

**Guide to BioRAFT
Research Management System**

Biological Laboratories with Exempt Protocols

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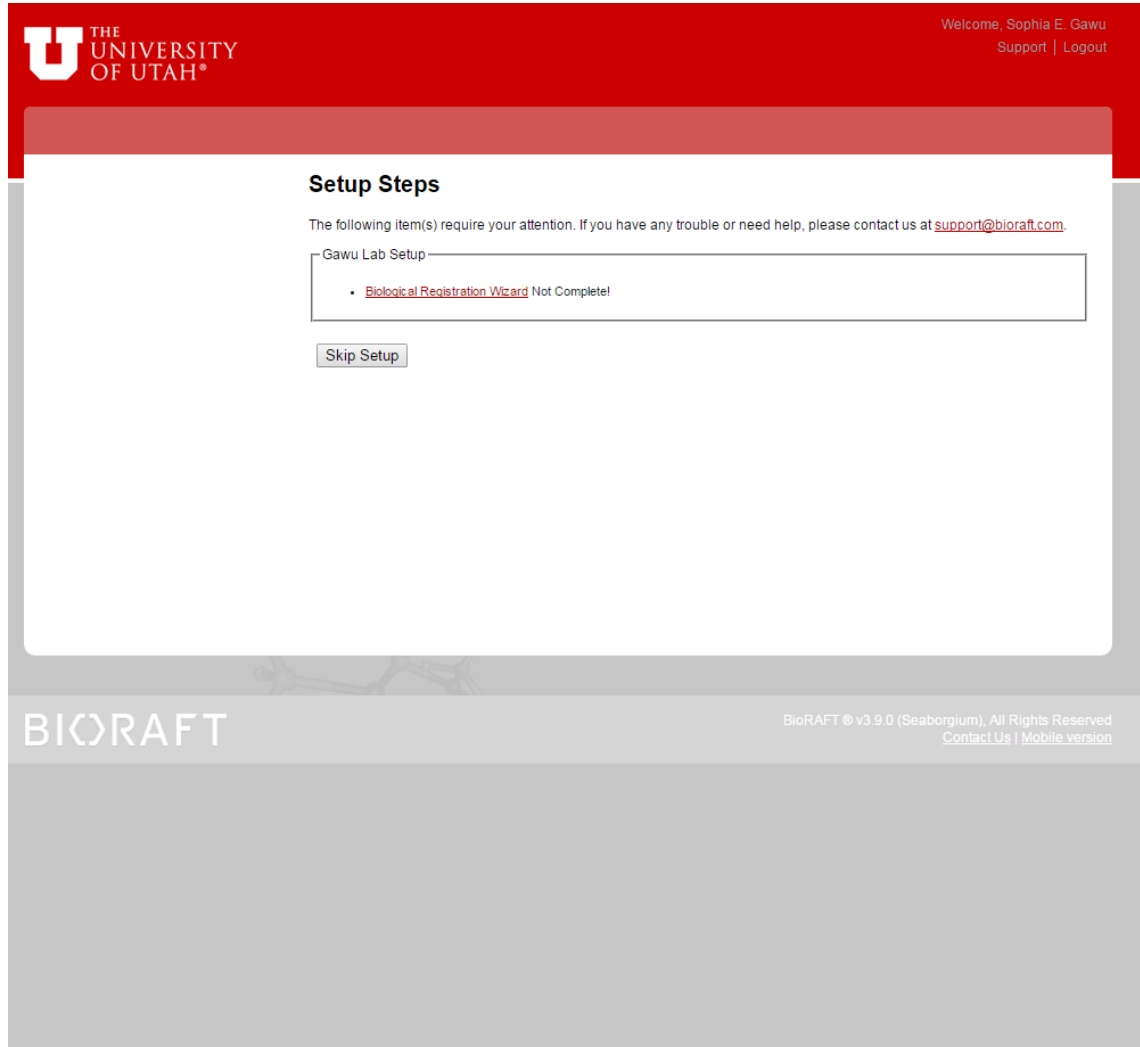
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Biological labs with exempt protocols

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.”

