

**Guide to BioRAFT  
Research Management System**

**Biological Laboratories with Non-Exempt Biological  
Protocols**

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### **Biological labs with non-exempt protocols**

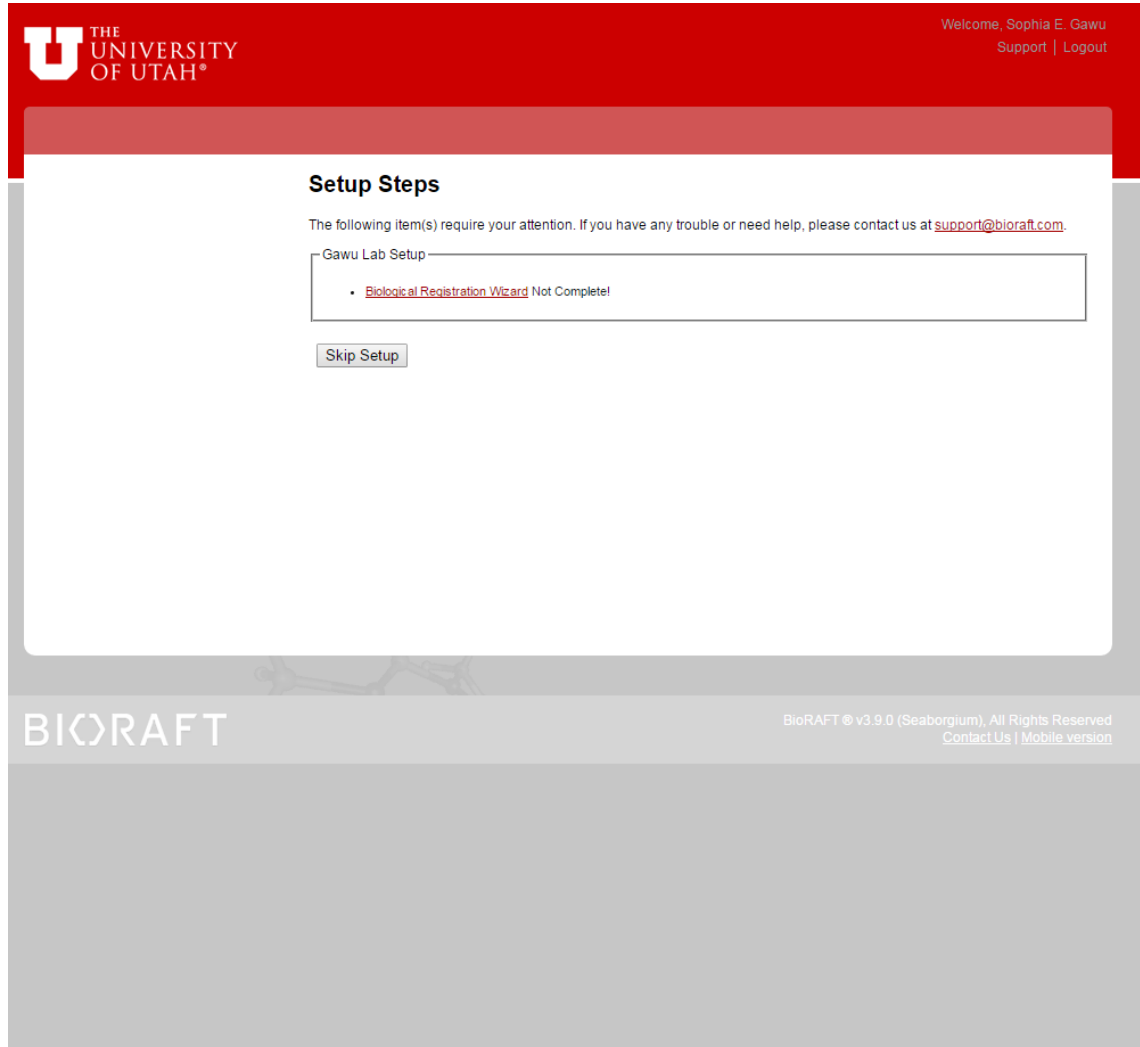
Principal Investigators with a Biological lab and projects that are **not** exempt from IBC review and approval (this includes work with human and animal pathogens (risk group 2 or higher), recombinant and synthetic DNA (as defined by the NIH Guidelines) and certain biological toxins) are required to 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.”

