

BioRAFT Biological Registration  
P.I. Quick Start Guide



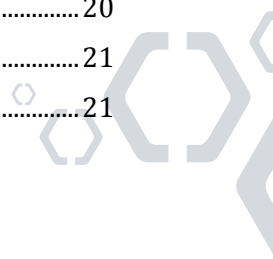
Prepared by BioRAFT Professional Services

*Confidential*

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## BioRAFT Biological Registration Module Introduction

The BioRAFT Biological Registration Module allows for easy to follow registration of biological activities in the laboratory. Through the Biological Registration Wizard [the](#) Principal Investigator will be asked to fill out information on their projects and make determinations as to the work they conduct in their laboratory. Those determinations may prompt further surveys or forms that may assist a Biological Safety Officer or Institutional Biological Safety Committee in the assessment of the Biological Safety Level and potential hazards associated with that laboratory.

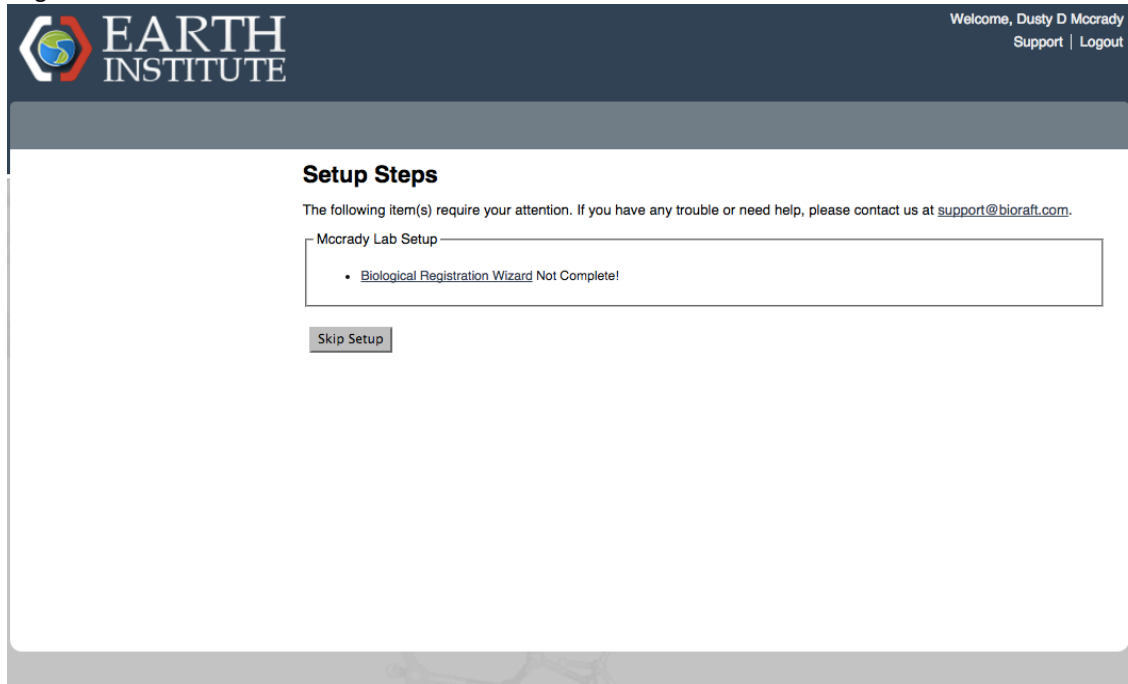




## Biological Registration- PI User Guide

### 1. Biological Registration Prompt

Upon log in, the PI will be prompted to fill out their Biological Registration using the Biological Registration Wizard.



The screenshot shows the Earth Institute website interface. At the top left is the Earth Institute logo. At the top right, it says "Welcome, Dusty D Mocrady" with links for "Support" and "Logout". The main content area is titled "Setup Steps" and contains the following text: "The following item(s) require your attention. If you have any trouble or need help, please contact us at [support@bioraft.com](mailto:support@bioraft.com)." Below this is a box for "Mocrady Lab Setup" with a bullet point: "• [Biological Registration Wizard](#) Not Complete!". At the bottom of the box is a "Skip Setup" button.

### 2. Biological Registration Wizard

The PI will be prompted with instructions on how to complete the Biological Registration Wizard. At this point they may delegate the Registration to an approved member of their laboratory. The PI should notice that there are no required Surveys or Data Entry at this point, because the Biological Usage has not yet been indicated in the Project Forms. Click "Continue" to begin the Biological Registration Wizard if you do not wish to delegate this task to someone else.