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Biological Registration Wizard

Welcome to the Biological Registration Process.

PIs are required to register their usage of biohazardous agents and materials with the Institutional Biosafety Committee (IBC).

This wizard will guide you through:

1. Adding Project Forms
2. A series of questions pertinent to your areas of research
3. Building your "Biological Registration Summary"
4. Submitting your summary to the Institutional Biosafety Committee (IBC)

Depending on your research this process will take 30 minutes to 2 hours for initial population of your profile. Survey and form data will autosave and you can return at a later time to complete and submit your registration. You will need to update your submissions or add additional forms for future re-registrations, mid-year modifications, or before new research projects begin to ensure your profile is up to date.

If you would like, you may delegate this process to another member of your lab: [Delegate Now](#)

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.

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Enter Laboratory's Research Projects

Please enter information about the specifics of your laboratory's projects. Entry of this information is important for compliance registration purposes.

These are the projects currently ongoing in the Bowles Lab as well as projects that are intended to start in the next year.

Project Title		
There are currently no projects listed for this lab.		

[Add a Project](#)

When finished please click "Next Step" to proceed

[Previous Step](#) [Next Step](#)

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
- ☒ 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
- ☒ 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:

Additional Information:

USDA/APHIS/PPQ Permits:

Additional Information:

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	<input type="checkbox"/>	<input type="checkbox"/>
0605	Environmental Health & Safety - 101 - office	<input type="checkbox"/>	<input type="checkbox"/>
L.S. Skaggs Jr. Research Building	4121 - Lab	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Project Team Members

Please identify all of the people involved in this project. Use the look up tool below to add people to the project who are not a member of your laboratory group.

Laboratory group members involved in this project:

Please identify all of the people involved in this project. Use the lookup tool below to add people to the project who are not a member of your laboratory group.

☒ Bowles, Neil - Principal Investigator
☒ Hedquist, Mysti - Co-Investigator

Other individuals involved in this project:

Martin Tristani-Firouzi - Pediatric Cardiology [Remove](#)

Please use the look up tool to add any additional people who are involved in this project.

External collaborators:

Please use the text area to provide any additional external collaborator(s) who are involved in this project.
Provide name and collaborator's place of work. eg. Bill Smith (Parent Institute)

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”

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Enter Laboratory's Research Projects

You have made a change which may impact your approval to perform biological research. Please review your [Biological Summary](#) and recertify if necessary.

Your *Biological Research Project* has been created.

Please enter information about the specifics of your laboratory's projects. Entry of this information is important for compliance registration purposes.

These are the projects currently ongoing in the Bowles Lab as well as projects that are intended to start in the next year.

Project Title		
The role of MYH6 in Cardiac Development	Edit	remove

[Add a Project](#)

When finished please click "Next Step" to proceed

[Previous Step](#)[Next Step](#)

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”

The screenshot displays the 'Biological Registration Wizard' interface. On the left is a sidebar menu with the following items: 'Biological Welcome', 'Enter Laboratory's Research Projects', 'Biological Surveys' (highlighted), 'Human Source Materials Survey' (highlighted in red), 'Recombinant or Synthetic Nucleic Acid Molecules Survey', 'Enter Biological Materials', 'Enter Human Cell Lines', 'Enter Human Tissues', 'Enter Microbial Agents', 'Enter Biological Toxins', 'Enter Nucleic Acid Reagents', 'Add Biological Forms', 'Review Biological Registration', 'Submit Biological Registration', and 'Biological Registration Complete'. The main content area is titled 'Human Source Materials Survey' and features a tabbed interface with tabs for 'Intro', 'Cell Lines', 'Tissues & Fluids', 'Describe', and 'Save & Continue'. The 'Intro' tab is active, showing the survey title and introductory text: 'Activities or experiments with human source materials can increase the risk of exposure to bloodborne pathogens. Experiments may also require review by the Institutional Review Board. Working with human source materials (cell lines, tissues, blood, etc.) may constitute a moderate risk to personnel and the environment. Please consult with institutional policies for any training requirements. Proceed to the next tab to begin the human source materials questions.' At the bottom right of the main content area, there is a link: 'Survey doesn't apply to you? [Opt Out](#)'.

