



Biosafety Protocol Management System Guide

Please Read This Notice

Research with biological materials, such as recombinant DNA and/or biological pathogens, is required to be approved through an Institutional Biosafety Committee (IBC). A biosafety protocol is generated by a Principal Investigator to describe such research to provide the IBC with information to:

- 1. accurately assess risks associated with the research**
- 2. recommend an appropriate biosafety level for conducting the research**
- 3. approve the protocol to allow research to continue**

Please be aware that all grants must be congruent with the biosafety protocol. If there is proposed work in a grant that is not in the biosafety protocol (but is required to be), the grant will be held.



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Create a New Protocol

1. To create a new registration:

1. Go to <https://myrehs.rutgers.edu/>
2. Click on “**Click Here to login with your Rutgers NetID**”. You will then need to login with your NetID and password



MyREHS is a web portal for all REHS-related online databases

Accessible Databases	Online Trainings Available	Other Actions
<ul style="list-style-type: none">• Accident Reporting Database• Biosafety Database• Fire Evacuation Plans• Laboratory Self-Audits• Radiation Safety Database• Right-To-Know Submissions	<ul style="list-style-type: none">• Art Safety• IATA Refresher• Radiation Refresher• Lab Safety Refresher• SPCC• X-Ray	<ul style="list-style-type: none">• View your Training Records• Training Calendar/Registration• Generate Training Certificates• Link Supervisors• Access other REHS programs

Click here to login with your Rutgers NetID

Click here to login with your REHS assigned UserID/Password

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Create a New Protocol

1. To create a new registration:

3. Once logged in, you will be able to click on **Biosafety Protocols** to access the BPMS

A row of navigation buttons: "Main Menu", "Training Calendar", "My Training Records", "Links", "Help", and "Logout".
Main Menu

Accident Database Access Allowed The Occupational Accident/Incident Reporting Database. If you are not an existing user in the database, then you will be taken to the "Self-Registration" Page.	Biosafety Protocols Access Allowed The Biosafety Database provides Principal Investigators and/or designees access to their biosafety and rDNA protocols. Access requires approval from REHS.	Fire Evacuation Plans Access Allowed Evacuation Plans & Maps are available for some buildings at Rutgers. You will be taken to the appropriate section based upon your status as student or an employee.
Laboratory Self-Audits --No Access-- The Laboratory Safety and Environmental Management Self Inspection Checklist Access requires approval from REHS.	MyLabs Access Allowed MyLabs	Radiation Safety Database --No Access-- The Radiation Safety Database contains information pertinent to your Radiation protocol. Also known as the "PI Information Database". Access requires approval from REHS.
Respirator Program Access Allowed Respirator Program	Right-To-Know Submissions Access Allowed The Rutgers Right-To-Know Inventory Reporting Database Exemptions and training records are also reported here. Access to the Chemical Inventory portion requires approval from REHS.	Select Agent / BSL3 Database Access Allowed Select Agent / Biosafety Level 3 related activities Access requires approval from REHS.



Create a New Protocol

1. To create a new registration:

4. In "My Protocols", click on "Create a new Protocol"
5. Verify that a similar protocol does not already exist in the "Existing Protocols" panel
6. Click "no" if there is no similar existing protocols
7. Click on "Click to create a New Protocol" button

Protocols ▼ Workers Locations

My Protocols

Please select from the listing below to Create, View/Add Workers, Renew, Terminate or Amend a protocol with the Institutional Biosafety Committee. Please contact biosafety@rutgers.edu with any questions regarding this protocol registration system.

Adding personnel who will work with **Human Materials** (e.g., established human cell lines) will require that an Amendment be submitted as changes must also be made to Addendum E for the respective worker(s) added.

Make sure to click on the "Save Progress" button as you populate/edit each tab. Click on "Submit Protocol" to indicate the protocol is ready for pre-review (does not go out to entire committee). Protocols created by non-PIs will require PI Assurance to be submitted by PI.