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](#)

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.

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. 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) <sup>?</sup>
- ☐ Non-Pathogenic Microorganisms
- ☐ Pathogenic Microorganisms
- ☐ Plants <sup>?</sup>
- ☐ 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 <sup>?</sup>
- ☐ Physical Hazards <sup>?</sup>
- ☐ Other Hazards <sup>?</sup>

**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, 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

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:

CDC Import/Export 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.G. 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)

[Cancel](#)

Click on Submit

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

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

Biological Registration Complete

## Enter Laboratory's Research Projects

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	<a href="#">Edit</a>	<a href="#">remove</a>

[Add a Project](#)

When finished please click "Next Step" to proceed

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

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”

The screenshot displays the 'Biological Registration Wizard' interface. On the left is a vertical sidebar with a list of steps: 'Biological Welcome', 'Enter Laboratory's Research Projects', 'Biological Surveys' (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 'Intro', 'Cell Lines', 'Tissues & Fluids', 'Describe', and 'Save & Continue'. The 'Intro' tab is active, showing introductory text about the risks of human source materials and a link to 'Opt Out' if the survey does not apply.

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

**Human Source Materials Survey**

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

Biological Registration Complete

**Human Source Materials Survey**

Intro Cell Lines Tissues & Fluids Describe Save & Continue

**Human Source Materials Survey**

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.

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

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

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

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

Biological Registration Complete

## Enter Human Cell Lines

The Cell Line has been updated.

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	Yes	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 StepNext Step

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).

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

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

Biological Registration Complete

## Enter Human Tissues

Your *Tissue* has been created.

Use this page to enter the human tissues used in your lab. Be sure to enter all tissues in which pathogens are present. Enter each tissue and click "Add". When you are finished, please click "Next Step" below.

Tissue Type	Preparation	Pathogen	Source		
Blood	Fluid - Blood, Sputum, etc.	No	Human Subject	<a href="#">Edit</a>	<a href="#">remove</a>
Cardiac	Fresh Frozen	No	Human Subject	<a href="#">Edit</a>	<a href="#">remove</a>

Tissue Type: \*

Preparation: \*

Autopsy

Biopsy - Live

Fixed - Tissue or Fluid

Fluid - Blood, Sputum, etc.

Fresh Frozen

Histological Sections / Smears

Ctrl + Click to select multiple. Multiple selection will create multiple entries.

Are pathogens known to be present?: \*

☐ Yes
 ☐ No

Source: \*

Colleague

Add Tissue

When finished please click "Next Step" to proceed

Previous Step

Next Step

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	<a href="#">Edit</a>	<a href="#">Remove</a>

→ [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.

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

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

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

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](#)

When finished please click "Next Step" to proceed

Previous StepNext Step

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.

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

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

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		
p.EF1a-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
<a href="#">Add Plasmid</a>				

Transgenic/Recombinant Animals Used By Bowles Lab		
Species	Type	Name
Transgenic/Recombinant Animals Used By Bowles Lab :		
None Listed		
<a href="#">Add Transgenic/Recombinant Animals</a>		

When finished please click "Next Step" to proceed

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

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”.

- 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.
- 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.**

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

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](#)

## 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.

The screenshot shows the 'Step I: Pathogen Information' section of a web-based registration form. At the top, there are navigation tabs: 'Introduction', 'Step I: Pathogen Information' (active), 'Step II: Project Information', 'Step III: Safety', 'Step IV: Risk Assessment', 'Step V: Personnel', and 'Review & Submit'. Below the tabs, the section title 'Step I: Pathogen Information' is followed by the instruction 'Provide information about this pathogen as it pertains to your laboratory.' The form contains several fields: 'Pathogen Type:' with a dropdown menu showing 'Bacteria' (selected), 'Fungus/Yeast', 'Parasite', 'Prion', and 'Virus'; 'Strain Information:' with a text box; 'Where will you obtain the infectious agent?:' with a text box; 'How will it be transported to your laboratory?:' with a text box; 'Have there been (or will there be) any genetic modifications to this agent?:' with radio buttons for 'Yes' and 'No'; and a table for 'List locations where the pathogen will be stored or used:' with columns for 'Building', 'Room', and 'Facility (Lab, Cell Culture, ARC, Flow lab, etc)'. The table has three rows, numbered 1, 2, and 3.