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.”

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Recombinant or Synthetic Nucleic Acid Molecules Survey

Intro Form Questions Exempt Experiments Save & Continue

Recombinant or Synthetic Nucleic Acid Molecules

In 2013 the NIH enacted a revised set of the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules ([NIH Guidelines](#)).

As per the NIH Guidelines: 1) As a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, the institution is required to ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, comply with the NIH Guidelines; and 2) On behalf of the institution, the Principal Investigator is responsible for full compliance with the NIH Guidelines in the conduct of recombinant or synthetic nucleic acid molecule research.

Each Principal Investigator is required to:

- Document those sections of NIH Guidelines that apply to their research
- Assist in a risk assessment and identification of appropriate containment levels
- Obtain approval (or an exemption) from the Institutional Biosafety Committee

This form is designed to help streamline this process by guiding you through the NIH Guidelines. It uses conditional logic to present the required questions. Answering "Yes" to certain questions will prompt follow up questions. Please contact your Biological Safety Officer if you need assistance.

NIH Guidelines Definition of Recombinant DNA and Synthetic Nucleic Acid Molecules [🔗](#)

Proceed to the next tab to begin the recombinant or synthetic nucleic acid molecules questions.

Survey doesn't apply to you? [Opt Out](#)

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

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Enter Human Cell Lines

Your Cell Line has been created.

Use this page to enter the 10 most common human cell lines used in your lab. Be sure to list any used for viral vector packaging. Enter each cell line and click "Add". When you are finished, please click "Next Step" below.

Cell Line Name	Cell Type/Origin	Viral Packaging		
293T	Human Embryonic Kidney	No	Edit	remove

Cell Line Name: *

Cell Type/Origin: *

E.g. Human Kidney, Glioma, etc

Viral Packaging: *

☐ No

☐ Yes

Add Cell Line

When finished please click "Next Step" to proceed

Previous Step

Next Step

After adding all cell lines, click on "Next Step".

On the next screen add Microbial Agents

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Enter Microbial Agents

Your *Microbial Agent - Bacteria* has been added/updated.

Use this page to enter the microbial agents used in your lab. When you are finished, please click "Next Step" below to proceed.

Please note: The NIH Risk Group listed does not correspond to the biosafety level at which work can be safely performed. Based on information provided, the biosafety level for the laboratory will be assigned by a biosafety officer.

Current Bacteria in Bowles Lab

Genus	Species	Sub Species	Strain	Risk Group Level	Pathogenicity	Select Agent		
Escherichia	coli, K-12 series		DH5 alpha	1		No	Edit	Remove

→ [Add Bacteria](#)

Current Fungi/Yeast in Bowles Lab

Genus	Species	Strain	Risk Group Level	Pathogenicity	Select Agent		
None Listed							

→ [Add Fungi/Yeast](#)

Current Viruses in Bowles Lab

Virus Name	Viral Group	Virus Strain	Risk Group Level	Pathogenicity	Select Agent		
None Listed							

→ [Add Viruses](#)

Current Parasites in Bowles Lab

Genus	Species	Risk Group Level	Pathogenicity	Select Agent		
None Listed						

→ [Add Parasites](#)

Current Prion Diseases in Bowles Lab

Genus	Risk Group Level	Select Agent	Pathogenicity		
None Listed					

→ [Add Prion Diseases](#)

When finished please click "Next Step" to proceed

[Previous Step](#)[Next Step](#)

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

Click on "Next Step"

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Enter Biological Toxins

Use this page to enter the biological toxins used in your lab. Enter each toxin and click "Add". When you are finished, please click "Next Step" below.