Please select an action to perform

- Create a new Protocol
- View Protocol/Add workers to an Existing Protocol
- Renew an Existing Protocol
- Terminate an Existing Protocol(s)
- Amend an Existing Protocol

Existing Protocols

Code	Title	Authoree	Status	BSL	Expiration Date
None					

Do you see your protocol listed above? Yes No

[Click to create a New Protocol](#)

Create a New Protocol

2. Initial PI Information:

1. Fill out Principal Investigator Information
 - i. Information should be up-to-date
 - ii. Biosafety Level is the projected biosafety level of the laboratory for this protocol
2. Click “Save Button”

Protocols Workers Locations

Add Protocol

PI Information	PI Information Section
Employees/Workers	Principal Investigator / Protocol Information
Locations of Study	Principal Investigator <input type="text"/>
PPE	<i>Once you select a PI the four locked fields (grey color) will unlock and become editable</i>
Biomedical Waste	Protocol Title <input type="text"/>
Disinfectants	Biosafety Level <input type="text"/>
Accidental Exposure	PI Title <input type="text"/>
Transportation	E-Mail Address <input type="text"/>
Dual Use	Department <input type="text"/>
Risk Assessment	Office Phone <input type="text"/>
Project Description	Emergency Phone (after hours) # <input type="text"/>
Materials Used	<input type="button" value="Save Button"/>

