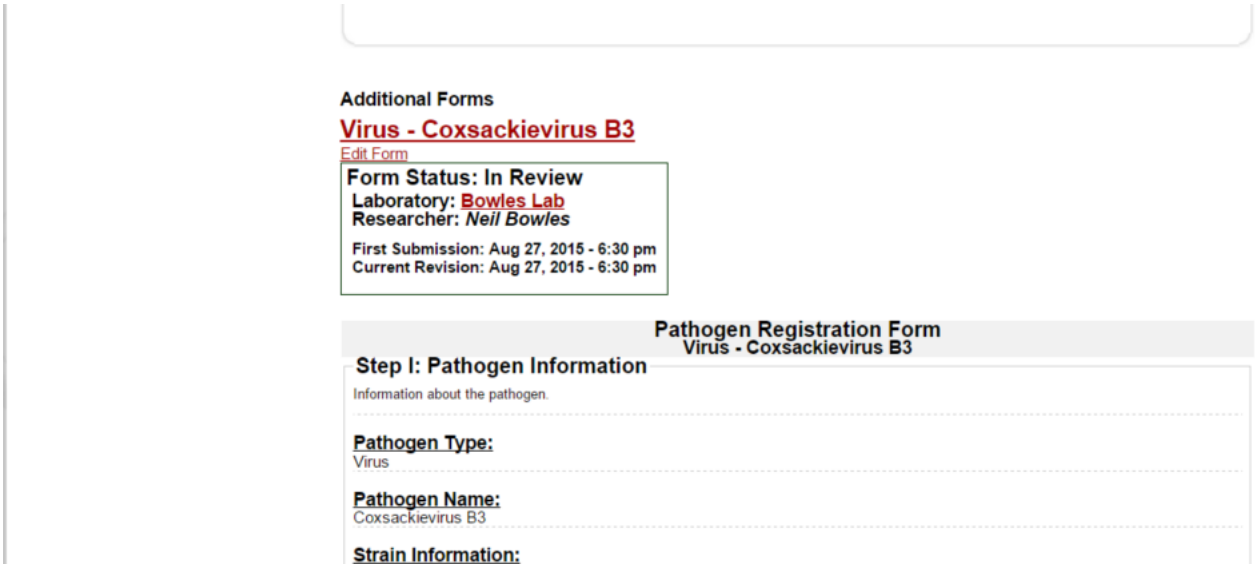
Make the necessary changes and click the "**Submit**" at the bottom of the page. This will take you back to the Biological Summary page.



If there are no additional changes follow the instructions beginning on page 30.

If you need to make an amendment to a viral vector or pathogen form, go to next page.