Biological Toxins

Current Bio Toxins in Bowles Lab

Toxin	CAS #	Max Quant. Stored	Stock Conc.	Working Conc.	Select Toxin	
There are currently no biological toxins listed for the Bowles Lab.						

Add Biological Toxins

Previous Step

Next Step

When finished please click "Next Step" to proceed

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”.

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Enter Nucleic Acid Reagents

Your Plasmid has been created.

Use this page to enter the nucleic acid reagents used in your lab. When you are finished, please click "Next Step" below.

Plasmids Used By Bowles Lab

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

[Add Plasmid](#)

Transgenic/Recombinant Animals Used By Bowles Lab

Species	Type	Name		
Transgenic/Recombinant Animals Used By Bowles Lab :				
None Listed				

[Add Transgenic/Recombinant Animals](#)

When finished please click "Next Step" to proceed

[Previous Step](#)
[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 Wizard

Biological Welcome

General Biological Usage Survey

Biological Surveys

Add Biological Forms

Enter Laboratory's Research Projects

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Biological Registration Forms

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
No Biological Registration Forms have been filled out for this lab.					

[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

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

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Biological Toxins Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Biological Toxins

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Biological Registration Wizard

The following is a summary of the information provided during your Lab Setup and Biological Registration. This summary will be wrapped as a PDF and will serve as an official time stamped record of your laboratory's activities. Following submission, this summary will be sent to the Biosafety Officer for review and then to the Institutional Biosafety Committee for review. Please review this carefully and click edit as necessary to update or add information. *When complete, please certify this summary by clicking the button at the bottom of this page.*

Bowles Lab
PI : Dr. Neil Bowles

Usage Summary

Primate Materials <ul style="list-style-type: none">• None	Non-Primate Materials <ul style="list-style-type: none">• None	Other Biological Source Materials <ul style="list-style-type: none">• Recombinant or Synthetic Nucleotides• Viral Vectors
---	---	---

This lab does not ship biological materials.

Applicable NIH Guideline Sections:

- [Section III-F-8](#)

Lab Focus: [\[edit\]](#)

Testing of the BioRAFT system

Projects: [\[add\]](#)
-The role of MYH6 in Cardiac Development

Researchers: [\[edit\]](#)
Neil Bowles
Mysti Hedquist

Detailed Pages

Recombinant or Synthetic Nucleic Acid Molecules Survey

Last updated on 11/06/2015 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

17

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”.

Biological Registration Wizard

Biological Welcome

General Biological Usage Survey

Biological Surveys

Add Biological Forms

Enter Laboratory's Research Projects

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

Biological Registration Wizard

Certify and Submit to the Institutional Biosafety Committee

Please read the following and initial each section.

By signing this form you are agreeing to all of these statements and certifying that all of the information currently displayed in the Biological Registration section of your lab profile is accurate and complete.

Please initial using NB.

I hereby certify that the information provided in this form represents the current and planned research in my lab. I am familiar with and agree to abide by the provisions of the current NIH Guidelines, the NIH Guide for Grants and Contracts, other specific NIH instructions pertaining to the proposed project as well as any Policies and Procedures related to biological research, and local state and federal regulations.: *

NB

a. I will initiate no recombinant DNA research subject to the NIH Guidelines or research with pathogenic organisms until that research has been reviewed and approved/registered with the Institutional Biosafety Committee.: *

NB

b. I will ensure that those working in my laboratory will follow laboratory techniques and practices outlined in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) and the Biosafety Manual appropriate for the designated biosafety level and the research done in my labs.: *

NB

c. I will supervise staff, and correct work errors and conditions that could result in unsafe laboratory practices or breaches of the NIH Guidelines.: *