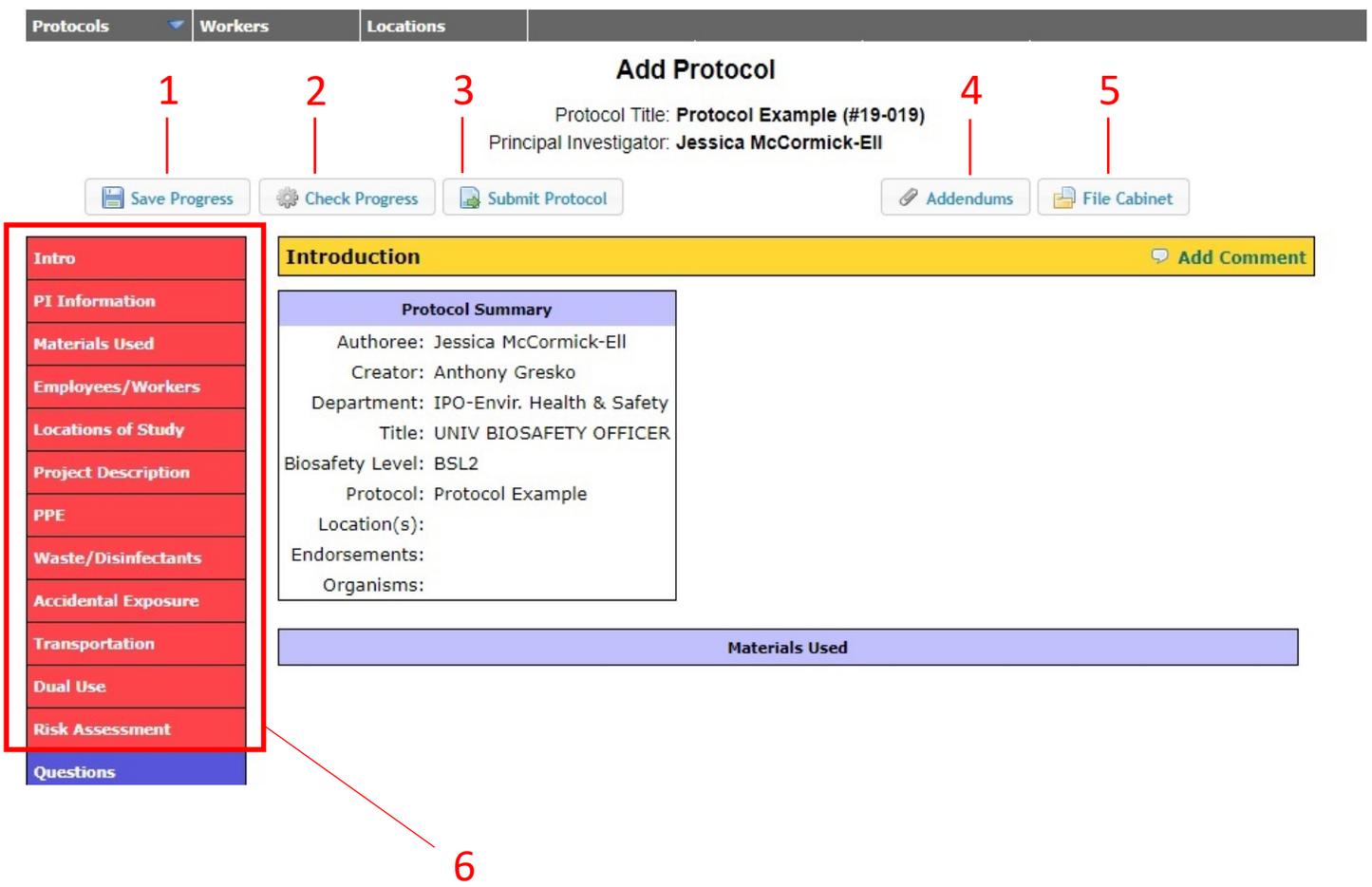
1

2

Create a New Protocol

3. Home Screen:

1. "Save Progress" button – *allows progress to be saved. **This should be clicked often to continually save your progress.***
2. "Check Progress" button – *provides indications of sections yet to be completed*
3. "Submit Protocol" button – *will submit protocol upon completion of ALL sections*
4. Addendums – *Additional sections of the protocol to describe materials used. Each addendum will be created only after you complete the "Materials Used" section of the Protocol*
5. File Cabinet – *allows uploads of additional documents (i.e. laboratory SOPs, plasmid/vector maps, permits, etc.)*
6. Protocol Sections – *must be completed (see next pages of this guide)*



The screenshot shows the 'Add Protocol' interface. At the top, there are navigation tabs for 'Protocols', 'Workers', and 'Locations'. The main heading is 'Add Protocol'. Below this, the protocol title is 'Protocol Example (#19-019)' and the Principal Investigator is 'Jessica McCormick-Ell'. There are five numbered callouts pointing to specific buttons: 1 points to 'Save Progress', 2 to 'Check Progress', 3 to 'Submit Protocol', 4 to 'Addendums', and 5 to 'File Cabinet'. On the left side, there is a vertical menu with sections: Intro, PI Information, Materials Used, Employees/Workers, Locations of Study, Project Description, PPE, Waste/Disinfectants, Accidental Exposure, Transportation, Dual Use, Risk Assessment, and Questions. A red box highlights the sections from 'Intro' to 'Risk Assessment'. A red arrow points from the bottom of this box to the number 6. The main content area shows the 'Introduction' section with a 'Protocol Summary' box containing details like Author, Creator, Department, Title, Biosafety Level, Protocol, Location(s), Endorsements, and Organisms. Below the summary is a 'Materials Used' section. An 'Add Comment' button is visible in the top right of the Introduction section.



Create a New Protocol

4. Check Protocol Status:

This section provides notifications of sections that are incomplete and must be completed prior to submission of protocol.

1. **“Back to Protocol”** – allows return to home page of protocol
2. Clicking on the Bold Section Header will bring you to that section to edit/view it

Check Protocol Status

1 [Back to Protocol](#)

- ✔ Indicates that the section/addendum is complete.
- ✘ Indicates that the section/addendum is NOT complete.

Application is NOT complete

This missing information is indicated below the section/addendum name.
Click on the section/addendum name to goto the page.