### 3. Adding Projects


After selecting “Continue” the PI will be brought to the “Enter Laboratory’s Research Projects” page. Click “Add a Project” to enter a new Project to your Biological Registration.

### 3a. Project Form

When adding a Biological Research Project there will be certain fields that are required for the PI to fill out. These will be indicated with an asterisk next to the field. Throughout the process, there are areas to



hover your mouse over for “Examples.” These will help guide the user to what should be entered in the prompted field.



Welcome, Dusty D Mccrady  
[Home](#) | [Support](#) | [Logout](#)

---

## 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: \***  
 PI-User Guide

Please provide a title for this project.

**Funding Sources: \***

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

**Brief Summary of Project: [Example]**

For example, although it is fairly well accepted that pulmonary tuberculosis is a major risk factor of lung cancer, the exact molecular mechanisms involved in its tumorigenesis are unclear. For this purpose, we will be examining the relationship between Mycobacterium tuberculosis (M-TB) infection and gene alteration in lung cancer. From previous clinical studies, tumors with M-TB infection have higher AKT Phosphorylation levels compared with tumors without M-TB infection. These findings indicate that M-TB infection is associated with changes in gene expression in lung cancer that is thought to be involved in systemic metabolic pathways. Our project aims to determine if Mycobacterium tuberculosis gene transfer in vitro to lung cancer cell lines and in vivo to lung tissue alters tumor incidence in lung cancer mouse models, or if simple presence of Mycobacterium tuberculosis increases the incidence.

Provide a brief non-technical summary of your project. Please expand any acronyms.

**Project Biological Materials & Details**  
 Please select any of the biological materials categories listed below that you plan to utilize for this project.

**Primate Materials:**

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

**Non-Primate Materials:**

- Amphibians
- Arthropods
- Bloodborne Pathogens
- Fish
- Lab Animal Source Materials (Non-Primate)
- Lab Animal Tissues (Non-Primate)
- Lab Animals (Non-Primate)
- Non-Pathogenic Microorganisms
- Pathogenic Microorganisms
- Plants
- Select Agent Pathogenic Microorganisms

**Other Biological Source Materials:**

- Biological Toxins
- Infectious Proteins
- Mutagenic Agents
- Recombinant or Synthetic Nucleotides

#### 4b. Project Biological Materials and Details

The next step is to select the appropriate materials in use for this project. These selections will trigger further surveys to be filled out for more accurate classification of experiments.

**Project Biological Materials & Details**  
 Please select any of the biological materials categories listed below that you plan to utilize for this project.

**Primate Materials:**

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

**Non-Primate Materials:**

- Amphibians
- Arthropods
- Bloodborne Pathogens
- Fish
- Lab Animal Source Materials (Non-Primate)
- Lab Animal Tissues (Non-Primate)
- Lab Animals (Non-Primate)
- Non-Pathogenic Microorganisms
- Pathogenic Microorganisms
- Plants
- Select Agent Pathogenic Microorganisms

**Other Biological Source Materials:**

- Biological Toxins
- Infectious Proteins
- Mutagenic Agents
- Recombinant or Synthetic Nucleotides





## 4c. Completion of the Project Form

In BioRAFT, spaces are associated with Laboratories. Those spaces will be pre-loaded into your Project Form for easy selection. During the General Setup Wizard the PI will be asked to add members to their lab. The Project Form will automatically include those members for selection for each Project. If there is a collaborator within the institution, but not in the lab, that member can be added to the Project Form through the institutional look up. After all the information is complete, the PI will be asked to “Submit” the project, at which point they will be prompted to add additional projects, or to continue to the Survey portion of the Registration.

**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
Schwartz School of Engineering	259 - Main Lab	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Schwartz School of Engineering	260 - Cyclotron	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Schwartz School of Engineering	261 - Freezer Room	<input 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.

Mccrady, Dusty - Principal Investigator  
 Mang, Elden - Co-Investigator

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

- Adah Annette Echard
- Adah Cherilyn Shupe
- Adah Dagny Sealls
- Adalberto Alan Hector
- Adan Augustus Albright
- Adan Ronald Wells
- Addie Ingeborg Hastings
- Addie Lanita Weingarten
- Addie Stefany Schrader
- Adele Latanya Coveney
- Adele Tarsha Wood
- Adena Lakesha Leech

**External collaborators:**  
Please use the look up tool to add any additional external collaborator(s) who are involved in this project.

Bill Smith (Parent Institute)



### 5a. Biological Material Surveys

In step 5 the PI selected work associated with Human Sourced Materials, Pathogenic Microbial Agents, and Recombinant DNA on the Project Form. Those selections are now what appear on the left hand menu for the Surveys required for submission. Surveys are associated with all selections but do not appear if not required.

