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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](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)
1. To begin your Biological Registration Wizard, click the ‘Biological Registration Wizard’ link.

Note if you have already completed the registration wizard (only available the first time) you will see a screen shown on page 37. Follow the instructions for editing the Biological Registration beginning on page 38.
An introductory screen will appear. You have the opportunity to delegate a member of the laboratory to complete the registration. Otherwise Click “Continue.”
**Entering Research Projects**

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

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

Click on “Add a Project.”
This will open a survey. Please complete as appropriate.
Other Biological Source Materials:
- Lab Animal Tissues (Non-Pediatric)
- Lab Animals (Non-Pediatric)
- Non-Pathogenic Microorganisms
- Pathogenic Microorganisms
- Pathogens
- Select Agent Pathogenic Microorganisms

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 at least one 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 or agricultural justification
- Contributes to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against the 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

Note: Dual-use research of concern is included in the following: Akanle influenza virus (high pathogenic), Bacillus anthracis, Bovine leukemia virus, Bovine pestivirus, Burkholderia mallei, Burkholderia pseudomallei, Ebola virus, Foot-and-mouth disease virus, Francisella tularensis, Marburg virus, Reconstructed H1N1 Influenza virus, Rinderpest virus, Toxoplasma gondii, Ovine listeriosis, Vaccinia major virus, Varicella zoster virus, or Variola pestis.

Description of Experimental and Procedural Details: [Example]

- Lentiviral vectors expressing OCT4, SOX2, KLF4 and c-Myc
- Characterize differences in cellular structure and gene expression between cells from patients and controls
- Determine if transduction with mMYD-MMR 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 downstream 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: 1000000

Additional Information:

USDA/APHIS/PPQ Permits:

Additional Information:

CDC Import/Export Permits:

Additional Information:
Click on Submit
Repeat for all research projects on-going in your laboratory.

When complete, Click “Next Step”
Completing Biological Surveys
This will initiate a series of Surveys, dependent on the answers in the registration.

Potential Surveys that may be triggered:
- Human Source Materials Survey
- Laboratory Animal Cell Lines (Non-Primate) Survey
- Non-Human Primate Source Materials Survey
- Plants Survey
- Microbial Agents Survey
- Biological Toxins Survey
- Recombinant & Synthetic Nucleic Acids Survey
- Research of Concern Survey

Answer the questions under each tab and click “Save”

If you believe the survey does not apply, click on “Opt Out.”
In this example the next step is the Recombinant or Synthetic Nucleic Acid Molecules Survey, which will confirm whether the work you are doing is exempt under the NIH guidelines. Click on each tab and answer each of the questions.

Under the second tab (Form questions), if you check yes to any of the questions your work is NOT exempt from IBC review.

Under the third tab (Exempt experiments), answer yes to any of the exemptions that apply. If you answer yes to at least one category of exemption then the work is likely exempt from IBC review. Note the expression of genes/cDNAs in a plasmid (non-viral) vector in eukaryotic cells would typically be exempt under Section III-F-8. However, if the plasmid is expressing an oncogene or biological toxin, Q8 should be answered “No.”

On the last tab, click “Save”
**Entering Biological Materials**

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

- Human Cell Lines
- Human Tissues
- Plants
- **Microbial Agents**
  - Bacteria, Viruses, Fungi, Parasites
- Biological Toxins
- **Nucleic Acid Reagents**
  - Plasmids and Inserts
  - Recombinant Animals
In this example the first screen asks you to enter cell lines that are used in your lab.

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

![Cell line entry screen](image-url)
In this example we have indicated that we use human tissue (blood and cardiac tissue collected during surgery).