Protocol Sections

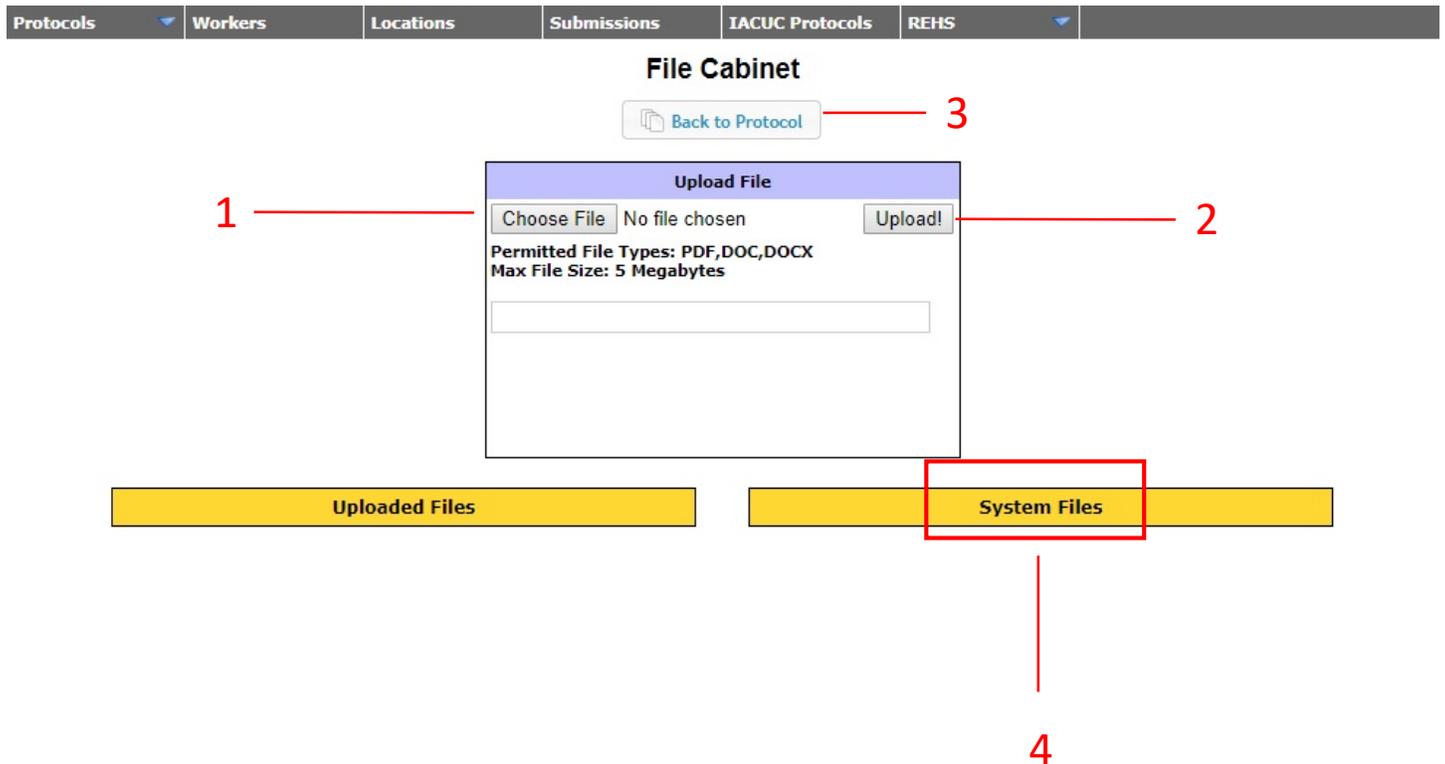
- ✘ **PI Information**
 - You must provide the US Government Agency(ies) and grant number(s)
 - You must provide the Non-US Government Agency(ies) and grant number(s)
 - You must provide the Agency(ies) which have issued permits
- ✘ **Employees/Workers**
 - You must check the Supervisor
- ✘ **Locations of Study**
 - You must provide at least one Location
- ✘ **PPE**
 - You must check at least one box in the "PPE for laboratory use" section
 - You must answer Question #1
- ✘ **Waste/Disinfectants**
 - You must check at least one checkbox in the "Question #1: Types" column OR provide a value in the "Other" field
 - You must check at least one checkbox in the "Question #1: How Treated/Disposed" column OR provide a value in the "Other" field
 - You must check at least one checkbox in the "Question #2: Types" column OR provide a value in the "Other" field
 - You must check at least one checkbox in the "Question #2: How Treated/Disposed" column OR provide a value in the "Other" field
 - You must check at least one checkbox in the "Question #3: Types" column OR provide a value in the "Other" field
 - You must check at least one checkbox in the "Question #3: How Treated/Disposed" column OR provide a value in the "Other" field
 - You must answer Question #5.
 - You must check at least one checkbox in the "Question #6: Equipment/Surfaces" column OR provide a value in the "Other" field
 - You must check at least one checkbox in the "Question #6: Spills" column OR provide a value in the "Other" field
- ✘ **Accidental Exposure**
 - You must check the box acknowledging that you read the information about Accidental Exposures
- ✘ **Transportation**
 - You must answer Question #1.
- ✘ **Dual Use**
 - You must check one of the options for "Dual Use"