## 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 PI's 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.**

### Submit Viral Vector Registration Form

Fill in the information on a single viral vector system as defined by the components used in the generation of the virus. If you are working with multiple systems, please complete a separate questionnaire for each.

IntroductionStep 1: Vector InformationStep 2: Vector ProductionStep 3: Insert InformationStep 4: Viral Usage LocationStep 5: SafetyStep 6: PersonnelReview & Submit

This Research Center maintains a listing of all human and animal pathogens and viral vectors in use at this Center in order to identify research areas where biohazards may exist.

Environmental Health and Safety uses this information to:

1. Provide a system for checking that containment practices and facilities are appropriate and adequate for the safety of workers in the laboratory and immediate environment.
2. Reviews this information with this Research Center's Biosafety Committee. This committee assists EHS in developing policies and procedures; in reviewing specific projects, if necessary; and in evaluating responses to potential emergencies.
3. Notify Occupational Medicine and Health Services of persons who are working with human pathogens. Occ. Med will review the individual's potential for occupational exposure to specific microorganisms, identify applicable surveillance programs, and provide employees with the opportunity for the appropriate immunizations, if applicable.
4. Inform emergency response personnel of potential hazards within a particular laboratory, should it be necessary to respond to accidents, fires, or other catastrophic events.
5. Comply with the requirements of granting agencies for registration of biohazardous materials.

As an integral part of this registration, Principal investigators are responsible for:

1. Suggesting the Biosafety Level to be used for work with the organism in accordance with this Research Center's policy.
2. Informing personnel, at risk of potential exposure, of the practices, procedures, and equipment required for the safe conduct of work with the organism.
3. Informing personnel at risk of occupational exposure of the signs and symptoms associated with infection by the organism.
4. Informing personnel of the necessity to report promptly to both the Principal Investigator and EHS any known or suspected exposure to the organism.
5. Reporting accidents with the organism to EHS, who will notify the appropriate personnel for follow-up.
6. Notifying EHS when changes in personnel occur, when the laboratory changes location, or when work with the human pathogen ends so that the records of EHS can be updated.

**For any questions please contact your BioSafety Officer.**

Use the tabs at the top of the page to jump between sections of the form.

*This form will **not** save until it has been submitted on the final page.*

Next

Cancel

## 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 PI's 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-Adenovirus type 5 expressing Myh6	Viral Vector Registration Form	Bowles, Neil	11/10/2015 - 12:22pm	11/10/2015 - 12:22pm	In Review	<a href="#">Edit</a>
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	<a href="#">Edit</a>

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

Biological Registration Wizard

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

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

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

<b>Primate Materials</b> <ul style="list-style-type: none"><li>Human Cell Lines</li><li>Human Tissues</li></ul>	<b>Non-Primate Materials</b> <ul style="list-style-type: none"><li>None</li></ul>	<b>Other Biological Source Materials</b> <ul style="list-style-type: none"><li>Recombinant or Synthetic Nucleotides</li><li>Viral Vectors</li></ul>
-----------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------

This lab does not ship biological materials.

Applicable NIH Guideline Sections:

- [Section III-D-1](#)
- [Section III-D-3](#)
- [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

##### Human Source Materials Survey

Last updated on 11/10/2015 by Neil Bowles

Actions: [Edit Responses](#) | [Remove Survey](#) | [View Revisions](#)

Which of the following do you do with human cell lines?:

- Culture transformed or immortalized human cell lines
- Introduce recombinant or synthetic nucleic acids into human cells/cell lines
- Infect/transduce human cells with recombinant viruses
- Infect/transduce human cells with viral vectors
- Isolate or use induced pluripotent stem cells (iPSCs)

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 Embryonic Kidney	Yes	<a href="#">Edit</a>	<a href="#">Remove</a>

[Add Cell Line](#)

Tissues Used in Lab:

Tissue Type	Preparation	Pathogen	Source		
Blood	Fluid - Blood, Sputum, etc.	No	Human Subject	<a href="#">Edit</a>	<a href="#">Remove</a>
Cardiac	Fresh Frozen	No	Human Subject	<a href="#">Edit</a>	<a href="#">Remove</a>