NB

d. I will follow all applicable Federal and international regulations whenever I ship biological materials domestically and internationally. I will also obtain the proper importation or exportation permits/licenses through the EHS Office before shipping to or receiving from any international location any biological material.: *

NB

e. I will ensure that staff are trained in: good microbiological practices and techniques required to ensure safety for this project, in the procedures for dealing with accidents, and in waste management procedures. In addition, I will assure that all listed personnel who have occupational exposure to human source materials will receive annual bloodborne pathogen training through EHS.: *

NB

f. I will inform the EHS Office of any significant research-related accident or illness as soon as possible after its occurrence.: *

NB

g. I will inform the EHS Office of any significant changes to my research.: *

NB

By clicking this button I, Neil Bowles, agree to all of the terms stated above.

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

The screenshot shows a web interface for the 'Biological Registration Wizard'. On the left is a vertical sidebar with a list of steps: 'Biological Welcome', 'General Biological Usage Survey', 'Biological Surveys' (highlighted in red), 'Add Biological Forms', 'Enter Laboratory's Research Projects', 'Review Biological Registration', 'Submit Biological Registration', and 'Biological Registration Complete'. The main content area is titled 'Biological Registration Wizard' and features a green success message box at the top with three bullet points: 'Email successfully sent to Derek Hedquist, [view message.](#)', 'Email successfully sent to NEIL BOWLES, [view message.](#)', and 'Your biological registration has been submitted for review.' Below this is a white box with a thank-you message and a 'Continue' button.

Biological Registration Wizard

- Email successfully sent to Derek Hedquist, [view message.](#)
- Email successfully sent to NEIL BOWLES, [view message.](#)
- Your biological registration has been submitted for review.

Thank you for submitting your Biological Registration! This document has been sent to your Biological Safety Officer for review. He or she may contact you for additional information or clarification. If necessary, your registration will then be passed on for review by the Institutional Biosafety Committee (IBC).

In the future, as your research changes, please return to this system and update your registration in your lab's profile. You will be notified in one year, when you will be required to review, update and recertify this information.

[Continue](#)

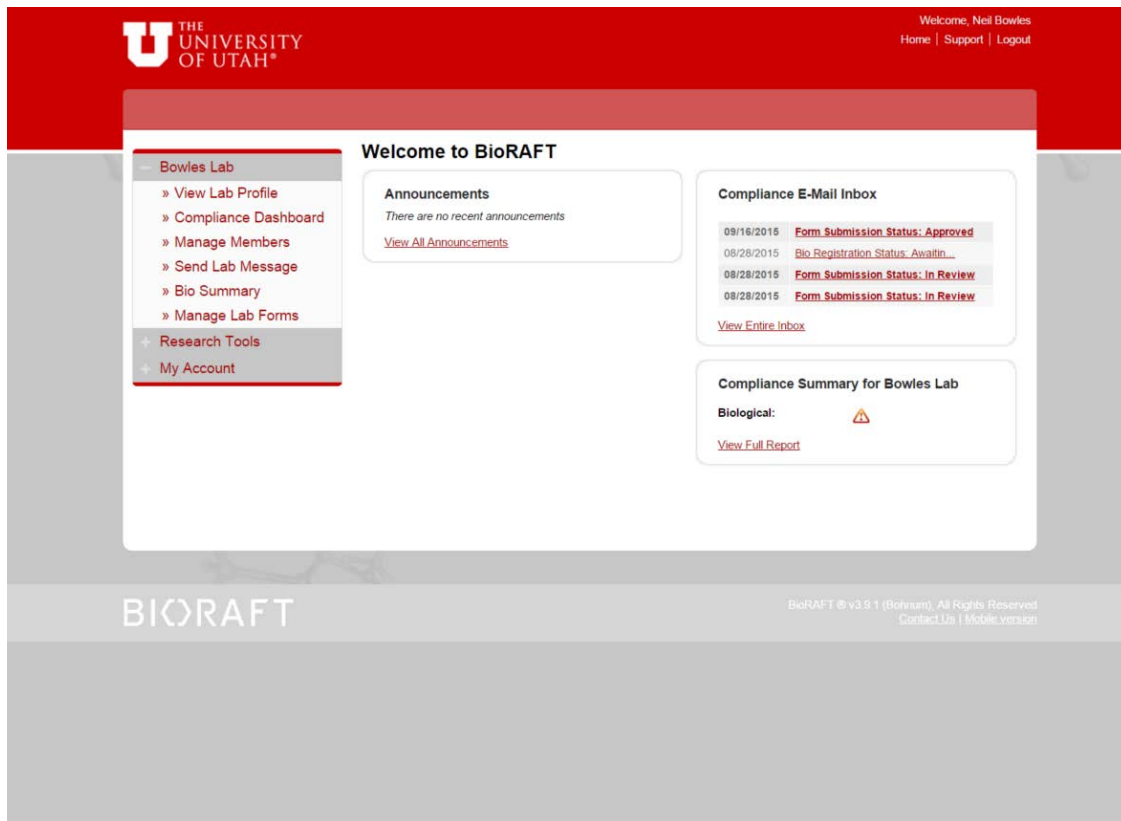
Click on “Continue.” This will take you back to BioRAFT Dashboard.