**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](#)*

### 5b. Material Surveys

The Material Surveys include questions and answers that may trigger additional surveys as needed. For instance, this PI indicated that their experiments “Inject human cells into laboratory animals,” therefore they will be prompted to fill out the Animal Material Survey. As you can see this is not prompted on the screen in the left hand menu at this time. When the PI completes and submits this survey, the “Animal Sourced Material Survey” will appear.

**Human Source Materials Survey**

Intro | **Cell Lines** | Tissues & Fluids | Describe | Save & Continue

**Human Cell Lines**


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

- Culture transformed or immortalized human cell lines
- Inject human cells into laboratory animals (mice, rats, etc.)
- Inject human cells into transgenic animals (mice, rats, etc.)
- Introduce recombinant or synthetic nucleic acids into human cells/cell lines
- Infect/transduce human cells with wild type viruses
- Infect/transduce human cells with recombinant viruses
- Infect/transduce human cells with viral vectors
- Introduce human pathogens into human cells
- Isolate or use primary human cells
- Isolate or use induced pluripotent stem cells (iPSCs)
- Isolate or use human embryonic stem cells (hESCs)
- Use cell lines for packaging viral vectors
- N/A

Click on the next tab at the top to navigate to the next page.

## 5c. Survey Process

The survey process will continue in this format until all triggered Biological Surveys are complete. As you will see here, the “Animal Sourced Material Survey” is now prompted. Each Survey has similar tabs with questions and formats.


Welcome, Dusty D Mccrady  
Support | Logout

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

**Animal Source Materials (Non-Primate) Survey**

Microbial Agents Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Nucleic Acid Reagents

### Animal Source Materials (Non-Primate) Survey

Intro
General
rDNA
Pathogens
Hosts
Describe
Save & Continue

**Animal Source Materials (Non-Primate)**

Activities or experiments with animals or animal source materials can increase the risk of exposure to certain pathogens or zoonosis. Experiments may be under the review of the Institutional Animal Care and Use Committee (IACUC).

The use of certain animal source materials (cell lines, tissues, blood, etc.) may constitute a moderate to severe risk to personnel and the environment.

*Please consult with the Institutional Biosafety Committee (IBC) or IACUC for any training requirements or policies.*


Proceed to the next tab to begin the animal source materials questions.

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



## 6a. Recombinant or Synthetic Nucleic Acid Molecules Survey

This survey will ask general questions regarding the overall use of Recombinant or Synthetic Nucleic Acid Molecules in the laboratory. When a topic is selected, that topic will expand, showing more relevant subsections of the NIH-Guidelines. This information will display the applicable NIH-Guideline to that specific question to the Labs Registration.


Welcome, Dusty D Mccrady  
Support | Logout

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

**Recombinant or Synthetic Nucleic Acid Molecules Survey**

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Nucleic Acid Reagents

### 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](#)*



## 6b. rDNA Survey Expansion

Answering “Yes” to the question below will show further questions with the related topics, the answer of “No” will not expand the sub-questions.

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

**Recombinant or Synthetic Nucleic Acid Molecules Survey**

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Nucleic Acid Reagents

Add Biological Forms

### Recombinant or Synthetic Nucleic Acid Molecules Survey

Intro | **Form Questions** | Exempt Experiments | Save & Continue

**Major Actions**

[NIH Guideline Section III-A-1](#)

**1 Do any of your experiments alter the host range, transmissibility, or virulence of a pathogen?: \***

Yes

No

**1-A Do any of your experiments involve the deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally?: \***

Yes

No

**Experiments Involving the Cloning of Toxins**

[NIH Guidelines Section III-B-1](#)

**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?: \***

Yes (Explain)

No

Definition of LD50

Transfer of Recombinant or Synthetic Nucleic Acid Molecules into Humans

## 6c. Additional information in the rDNA Survey

The selection of the applicable links (i.e., “[NIH Guideline Section-III-A-1](#)”) will bring you to the website of applicable NIH Guidelines. Hovering over the (?) icon will displays help text for the applicable topics.

Enter Microbial Agents

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

Biological Registration Complete

**1-A-ii Will the acquired drug resistance trait(s) render the micro-organism resistant to the primary drug available and/or indicated for certain populations such as children, the elderly, or pregnant women?: \***

Yes (Explain)

No

**Experiments Involving the Cloning of Toxins**

[NIH Guidelines Section III-B-1](#)

**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?: \***

Yes (Explain)

No

Definition of LD50

**Definition of LD50**

LD50 - the LD50 value, defined as the statistically derived dose that, when administered in an acute toxicity test, is expected to cause death in 50% of the treated animals in a given period.