Create a New Protocol

5. File Cabinet:

This section allows uploads of additional documents (i.e. laboratory SOPs, plasmid/vector maps, permits, etc.)

1. Click **“Choose File”** to choose a file from computer
2. Once file displays next to **“Choose File”** button, click **“Upload!”** button
3. Click **“Back to Protocol”** to return to protocol
4. System files will show approval letters and PDFs once submitted/approved.





Create a New Protocol

6. PI Information Tab:

This section requires information surrounding funding sources and permits related to the research. Each question must be answered. If “yes” is answered, additional information is required to be input into the text box.

1. Question 3 requires PDF versions of permits to be uploaded to the File Cabinet tab.
2. Another reminder, it is good practice to click the “**Save Progress**” button as you complete each tab.

Protocols | Workers | Locations

Add Protocol

Protocol Title: **Protocol Example (#19-019)**
 Principal Investigator: **Jessica McCormick-Ell**

Save Progress
Check Progress
Submit Protocol
Addendums
File Cabinet

2

- Intro
- PI Information
- Materials Used
- Employees/Workers
- Locations of Study
- Project Description
- PPE
- Waste/Disinfectants
- Accidental Exposure
- Transportation
- Dual Use
- Risk Assessment
- Questions

PI Information Section Add Comment

Principal Investigator / Protocol Information

Protocol Title:

Biosafety Level:

PI Name: [Change PI]

PI Title:

E-Mail Address:

Department:

Office Phone:

Emergency Phone (after hours) ≠

1. Does any funding come from a US Government Agency?

Yes
 No

If "Yes", please list all agencies along with grant numbers.

2. Does any funding come from a Non-US Government Agency?

Yes
 No

If "Yes", please list all agencies along with grant numbers.

3. Are there any permits related to this research?

Yes
 No

If "Yes", please upload all permits to the file cabinet
 Please list the agencies that have issued permits for this work.

1

Create a New Protocol

7. Materials Used:

Each question must be answered with either “Yes” or “No”. Each time a “Yes” is checked, another Addendum tab (named A-1, A-2, A-3, B, C, etc.) is added in the Addendum section.

- Once all questions in this section have been answered, Addendum tabs will be created in the Addendum section, which is described later in this guide.

Save Progress
 Check Progress
 Submit Protocol

Addendums
 File Cabinet

- Intro
- PI Information
- Materials Used
- Employees/Workers
- Locations of Study
- Project Description
- PPE
- Waste/Disinfectants
- Accidental Exposure
- Transportation
- Dual Use
- Risk Assessment
- Questions
- Comments
- REHS Admin

Materials Used Add Comment

To determine which Addendum(s) you may need to complete, please check "Yes" or "No" and complete the assigned Addendum, as necessary. Select all the materials this project will use or produce.