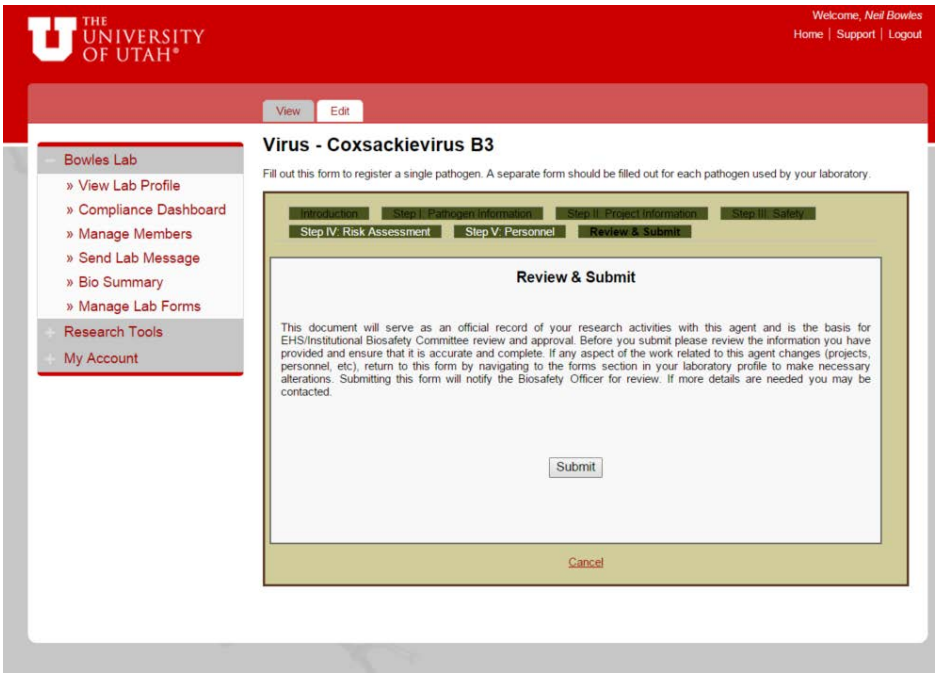
Editing Viral Vector or Pathogen Forms



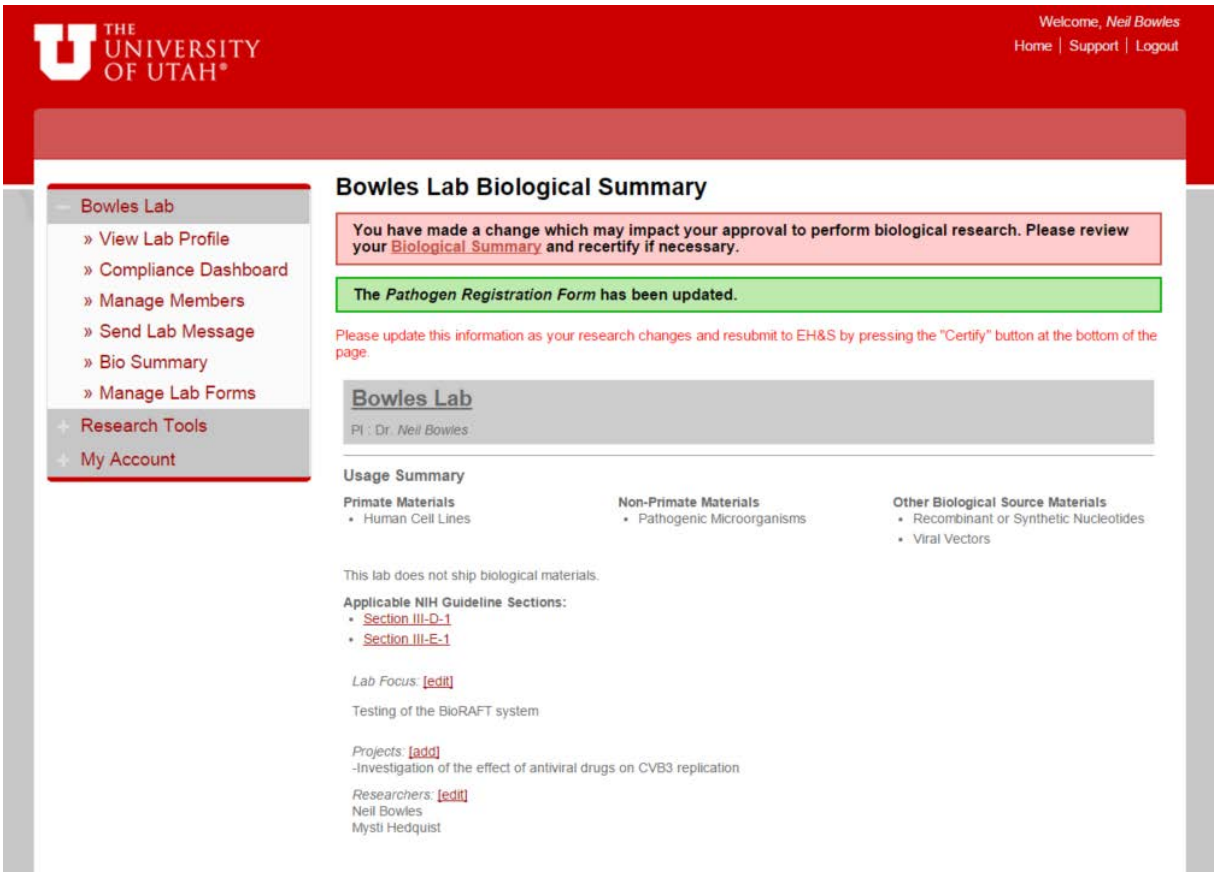
Click on "**Edit form**" below the name of the agent/vector.

Make the necessary changes, clicking through the tabs.

Click on "**Review and Submit**" tab and click "**Submit**"



This will take you back to the Biological Summary page.



If there are no additional changes follow the instructions beginning on page 30.

If you need to make additional changes repeat above steps.