**Transfer of Recombinant or Synthetic Nucleic Acid Molecules into Humans**

[NIH Guidelines Section III-C-1](#)

**3 Do you conduct experiments involving the transfer of nucleic acid molecules into human subjects? (E.g., gene transfer, gene therapy, or gene editing): \***

Yes (Explain)

No

Definition of Human Gene Transfer

**Pathogens & Pathogen Cloning for Host-Vector Systems**

[NIH Guideline Sections III-D-1, Section III-D-2](#)

**4 Does your research involve the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2, 3, 4 or Restricted Agents?: \***

Yes

No

=146640#ld50-definition-help



## 6d. The rDNA Survey also covers Exempt Experiments

If you indicate that you perform Exempt Experiments, the survey will trigger additional information to capture details about this research.

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

**Recombinant or Synthetic Nucleic Acid Molecules Survey**

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Nucleic Acid Reagents

Add Biological Forms

### Recombinant or Synthetic Nucleic Acid Molecules Survey

Intro
Form Questions
Exempt Experiments
Save & Continue

**Exempt Experiments**

[NIH Guidelines Section III-F](#)

Please read each statement below to determine if any of the experiments conducted under your research are exempt from the NIH Guidelines.

(Note: Experiments exempt from the NIH Guidelines may still fall under institutional biosafety and biosecurity review.)

**Section III-F-1**

For experiments to be exempt under this section of the NIH Guidelines, the following statement must be true:

The recombinant or synthetic nucleic acid molecules in use: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g. oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.

If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.

1 **Are any experiments conducted under your research exempt under NIH Guidelines Section III-F-1? \***

Yes

No


**Section III-F-2**

For experiments to be exempt under this section of the NIH Guidelines, the following statement must be true:

The recombinant or synthetic nucleic acid molecules in use are not in organisms, cells, or viruses and have not been modified or manipulated (e.g. encapsulated into synthetic or natural vehicles) to render them capable of penetrating

## 6e. Survey and Form Submission Correction

BioRAFT's Biological Registration Process will ensure that all applicable information is captured through the use of prompts and messaging if a question is missed during the process.



**EARTH INSTITUTE**

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[Support](#) | [Logout](#)

**Biological Registration Wizard**

Biological Welcome

### Recombinant or Synthetic Nucleic Acid Molecules Survey

"Do your experiments involve plants containing recombinant or synthetic nucleic acid molecules?" field is required.

-The applicable section will be highlighted until it is filled out with either a "Yes" or a "No"

**Experiments Involving Whole Plants**

[NIH Guideline Section III-D-5, Section III-E-2](#)

8 **Do your experiments involve plants containing recombinant or synthetic nucleic acid molecules?: \***


Yes

No



## 7. Material Data Entry

After all Material Surveys are completed, the PI will be prompted to provide additional information about the materials they work with. This PI indicated that he works with Human Sourced Materials, Pathogenic Organisms, and Recombinant DNA; therefore those Material Data Entry points are triggered for the PI to add.


Welcome, Dusty D Mccrady  
Support | Logout

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

**Enter Human Cell Lines**

### Enter Human Cell Lines

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/Organ	Viral Packaging
There are currently no cell lines listed for the Mccrady Lab.		

**Cell Line Name: \***  
HEK-293

**Cell Type/Organ: \***  
Human Kidney  
E.g. Human Kidney, Glioma, etc


**Viral Packaging: \***

No  
 Yes

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

## 8. Enter Microbial Agents

From this view the PI will be able to enter what Bacteria, Fungi/Yeasts, Viruses, and Parasites they use in their research.


Welcome, Dusty D Mccrady  
Support | Logout

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

**Enter Microbial Agents**

Enter Nucleic Acid Reagents

### Enter Microbial Agents

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 Mccrady Lab**

Genus	Species	Sub Species	Strain	Risk Group Level	Pathogenicity	Select Agent
None Listed						

- [Add Bacteria](#) -

**Current Fungi/Yeast in Mccrady Lab**

Genus	Species	Strain	Risk Group Level	Pathogenicity	Select Agent
None Listed					

- [Add Fungi/Yeast](#) -

**Current Viruses in Mccrady Lab**

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

- [Add Viruses](#) -

**Current Parasites in Mccrady Lab**

Genus	Species	Risk Group Level	Pathogenicity	Select Agent
None Listed				

## 8b. Selecting Microbial Agents

By selecting "Add Bacteria," "Add Virus," etc. the PI will be prompted to choose the Genus/Species or applicable information for the submission of this agent from a dropdown menu.