Click on “Next Step”
On the next screen add Microbial Agents

<table>
<thead>
<tr>
<th>Current Bacteria in Bowles Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genus</strong></td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Escherichia</td>
</tr>
</tbody>
</table>

- Add Bacteria

<table>
<thead>
<tr>
<th>Current Fungi/Yeast in Bowles Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genus</strong></td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>None Listed</td>
</tr>
</tbody>
</table>

- Add Fungi/Yeast

<table>
<thead>
<tr>
<th>Current Viruses in Bowles Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Virus Name</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>None Listed</td>
</tr>
</tbody>
</table>

- Add Viruses

<table>
<thead>
<tr>
<th>Current Parasites in Bowles Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genus</strong></td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>None Listed</td>
</tr>
</tbody>
</table>

- Add Parasites

<table>
<thead>
<tr>
<th>Current Prion Diseases in Bowles Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genus</strong></td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>None Listed</td>
</tr>
</tbody>
</table>

- Add Prion Diseases

When finished please click "Next Step" to proceed

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

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

Click “Next Step”
Plasmids
Add the names of plasmids commonly used in your laboratory by clicking the “Add Plasmid” button. Please note that EHS is not expecting all plasmids that are used in your lab, just the ones relevant to the registration. However, please include all plasmids that:
1) Can replicate in eukaryotic cells, or
2) Encode DNA elements that can integrate into DNA, or
3) Express an oncogene or biological toxin that is lethal for vertebrates at an LD50 of less than 100ng/kg body weight, or
4) Express genes of human pathogens (viruses, bacteria, etc).
5) Viral vectors

Transgenic/Recombinant Animals
Only add transgenic/recombinant animals if you are creating them in your laboratory (i.e. do not enter commercially purchased animals or generated in the University of Utah Core). However, if you are using a recombinant vector to introduce mutations/genes or knockout genes please list the animals here.

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

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

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

Click “Next Step”.

Click “Next Step”.

Click “Next Step”.

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Add Biological Registration Forms

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

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

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

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

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

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

Notes

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

1) The laboratory-specific SOPs can be attached to the Registration (see page 33). All questions should be answered but description can be brief or refer to the SOPs. In order to assist the PI the IBC has developed model SOPs for BSL2 and BSL2 enhanced laboratories, which can be
downloaded from the IB website (http://ehs.utah.edu/research-safety/biosafety/protocol-review/recombinant-dna-registration). **This is the preferred option for the IBC** because:

a. It ensures that the laboratory has SOPs in place that will provide information on all aspects of safe operating procedures to personnel

b. NIH and the Institution expect comprehensive SOPs to be available to all personnel
c. It will be incorporated into training
d. If the SOPs are complete, it reduces the likelihood that registrations will require prolonged IBC review

2. Complete descriptions of laboratory procedures can be provided on these forms. For PIs renewing IBC approved protocols much of the narrative can be copied from their current SOPs. For Step II: Project Information, in the box entitled “Provide a brief description of project(s) involving this agent”, provide SOPs including, as applicable, but not limited to:

   e. Methods of production
   f. Methods of titering
   g. What happens to infected cells
   h. Decontamination procedures

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

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

**NOTE:** If you are using pathogens with similar properties/containment requirements/SOPs you can list multiple agents on one form, as long as all checkboxes require the same response.
Viral Vector Registration Form
The Viral Vector replaces the recombinant and synthetic nucleic acid registration forms currently used by the IBC. This form will auto save every 75 seconds. A bar will appear at the bottom of the page to alert you when the form has been saved.

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

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

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

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

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

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

   These forms cannot be cloned or copied at present. Therefore, if you need to submit multiple Viral Vector Registration forms with similar narratives we recommend that you prepare the text in Word (or other word processing software) and copy into the text boxes.
NOTE: If you are using vectors with similar properties/containment requirements/SOPs you can list multiple agents on one form, as long as all checkboxes require the same response. For example using vectors expressing different transgenes could be on a single form.