[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-17?:  
No
- 2) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-27?:  
No
- 3) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-37?:  
No
- 4) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-47?:  
No
- 5) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-57?:  
No
- 6) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-67?:  
No
- 7) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-77?:  
No
- 8) Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-87?:  
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.EF1a-hSTEMCCA-LoxP (OKS/L-Myc)	OCT4, Klf4, SOX2, Myc	Lentiviral	<a href="#">Edit</a>	<a href="#">Remove</a>
pRSV-REV	Rev	Lentiviral	<a href="#">Edit</a>	<a href="#">Remove</a>
pMDLg/pRRE	Gag and Pol	Lentiviral	<a href="#">Edit</a>	<a href="#">Remove</a>
pMD2.G	VSV-G	Other (Details Below)	<a href="#">Edit</a>	<a href="#">Remove</a>

[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-Adenovirus 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-Adenovirus type 5 expressing Myh6

#### Step 1: Vector Information

Information on the viral vector system.

**Viral Vector System name:**

Adenovirus 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

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.

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.

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:

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

- 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.

Bowles Lab

Research Tools

My Account

» My Profile

» Bowles Lab

» Messaging

» Log out

Announcements

There are no recent announcements

[View All Announcements](#)


Compliance E-Mail Inbox

08/28/2015	<a href="#">Bio Registration Status: Awaiting...</a>
08/28/2015	<a href="#">Form Submission Status: In Review</a>
08/28/2015	<a href="#">Form Submission Status: In Review</a>
08/27/2015	<a href="#">Form Submission Status: In Review</a>

[View Entire Inbox](#)

Compliance Summary for Bowles Lab

Biological:



[View Full Report](#)

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”

View

Edit

Dashboard

Members

Bio

Summary

Spaces

Documents

Forms

Bowles Lab

» View Lab Profile

» Compliance Dashboard

» Manage Members

» Send Lab Message

» Bio Summary

» Manage Lab Forms

+ Research Tools

+ My Account

**Bowles Lab**

Contact Info

Principal Investigator: [Neil Bowles](#)

Department: 0605 - Environmental Health & Safety

Building: 1

Room Number: 1

Mail Code: 585-9325


Phone 1:

Phone 2:

Fax Number:

Compliance Summary

Biological:



[View Full Report](#)

Research Focus

Testing of the BioRAFT system

Lab Status: Active

Click on “Documents”

The screenshot shows a web application interface for 'Bowles Lab'. At the top, there is a red navigation bar with tabs: 'View', 'Edit', 'Dashboard', 'Members', and 'Bio'. Below this, a secondary navigation bar shows 'Summary', 'Spaces', 'Documents' (which is highlighted), and 'Forms'. On the left side, there is a sidebar menu for 'Bowles Lab' with options: '» View Lab Profile', '» Compliance Dashboard', '» Manage Members', '» Send Lab Message', '» Bio Summary', '» Manage Lab Forms', '+ Research Tools', and '+ My Account'. The main content area is titled 'Bowles Lab Documents'. It features two dropdown menus: 'File Type:' and 'Classification:', both set to '<All>', with a 'Submit' button to the right. Below these is a table with headers: 'File Name', 'File Type', 'Description', 'Date uploaded', and 'Submitted By'. The table body contains a single row with the text 'There are currently no files attached to this Laboratory --'. At the bottom right of the table area, there is a red link that says 'Attach a New Document'.

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”

Bowles Lab

» View Lab Profile

» Compliance Dashboard

» Manage Members

» Send Lab Message

» Bio Summary

» Manage Lab Forms

+ Research Tools

+ My Account

## Submit Document

Categories

File Type: \*

Standard Operating Procedure

Classification:

☐ ARC

☒ Bio

☐ Chem

☐ Rad

File to attach

Attach new file:

Browse...

2015 Biosafety Manual.pdf

Description:

EHS Biosafety SOPs

Enter a description of the document.