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

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**Enter Biological Materials**

Enter Human Cell Lines

**Enter Microbial Agents**

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

### Enter Microbial Agents

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 Mccrady Lab**

Genus	Species	Sub Species	Strain	Risk Group Level	Pathogenicity	Select Agent	
None Listed							

▼ [Add Bacteria](#)

**Select Bacteria to be added to the above table:**

**Sub Species:**

**Strain:**

**Pathogen:**  
 HP = Human Pathogen  
 AP = Animal Pathogen  
 IP = Insect Pathogen  
 PP = Plant Pathogen

HP  
 AP  
 IP  
 PP

**Notes (optional):**

If necessary, enter any notes that will clarify for the Biosafety officer names entered or selections made. Do not include information about its use.

■ ■ ■ Please wait...

## 8c. Addition/Update of the Microbial Agents

We can now see that the microbial agent is listed as a bacterium in the lab, as well as the appropriate Risk Group and Select Agent designation. The PI has the ability to Edit or Remove these agents, or add additional bacteria by selecting "Add Bacteria."

Welcome, Dusty D Mccrady  
Support | Logout

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

Biological Surveys

Human Source Materials Survey

### 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 Mccrady Lab**

Genus	Species	Sub Species	Strain	Risk Group Level	Pathogenicity	Select Agent	
Yersinia	pestis			3		Yes	<a href="#">Edit</a> <a href="#">Remove</a>


→ [Add Bacteria](#)





## 9. Pathogen and Viral Vector Forms

A Pathogen Registration or a Viral Vector Form will provide additional safety information for risk assessments, as needed for the agents you are using.


Welcome, Dusty D Mccrady  
Support | Logout

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

### 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](#)

### 9a. Filling out a Pathogen Form or Viral Vector Form

This form can be filled out by using the tabs at the top of the form to navigate between the required information.


Welcome, Dusty D Mccrady  
Home | Support | Logout

### Submit Pathogen Registration Form

Fill out this form to register a single pathogen. A separate form should be filled out for each pathogen used by your laboratory.

Introduction
Step I: Pathogen Information
Step II: Project Information
Step III: Safety

Step IV: Risk Assessment
Step V: Personnel
Review & Submit

This Research Center maintains a listing of all human and animal pathogens and viral vectors in use at this Research Center in order to identify research areas where potential 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 lab and immediate environment.
2. Review this information with the 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

## 10. Registration Completion

Once the Biological Forms are completed, the PI will be prompted to review all the content that has been provided. At the top of the page we can see the Usage Summary for the materials selected in the project, the lab focus that was provided during the General Set up Wizard, and the links to the relevant NIH Guidelines (completed in the Recombinant and Synthetic DNA Survey, section 7) with external links to the applicable guidelines. The PI will be asked to scroll down and review the data, then certify its accuracy.

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

**Enter Biological Materials**

Enter Human Cell Lines

Enter Microbial Agents

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

Submit Biological Registration

### 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.*

**Mccrady Lab**

PI: Dr. Dusty D Mccrady

Delegate(s): Elden L Mang

Registration Last Approved: --

PI Last Certified: --

**Usage Summary**

Primate Materials	Non-Primate Materials	Other Biological Source Materials
<ul style="list-style-type: none"> <li>Human Body Fluids</li> <li>Human Cell Lines</li> </ul>	<ul style="list-style-type: none"> <li>Lab Animals (Non-Primate)</li> <li>Non-Pathogenic Microorganisms</li> <li>Pathogenic Microorganisms</li> </ul>	<ul style="list-style-type: none"> <li>Recombinant or Synthetic Nucleotides</li> </ul>

This lab does not ship biological materials.

Applicable NIH Guideline Sections

- [Section III-A-1](#)
- [Section III-F-1](#)

*Lab Focus* [\[Edit\]](#)