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**”

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Welcome, Neil Bowles
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View
Edit
Dashboard
Members
Bio

Snapshot
Projects
Cell Lines
Microbes
rDNA
NIH Guidelines

Bowles Lab
» View Lab Profile
» Compliance Dashboard
» Manage Members
» Send Lab Message
» Bio Summary
» Manage Lab Forms

Research Tools
My Account

Bowles Lab Biologicals

Biological Summary

Principal Investigator: [Neil Bowles](#)

Delegate(s): [Mysh Hedquist](#)

Biosafety Level: 1

Review Level: C (overridden)

Dual Use Research of Concern: No

	Number
Projects	1
Viral Vector Forms	1
Pathogen Forms	1
Cell Lines	2
Microbes	1
rDNA	2

[View or Update Biological Usage Summary](#)

Usage Summary

Primate Materials

- Human Cell Lines

Non-Primate Materials

- Pathogenic Microorganisms

Other Biological Source Materials

- Recombinant or Synthetic Nucleotides
- Viral Vectors

Registration Summary

Submission: Current

Awaiting EHS Review

Biosafety Level: 1

Current Reg Status: Awaiting EHS Review

Next Review Date: 1 Year

Review Frequency: 1 Year

Started: 08/27/2015

PI Certified: 09/22/2015 [Download PDF](#) | [View](#)

Approved: --

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

Research Projects

Project Title: Investigation of the effect of antiviral drugs on CVB3 replication [\[edit project\]](#) [\[remove\]](#)
Project Number: 4
Funding Sources: NIH Project # XXXXXXXX


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: 08/28/2015
Last Edited By: Neil Bowles
Status: Approved
Approved On: 09/16/2015

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.



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Welcome, Neil Bowles

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Bowles Lab

» View Lab Profile

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» Manage Members

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» Bio Summary

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+ Research Tools

+ My Account

Bowles Lab Biological Summary

You have made a change which may impact your approval to perform biological research. Please review your [Biological Summary](#) and recertify if necessary.

The *Biological Research Project* has been updated.

Please update this information as your research changes and resubmit to EH&S by pressing the "Certify" button at the bottom of the page.

Bowles Lab

PI : Dr. Neil Bowles

Usage Summary

Primate Materials

- Human Cell Lines

Non-Primate Materials

- Pathogenic Microorganisms

Other Biological Source Materials

- Recombinant or Synthetic Nucleotides
- Viral Vectors

This lab does not ship biological materials.

Applicable NIH Guideline Sections:

- [Section III-D-1](#)

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