Note: The use of primary human materials requires the selection of both "Human Subjects" as well as "Human/Non-Human Primate material", as Addendums C and E serve different purposes.

Yes	No	Materials	Addendum
<input checked="" type="radio"/>	<input type="radio"/>	Recombinant DNA, gene transfer and/or host vector systems	A-1
<input checked="" type="radio"/>	<input type="radio"/>	Creation of Transgenic Animals	A-2
<input checked="" type="radio"/>	<input type="radio"/>	Use of Transgenic Plants	A-3
<input checked="" type="radio"/>	<input type="radio"/>	Use of Microorganisms (includes ALL strains of E. coli)	B
<input checked="" type="radio"/>	<input type="radio"/>	Human subjects (includes use of Embryonic Stem Cells). If the study is associated with an IRB protocol, please complete this section.	C
<input checked="" type="radio"/>	<input type="radio"/>	The use of Embryonic Stem Cells (including Somatic Cells [to be used for SCNT], Fetal Tissue/Cells, Embryos, Sperm, Oocytes)	C-1
<input checked="" type="radio"/>	<input type="radio"/>	Administration of Biological/ Recombinant Materials to Animals	D
<input checked="" type="radio"/>	<input type="radio"/>	Human/Non-Human Primate material including established human cell lines (Bloodborne Pathogens)	E
<input checked="" type="radio"/>	<input type="radio"/>	CDC/APHIS Select Agents	F
<input checked="" type="radio"/>	<input type="radio"/>	Toxins of Biological Origin (NOT select agents, NOT toxic chemicals)	G
<input checked="" type="radio"/>	<input type="radio"/>	Administration of Potentially Infectious Materials or Recombinant/Synthetic Nucleic Acids to Human Subjects	H
<input checked="" type="radio"/>	<input type="radio"/>	Cell Sorting and/or Flow Cytometry	I
<input checked="" type="radio"/>	<input type="radio"/>	Use of Arthropods	J

Create a New Protocol

8. Employees/Workers:

- Follow the directions displayed to Add Workers to the protocol. Start by clicking the **“Add Worker”** button.
- ** Adding new workers to an existing protocol can be done at this page and does NOT need to be submitted in an amendment.
- You must mark what role the worker has in the laboratory. Working with human cell lines (established cell lines) is working with Human materials
 - Shipping/Transport should only be marked if someone is transporting materials on a road or by air (not hand carrying)

- Intro
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Employees/Workers Section Add Comment

Check the box to the left of all workers who are associated with this specific protocol
**Click the "Add Worker" button if the worker is NOT already in the Employees table.*

Check the applicable boxes in each row to indicate whether workers will handle BSL-3 agents, Human Materials, Viral Vectors, and/or will administer materials to Animals. Also, check boxes to indicate whether the worker will Ship/Transport any materials involved in this protocol.

All listed workers must be up to date with required Laboratory Safety/Biosafety training, Online Viral Vector Training, online Plant Pathogen Training and/or Shipping Training, as applicable. Training status may be checked by floating over each name and clicking.

Employees								
Name	Supervising	BSL3	Human Materials	Animals	Shipping / Transport	Viral Vectors	Most Recent Acknowledge Assigned	Most Recent Acknowledge Completed
<input checked="" type="checkbox"/> Delmas, Guillaume	<input type="radio"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<input checked="" type="checkbox"/> Eggert, Brian	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
<input checked="" type="checkbox"/> Gresko, Anthony	<input type="radio"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<input checked="" type="checkbox"/> McCormick-Ell, Jessica	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<input checked="" type="checkbox"/> Pfromm, Tracy	<input type="radio"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Add Worker

1



Create a New Protocol

9. Locations of Study:

Add each room that workers will be utilizing for any work involved in this protocol, **including autoclave rooms**. Describe the function and containment controls utilized in each room.

Save Progress

Check Progress

Submit Protocol

Addendums

File Cabinet

- Intro
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Locations of Study Add Comment

Check all locations which are used with this protocol. Make sure to include Vivarium Procedure Rooms, as applicable.