The tetragonal Ca<sub>2</sub>MgSi<sub>2</sub>O<sub>7</sub>:Eu<sup>2+</sup>,R<sub>3</sub><sup>+</sup> persistent luminescence materials were prepared by a solid state reaction. The UV excited and persistent luminescence was observed in the green region centred at 535nm. Both luminescence phenomena are due to the same Eu<sup>2+</sup> ion occupying the single Ca<sub>2</sub> site in the host lattice. The R<sub>3</sub><sup>+</sup> codoping usually reduced the persistent luminescence of Ca<sub>2</sub>MgSi<sub>2</sub>O<sub>7</sub>:Eu<sup>2+</sup>, which differs from the M<sub>2</sub>MgSi<sub>2</sub>O<sub>7</sub>:Eu<sup>2+</sup> (M=Sr,Ba) and MAl<sub>2</sub>O<sub>4</sub>:Eu<sup>2+</sup> (M=Ca,Sr) materials. Only the Tb<sup>3+</sup> ion enhanced slightly the persistent luminescence. With the aid of synchrotron radiation, the band gap energy of Ca<sub>2</sub>MgSi<sub>2</sub>O<sub>7</sub>:Eu<sup>2+</sup> was found to be about 7eV that is very similar to those of the M<sub>2</sub>MgSi<sub>2</sub>O<sub>7</sub>:Eu<sup>2+</sup> (M=Sr,Ba) materials. Thermoluminescence results suggested that the R<sub>3</sub><sup>+</sup> ions might act as electron traps, but only the TL peaks created by Tm<sup>3+</sup> and Sm<sup>3+</sup> can be found in the temperature range accessible. Lattice defects (e.g. oxygen vacancies) are also important, since the same main thermoluminescence peak was observed at about with and without R<sub>3</sub><sup>+</sup> codoping.

[Projects](#) [\[Add\]](#)

-.PI-User Guide



## 10a. Bio Summary Review

The Survey selections and applicable material data are summarized for review. At this point edits can be made to surveys or data collection by selecting “Edit Responses” or other prompts such as “Add Cell Line.”

Detailed Pages

---

**Human Source Materials Survey**  
 Last updated on 03/22/2016 by Dusty D Mccrady  
 Actions: [Edit Responses](#) | [Remove Survey](#) | [View Revisions](#)

**Which of the following do you do with human cell lines?:**  
 Inject human cells into laboratory animals (mice, rats, etc.)

**Do you plan to obtain human tissues or fluids that carry pathogenic organisms?:**  
 No

**Describe:**  
 PI-User Guide

**Cell Lines Used in Lab:**

Cell Line Name	Cell Type/Origin	Viral Packaging		
HEK-293	Human Kidney	No	<a href="#">Edit</a>	<a href="#">Remove</a>

[Add Cell Line](#)

**Tissues Used in Lab:**

Tissue Type	Preparation	Pathogen	Source		
There are currently no human tissues listed for the Mccrady Lab.					

[Add Tissue](#)

---

**Animal Source Materials (Non-Primate) Survey**  
 Last updated on 03/22/2016 by Dusty D Mccrady  
 Actions: [Edit Responses](#) | [Remove Survey](#) | [View Revisions](#)

**Indicate which of the following you do with non-primate animal source materials (e.g. mouse, rat, etc.):**  
 Culture immortalized or transformed cell lines

**Indicate which of the following will be done in your lab with non-primate laboratory animal cell lines and/or tissues:**  
 Introduce recombinant DNA or synthetic nucleic acids into cells/cell lines

**Indicate which of the following will be done in your lab with non-primate laboratory animal cell lines and/or tissues:**  
 N/A

**Work in my lab will include injecting non-primate laboratory animal cell lines and/or tissues:**  
 .....



## 10b. Review and Certify

After a full review of the Biological Registration the PI will be asked to “Certify” their project.

No Dual-Use categories were selected.

No explanation of experimental details has been specified for this project.

### 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
Schwartz School of Engineering	259 - Main Lab	X	
Schwartz School of Engineering	260 - Cyclotron	X	
Schwartz School of Engineering	261 - Freezer Room		

### Project Team Members

**Laboratory group members involved in this project:**

- Mccrady, Dusty

### Additional Forms

No Pathogen or Viral Vector registration forms have been filled out for this lab.

[Add a Viral Vector Form](#)

[Add a Pathogen Registration Form](#)

Certify



## 10c. Certify and Submit

The PI will be prompted to initial each statement to indicate that they will comply with institutional policies, and then submit the registration for the Biological Safety Officers Review

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

Human Source Materials Survey

Animal Source Materials (Non-Primate) Survey

Microbial Agents Survey

Recombinant or Synthetic Nucleic Acid Molecules Survey

Enter Biological Materials

Enter Human Cell Lines

Enter Microbial Agents

Enter Nucleic Acid Reagents

Add Biological Forms

Review Biological Registration

**Submit Biological**

### 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 DM.

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.: \*

DM

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.: \*

DM

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.: \*

DM

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

DM

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 EH&S Office before shipping to or receiving from any international location any biological material.: \*

DM


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 EH&S.: \*

DM

f. I will inform the EH&S Office of any significant research-related accident or illness as soon as possible after its

## 10d. Confirmation screen

After certification, a message is displayed to confirm submission.