Attach vector maps (PDF format) in the documents section of the Laboratory Registration: see page 33 for instructions.
Once you have completed the Pathogen or Viral Vector forms click on “Next Step”

**Biological Registration Forms**

*Your Viral Vector Registration Form has been created.*

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

**Biological Forms Submitted**

<table>
<thead>
<tr>
<th>Regarding</th>
<th>Submitted Form</th>
<th>Submitted By</th>
<th>Submission Date</th>
<th>Last Updated</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral Vector Registration Form-Adnovirus type 5 expressing Myh8</td>
<td>Viral Vector Registration Form</td>
<td>Bowles, Neil</td>
<td>11/10/2015 - 12:22pm</td>
<td>11/10/2015 - 12:22pm</td>
<td>In Review</td>
</tr>
<tr>
<td>Viral Vector Registration Form-Third Generation Lentivirus System</td>
<td>Viral Vector Registration Form</td>
<td>Bowles, Neil</td>
<td>08/26/2015 - 9:30am</td>
<td>11/10/2015 - 12:17pm</td>
<td>Denied</td>
</tr>
</tbody>
</table>

Thank you for entering a form

**Add Pathogen Registration**

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

**Add Viral Vector Form**

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

*When finished please click "Next Step" to proceed*

[Previous Step] [Next Step]
Review Biological Registration
On the next screen you will see a summary of your Registration. If everything is correct, click “Certify” at the bottom of the screen. If there are errors they can be edited by clicking on the “edit” or “edit responses” buttons.
Upon initial receipt, human tissues and/or fluids used by my laboratory are:

- Tissues
- Cells

**Describe:** Generate IPS cardiomyocytes from blood samples from patients with CHD. Transduce IPS cardiomyocytes with recombinant adenoviral vectors expressing IFN.

**Cell Lines Used in Lab:**

<table>
<thead>
<tr>
<th>Cell Line Name</th>
<th>Cell Type/Origin</th>
<th>Viral Packaging</th>
<th>Cell Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>293T</td>
<td>Human Embryonic Kidney</td>
<td>Yes</td>
<td>HCT116</td>
</tr>
</tbody>
</table>

**Tissues Used in Lab:**

<table>
<thead>
<tr>
<th>Tissue Type</th>
<th>Preparation</th>
<th>Pathogen</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td>Fluid - Blood, Sputum, etc.</td>
<td>No</td>
<td>Human Subject</td>
</tr>
<tr>
<td>Carcass</td>
<td>Fresh Frozen</td>
<td>No</td>
<td>Human Subject</td>
</tr>
</tbody>
</table>

**Recombinant or Synthetic Nucleic Acid Molecules Survey**

- **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 LDR of less than 100 mg/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 non-pathogenic prokaryotic or lower eukaryotic host vector systems?: No
- 6) Do your experiments involve the use of infectious DNA or RNA Viruses in tissue culture systems? (This includes the use of a packaging cell line) to generate viral particles for transmission?: Yes
- 6a) Do your experiments involve the formation of DNA molecules containing no more than 2/3 of the genome of any eukaryotic virus?: No
- 6b) Do your experiments involve the use of defective DNA or RNA viruses in the presence of a helper virus in tissue culture?: No
- 6c) 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 8-F-1?: No
- 2) Are any experiments conducted under your research exempt under NIH Guidelines Section 8-F-2?: No
- 3) Are any experiments conducted under your research exempt under NIH Guidelines Section 8-F-3?: No
- 4) Are any experiments conducted under your research exempt under NIH Guidelines Section 8-F-4?: No
- 5) Are any experiments conducted under your research exempt under NIH Guidelines Section 8-F-5?: No
- 6) Are any experiments conducted under your research exempt under NIH Guidelines Section 8-F-6?: No
- 7) Are any experiments conducted under your research exempt under NIH Guidelines Section 8-F-7?: No
- 8) Are any experiments conducted under your research exempt under NIH Guidelines Section 8-F-8?: Not a toxin or cognate

**Transgenic/Recombinant Animals Used in Lab:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Type</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add Transgenic/Recombinant Animals</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Research Projects

**Project Title:**
The role of MYH6 in Cardiac Development

**Project Number:**
22

**Funding Sources:**
National Institutes of Health

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Dual-Use Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brenner Lab</td>
<td>No</td>
</tr>
</tbody>
</table>

**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 explain 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 Considerations:**
No dual-use categories were selected.