If a location is not present, then click the "Add Location" button to add it to the table below.

Saved Locations	
<input checked="" type="checkbox"/>	International Center for Public Health ICPH 1190
	<p>Shared Space: No</p> <p>Room Functions: Bench Work, Tissue Culture, Agent Storage</p> <p>Containment Control: Fume Hood, Biosafety Cabinet</p>
<input checked="" type="checkbox"/>	International Center for Public Health ICPH 2170 (Autoclave Room)
	<p>Shared Space: Yes (Multiple)</p> <p>Room Functions: Autoclave</p> <p>Containment Control:</p>

Add Location

Create a New Protocol

10. Project Description:

1. Please describe your research in terms that a lay person can understand. Do NOT copy and paste from a grant what the specific aims are.
2. This question asks to describe experiments that you will be performing and why specific biological material is needed for those experiments. For each experiment, describe what precautions will be used to minimize risk (engineering controls, work practices, etc.). This is NOT a recreation of your grant but instead is a section to describe how you will perform each of your experiments safely. Please include work with animals, human subjects, and analysis of infected tissues.

SEE NEXT PAGE FOR VERY HELPFUL HINTS

Intro
PI Information
Materials Used
Employees/Workers
Locations of Study
Project Description
PPE
Waste/Disinfectants
Accidental Exposure
Transportation
Dual Use
Risk Assessment
Questions
Comments
REHS Admin

Project Description Add Comment

The Institutional Biosafety Committee (IBC) is made up of a diverse group of people. It is therefore important to use language that will be detailed enough for scientific evaluation as well as general enough to be understood by people with non-scientific backgrounds. Please provide sufficient information for Committee members to evaluate the work for purposes of making a biohazard risk assessment. Project descriptions taken from grant applications will not be accepted

REHS has Standard Operating Procedures (SOPs) for Viral Vectors and other Biomaterials. Please visit the following link to view the available SOPs. Review any applicable SOPs with your staff and upload the completed, signed SOPs into the File Cabinet section of this protocol.

URL: <https://ipo.rutgers.edu/rehs/standard-operating-procedures>

1. In lay language, describe your research objectives and hypotheses

THIS IS AN EXAMPLE PROTOCOL. This research is entirely fabricated for the use of providing resource material for our clients.

Our laboratory investigates the mechanisms of immunity and disease pathogenesis associated with viral infection of the family Exampleviridae. We study innate and adaptive immune responses to help discover disease prevention strategies including therapeutic intervention as well as vaccination. Using cell culture and animal models, we investigate host cell

2. Provide a step by step "walk-through" of your research methodology. Be sure to explain how and why specific agents are used. If there is a connection between this IBC protocol, IRB, ESCRO and/ or IACUC be sure to describe the links.

Amendment 2019
I wish to add ABC cells to propagate a new viral vector. I wish to add a 3rd generation lentiviral vector to this protocol for use in mice.

THIS IS AN EXAMPLE PROTOCOL. This research is entirely fabricated for the use of providing resource material for our clients.

Creating a New Protocol

10. Project Description

HELPFUL HINT 1: This section is NOT a copy/paste from the specific aims section of a grant. If the grant is selling how impactful the research will be, the project description is selling how safe the research will be.

- **Grant Example:** “Performing our vaccine challenge into mice will determine the efficacy of the vaccine in inducing both cellular and humoral immunity against infection which will determine possibility of a platform to prevent human disease”
- **Project Description Example:** “Performing our vaccine challenge into mice will be done inside a Class II biosafety cabinet to protect against potential aerosols. Injection will be performed with safe sharps to reduce the chance of needle stick exposure.

This is going to a Biosafety Officer and IBC reviewer, not a funding committee. They are not checking for the validity and/or reasoning for doing your science, but instead are reviewing for the safety of your science.