Welcome, Dusty D Mccrady  
Support | Logout

**Biological Registration Wizard**

Biological Welcome

Enter Laboratory's Research Projects

**Biological Surveys**

### Biological Registration Wizard

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](#)



## 11. Awaiting Approval

After submission, this Biological Registration is now awaiting EHS Review. This screen is available in the “Biological Snapshot” page. We have quick access to detailed information about the Biological Registration by selecting the links for the appropriate category at the top of the page.

View | Edit | Dashboard | Members | Bio | Rad | Training

---

**Mccrady Lab**

- » View Lab Profile
- » Compliance Dashboard
- » Manage Members
- » Send Lab Message
- » Bio Summary
- » Rad Summary
- » Self Inspections
- » Manage Lab Forms
- + Research Tools
- + Training
- + Equipment
- + My Account

**Snapshot** | [Biological Summary](#) | [Projects](#) | [Cell Lines](#) | [Microbes](#) | [rDNA](#) | [NIH Guidelines](#)

### Mccrady Lab Biologicals

**Biological Summary**

Principal Investigator: [Dusty D Mccrady](#)  
 Delegate(s): [Elden L Mang](#)  
 Biosafety Level:  
 Dual Use Research of Concern: No

	Number
Projects	1
Viral Vector Forms	0
Pathogen Forms	0
Cell Lines	1
Microbes	1
rDNA	1

[View or Update Biological Usage Summary](#)

**Usage Summary**

Primate Materials

- Human Body Fluids
- Human Cell Lines

Non-Primate Materials

- Lab Animals (Non-Primate)
- Non-Pathogenic Microorganisms
- Pathogenic Microorganisms

Other Biological Source Materials

- Recombinant or Synthetic Nucleotides

**Registration Summary**

Submission: Current ⌵ **Awaiting EHS Review**


Biosafety Level:  
 Current Reg Status: Awaiting EHS Review  
 Next Review Date:  
 Review Frequency: 1 Year  
 Last Confirmed: 03/22/2016  
 Confirmation Frequency: 1 Year

Started: 03/22/2016  
 PI Certified: 03/22/2016 [Download Changed PDF](#) | [View](#)  
 Approved: --  
 Last Confirmed: 03/22/2016



## 12. Health and Safety / Bio Safety Officer Approval Process

The Biological Safety Officer will get a notice to review the submitted Biological Registration. Once the Biological Safety Officer has reviewed the documentation, it may be slated for IBC. The PI will be notified of his biological registration status change via the Compliance Mailbox. This will also be reflected in the Compliance Summary by a green check mark next to the Biological category.


Welcome, Dusty D Mccrady  
Home | Support | Logout

- + Mccrady Lab
- + Research Tools
- + Training
- Equipment
- » My Equipment
- + My Account

### Welcome to BioRAFT

Your training in the following course is overdue: [Radiation Safety - Web Launch Course.](#)

#### Announcements

**01/12/2016:** [New Lab Coats](#)  
Check in 5th Floor Closet

**12/30/2015:** [Happy New Year 2016!](#)  
Thank you everyone for a great 2015! As we move into the new year we will be offering extra tool... [\[more\]](#)

[View All Announcements](#)

#### Compliance E-Mail Inbox

03/22/2016	<a href="#">Biological Registration Status: ...</a>
03/22/2016	<a href="#">Form Submission Status: <b>Approved</b></a>
03/22/2016	<a href="#">Biological Registration Status: ...</a>
03/22/2016	<a href="#">Biological Registration Status: ...</a>

[View Entire Inbox](#)

#### Required Training

	Course Name	Renewal Date
	<a href="#">X-ray Equipment Safety - Web</a>	Overdue!
	<a href="#">Radiation Safety - Web</a>	12/30/2015
	<a href="#">Hazard Communication - Web</a>	09/24/2016
	<a href="#">Laboratory Safety - Classroom</a>	Never
	<a href="#">Introduction to Laboratory Safety - Web</a>	Never
	<a href="#">Radiation Safety - Classroom</a>	Never

#### Compliance Summary for Mccrady Lab

**Biological:**   
**Radiological:**   
**Chemical:**   
**Training:**   
**Equipment:**

[View Full Report](#)

#### Chemical Lookup

Chemical Name:

## 13. Message Received

Below is an example of the message that is sent after submission of a Biological Registration.