Submit

Once submitted the screen will show:

The screenshot displays a web application interface for 'Bowles Lab Documents'. The top navigation bar includes 'View', 'Edit', 'Dashboard', 'Members', and 'Bio'. The sidebar on the left lists navigation options: 'Bowles Lab' (with sub-links: 'View Lab Profile', 'Compliance Dashboard', 'Manage Members', 'Send Lab Message', 'Bio Summary', 'Manage Lab Forms'), 'Research Tools', and 'My Account'. The main content area has tabs for 'Summary', 'Spaces', 'Documents' (selected), and 'Forms'. A green message box states 'Your Document has been created.' Below this is a form with 'File Type' and 'Classification' dropdown menus (both set to '<All>') and a 'Submit' button. A table lists documents with columns: File Name, File Type, Description, Date uploaded, Submitted By, and actions (Edit, Remove). The table contains one entry: '2015\_Biosafety\_Manual.pdf', 'Standard Operating Procedure', 'EHS Biosafety SOPs', '08/28/2015 - 3:20pm', and 'Bowles, Neil'. A link 'Attach a New Document' is at the bottom right.

File Name	File Type	Description	Date uploaded	Submitted By		
<a href="#">2015_Biosafety_Manual.pdf</a>	Standard Operating Procedure	EHS Biosafety SOPs	08/28/2015 - 3:20pm	<a href="#">Bowles, Neil</a>	<a href="#">Edit</a>	<a href="#">Remove</a>

[Attach a New Document](#)

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.

The screenshot shows the BioRAFT web application interface. At the top, there is a red header with the University of Utah logo on the left and a welcome message "Welcome, Neil Bowles" with links for "Home", "Support", and "Logout" on the right. Below the header, the main content area is divided into several sections. On the left, there is a sidebar menu with a red border containing links for "Bowles Lab" (with sub-links: "View Lab Profile", "Compliance Dashboard", "Manage Members", "Send Lab Message", "Bio Summary", "Manage Lab Forms"), "Research Tools", and "My Account". The main content area is titled "Welcome to BioRAFT" and contains three primary sections: "Announcements" (stating "There are no recent announcements" with a link to "View All Announcements"), "Compliance E-Mail Inbox" (listing four entries with dates and statuses: "09/16/2015 Form Submission Status: Approved", "08/28/2015 Bio Registration Status: Awaitin...", "08/28/2015 Form Submission Status: In Review", and "08/28/2015 Form Submission Status: In Review", with a link to "View Entire Inbox"), and "Compliance Summary for Bowles Lab" (showing a "Biological:" status with a warning icon and a link to "View Full Report"). At the bottom of the page, there is a grey footer with the "BioRAFT" logo on the left and copyright information "BioRAFT © v3.9.1 (Bohrum), All Rights Reserved. Contact Us | Mobile version" on the right.

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

Home | Support | Logout

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:

Review Frequency:

1 Year

Started:

08/27/2015

PI Certified:

09/22/2015

Approved:

--

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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

### 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

Home | Support | Logout

Bowles Lab

» View Lab Profile

» Compliance Dashboard

» Manage Members

» Send Lab Message

» Bio Summary

» Manage Lab Forms

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 30.

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



This will take you back to the Biological Summary page.

The screenshot shows the 'Bowles Lab Biological Summary' page. At the top, the University of Utah logo is on the left, and 'Welcome, Neil Bowles' with links for 'Home', 'Support', and 'Logout' is on the right. A left-hand navigation menu for 'Bowles Lab' includes links to 'View Lab Profile', 'Compliance Dashboard', 'Manage Members', 'Send Lab Message', 'Bio Summary', 'Manage Lab Forms', 'Research Tools', and 'My Account'. The main content area features a red warning box stating: 'You have made a change which may impact your approval to perform biological research. Please review your [Biological Summary](#) and recertify if necessary.' Below this is a green success box: 'The Pathogen Registration Form has been updated.' A red text prompt asks the user to 'Please update this information as your research changes and resubmit to EH&S by pressing the "Certify" button at the bottom of the page.' The 'Bowles Lab' header shows 'PI : Dr. Neil Bowles'. Under 'Usage Summary', there are three categories: 'Primate Materials' (Human Cell Lines), 'Non-Primate Materials' (Pathogenic Microorganisms), and 'Other Biological Source Materials' (Recombinant or Synthetic Nucleotides, Viral Vectors). A note states 'This lab does not ship biological materials.' 'Applicable NIH Guideline Sections' include 'Section III-D-1' and 'Section III-E-1'. 'Lab Focus' is '[edit]' and 'Testing of the BioRAFT system'. 'Projects' includes '[add]' and '-Investigation of the effect of antiviral drugs on CVB3 replication'. 'Researchers' lists '[edit]', 'Neil Bowles', and 'Mysti Hedquist'.

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

If you need to make additional changes repeat above steps.