**Description of Experimental and Procedural Details:**

VIA mines develop RPS 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 RPS cardiomyocytes from patient and unaffected relatives using plasmid vectors expressing OCT4, SCNT, K56, and OTX2
2. Characterize differences in cellular structure and gene expression between cells from patients and controls
3. Generate cardiomyocytes with ADHr/myh6 knock in the phenotype in patient RPS cardiomyocytes

**Authorizations and Permits**

**RSP Number:**
10000212

**Additional Information:**

All 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:**

<table>
<thead>
<tr>
<th>Room</th>
<th>Surgical</th>
<th>Training</th>
<th>Work</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>8031</td>
<td>Medical Research &amp; Education Bldg - 101 - Lab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>803</td>
<td>Environmental Health &amp; Safety - 101 - Office</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4121</td>
<td>L.S. Stagg Jr Research Building - Lab</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

27
Additional Forms

Viral Vector Registration Form - Adenovirus type 5 expressing Myh6

Form Status: In Review
Laboratory: Broad Lab
Researcher: Neil Bovars
First Submission: Nov 10, 2015 - 2:22 pm
Current Revision: Nov 10, 2015 - 2:22 pm

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 prep?:
No

Step 2: Vector Production
Information on the viral vector production methods.

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

Offsite/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 be produced?:

Step 3: Insert Information
Information about the insert to be used with this viral vector system.

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

<table>
<thead>
<tr>
<th>Gene/Insert Name</th>
<th>Source/Species</th>
<th>Type (e.g. cDNA)</th>
<th>Gene Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Human</td>
<td>cDNA</td>
<td>Structural</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

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

Will there be deliberate formation of cDNAs 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 projects involving this viral system:

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

<table>
<thead>
<tr>
<th>Location</th>
<th>Volume</th>
<th>Project Name</th>
<th>Facility (Lab, Cell Culture, ABC, Flow lab, etc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>750</td>
<td>-</td>
<td>Lab</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Once you have finished reviewing your summary, click the ‘Certify’ button at the bottom of the page. Go to page 30.

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

You should receive the message:

- **Email successfully sent to PI name, view message.**
- **PI name** has been notified via email that the registration is ready for submission

The PI should be prompted to complete the registration as described on the next page.
Submit Registration
To certify and submit your Biological Registration to the Biosafety Officers, read the following sections and initial in each box.

Once you are ready to submit your Biological Registration, click the ‘Certify and Submit’ button at the bottom of the page.
The Registration is submitted to the Biosafety Program. The screen will show:
Click on “Continue.” This will take you back to BioRAFT Dashboard.

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

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

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

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

Viral Vector maps

Spills and Exposure Procedures

Lab specific SOPs (if additional information or detail needs to be added to the Registration narrative). The IBC has generated model SOPs for BSL2 and BSL2 enhanced laboratories (link to model documents). These can be modified for BSL1 laboratories.
Select the File type. Put a check in the “Bio” box. Browse for the file and add a description. Click “Submit”
Once submitted the screen will show:

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

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

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

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

Log in to BioRAFT.

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

To make changes to your Biological Registration, Click on “Bio Summary”
Click on “View or Update Biological Usage Summary”

This will open the Biological Usage summary page.

If there are no additional changes follow the instructions beginning on page 30. Note that if the new personnel are using viral vectors or pathogens they will need to be added to the project form as described below.

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

Click on the “edit project” button to the right of the project title.

Make the necessary changes and click the “Submit” at the bottom of the page. This will take you back to the Biological Summary page.
If there are no additional changes follow the instructions beginning on page 30.

If you need to make an amendment to a viral vector or pathogen form, go to next page.
Editing Viral Vector or Pathogen Forms

Click on “Edit form” below the name of the agent/vector.

Make the necessary changes, clicking through the tabs.

Click on “Review and Submit” tab and click “Submit”
This will take you back to the Biological Summary page.

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

If you need to make additional changes repeat above steps.