- + Mccrady Lab
- + Research Tools
- + Training
- Equipment
- » My Equipment
- + My Account

### Biological Registration Status: Approved

**From** Jerold.C.Downing@bioraft.org  
**To** Dusty.D.Mccrady@bioraft.org  
**Subject** Biological Registration Status: Approved  
**Date** Tuesday, March 22, 2016 - 16:18

Thank you for your recent Biological Registration submission on 03/22/2016. The status of this registration has been changed to: "Approved". You will be notified of all future changes to this status.

If you have any questions, please reply to this message.

Thank you.



## 14. Amendments

After the Biological Registration is approved, the PI can still submit changes to their registration. If the PI or a delegate would like to update this information, they can to the appropriate category next to the Biological **Snapshot** (Projects, Cell lines, Microbes, rDNA Materials). Once an amendment has been made, select the link for “View or update Biological Usage Summary” to Certify the Amendment and resubmit it for review.

**EARTH INSTITUTE** Welcome, Dusty D Mccrady  
Home | Support | Logout

View Edit Dashboard Members Bio Rad Training

Snapshot | Biological Summary | Projects | Cell Lines | Microbes | rDNA | NIH Guidelines

**Mccrady Lab Biologicals**

**Biological Summary**  
Principal Investigator: [Dusty D Mccrady](#)  
Delegate(s): [Elden L Mang](#)  
Biosafety Level:  
Dual Use Research of Concern: No

	Number
Projects	1
Viral Vector Forms	0
Pathogen Forms	0
Cell Lines	1
Microbes	1
rDNA	1

[View or Update Biological Usage Summary](#)

**Usage Summary**

Primate Materials

- Human Body Fluids
- Human Cell Lines

Non-Primate Materials

- Lab Animals (Non-Primate)
- Non-Pathogenic Microorganisms
- Pathogenic Microorganisms

Other Biological Source Materials

- Recombinant or Synthetic Nucleotides

**Registration Summary**  
Submission:  **Approved**

Biosafety Level:  
Current Reg Status: Approved  
Next Review Date: 03/22/2017  
Review Frequency: 1 Year  
Last Confirmed: 03/22/2016

### 14a. Amendment Submission

After any changes are made, the PI will be asked to review the Biological Usage Summary and select “Submit Amendment.”

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
Schwartz School of Engineering	259 - Main Lab	X	
Schwartz School of Engineering	260 - Cyclotron	X	
Schwartz School of Engineering	261 - Freezer Room		

**Project Team Members**  
**Laboratory group members involved in this project:**

- Mccrady, Dusty

**Additional Forms**  
No Pathogen or Viral Vector registration forms have been filled out for this lab.  
[Add a Viral Vector Form](#)  
[Add a Pathogen Registration Form](#)

Please click "Submit Amendment" if changes have been made to the existing registration. You will be prompted to certify that the information provided is accurate and up to date.

Should the current Bio Registration no longer apply to your group, click "Terminate Registration". You may also [Request Assistance](#) with this process.





## 14b. Amendment Review

After you submit the amendment, the status of the Biological Registration will then change to “Amendment Awaiting Review,” at which time the process of the Bio Safety Officer review/IBC approval will be repeated as needed.

The screenshot shows the Earth Institute BioRAFT web interface. At the top right, it says "Welcome, Dusty D Mccrady" with links for "Home | Support | Logout". The main navigation bar includes "View", "Edit", "Dashboard", "Members", "Bio", "Rad", and "Training". Below this is a breadcrumb trail: "Snapshot | Biological Summary | Projects | Cell Lines | Microbes | rDNA | NIH Guidelines".

The main content area is titled "Mccrady Lab Biologicals" and features a green alert box with the following text:

- Amended Bio Registration has been submitted for review
- Details of Bio Registration have been confirmed

Below the alert box are three summary sections:

- Biological Summary:**
  - Principal Investigator: [Dusty D Mccrady](#)
  - Delegate(s): [Elden L Mang](#)
  - Biosafety Level: [unspecified]
  - Dual Use Research of Concern: No

	Number
Projects	1
Viral Vector Forms	0
Pathogen Forms	0
Cell Lines	1
Microbes	2
rDNA	1

[View or Update Biological Usage Summary](#)
- Usage Summary:**
  - Primate Materials
    - Human Body Fluids
    - Human Cell Lines
  - Non-Primate Materials
    - Lab Animals (Non-Primate)
    - Non-Pathogenic Microorganisms
    - Pathogenic Microorganisms
  - Other Biological Source Materials
    - Recombinant or Synthetic Nucleotides
- Registration Summary:**
  - Submission:  **Amended Awaiting Review**
  - Biosafety Level: [unspecified]

If you have any questions or need further assistance, please contact BioRAFT support

- [support@bioraft.com](mailto:support@bioraft.com)
- 1-800-939-7238 X82