HELPFUL HINT 2: The **Project Description** section should describe how each experiment is done TO A CERTAIN EXTENT. This means that each experiment should be described as to what they are doing and how, but specific SOPs are not to be written here. Example below.

Good: Cells will be transfected with RNAi molecules against XYZ gene and are then infected with example virus in a biosafety cabinet. Cell monolayer is harvested for total nucleic acid or protein purification to determine gene expression using SOP 1 (uploaded to file cabinet)

Bad: 1. Open flask. 2. Remove media. 3. Wash with PBS. 4. Transfect cells with 50 nanograms/1 million cells of siRNA targeting XYZ gene. (And continuing like this)

The bad example above is in SOP format. SOPs can be mentioned but should not be written out in the **Project Description**. They should be uploaded into the **File Cabinet**, which is a section to store all external files (SOPs, plasmid maps, permits, publications showing data).



Create a New Protocol

11. PPE:

Check all boxes that would apply to PPE that would be required to work with the biological hazards in your laboratory.

Protocols Workers Locations

Add Protocol

Protocol Title: **Protocol Example (#19-019)**
 Principal Investigator: **Jessica McCormick-Ell**

Save Progress Check Progress Submit Protocol Addendums File Cabinet

- Intro
- PI Information
- Materials Used
- Employees/Workers
- Locations of Study
- Project Description
- PPE**
- Waste/Disinfectants
- Accidental Exposure
- Transportation
- Dual Use
- Risk Assessment
- Questions

Personal Protective Equipment Add Comment

Check all the applies while handing biological agents:

PPE for laboratory use

<input type="checkbox"/> Eye Protection	<input type="checkbox"/> Disposable Gloves
<input type="checkbox"/> Shoe Covers	<input type="checkbox"/> Full Face Shield
<input type="checkbox"/> Lab Coat	<input type="checkbox"/> Hair Covers
<input type="checkbox"/> Surgical Mask	<input type="checkbox"/> N-95 Respirator
<input type="checkbox"/> N-100 Respirator	<input type="checkbox"/> Powered Air Purifying Respirator
<input type="checkbox"/> Tyvek Coverall	<input type="checkbox"/> Aprons with sleeves
<input type="checkbox"/> Aprons without sleeves	<input type="checkbox"/> Cover sleeves

Other:

--Respirators require fit testing--

PPE for use with human patients or animals

<input checked="" type="checkbox"/> Eye Protection	<input checked="" type="checkbox"/> Disposable Gloves
<input type="checkbox"/> Shoe Covers	<input type="checkbox"/> Full Face Shield
<input type="checkbox"/> Lab Coat	<input type="checkbox"/> Hair Covers
<input type="checkbox"/> Surgical Mask	<input type="checkbox"/> N-95 Respirator
<input type="checkbox"/> N-100 Respirator	<input type="checkbox"/> Powered Air Purifying Respirator
<input type="checkbox"/> Tyvek Coverall	<input type="checkbox"/> Aprons with sleeves
<input type="checkbox"/> Aprons without sleeves	<input type="checkbox"/> Cover sleeves

Other:

--Respirators require fit testing--

1. Will working with human patients or animals be required?

Yes

No



Create a New Protocol

12. Waste/Disinfectants:

Describe how all types of waste will be treated. If you need more information, please refer to the RU bioguide for more information (see link below).

<https://ipo.rutgers.edu/sites/default/files/RU%20Biosafety%20Guide.pdf>

- 70% ethanol is never acceptable as a primary disinfectant

Protocols Workers Locations

Add Protocol

Protocol Title: **Protocol Example (#19-019)**
Principal Investigator: **Jessica McCormick-Ell**

Save Progress Check Progress Submit Protocol Addendums File Cabinet

- Intro
- PI Information
- Materials Used
- Employees/Workers
- Locations of Study
- Project Description
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- Waste/Disinfectants**
- Accidental Exposure
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- Dual Use
- Risk Assessment
- Questions

Waste / Disinfectants Add Comment

Complete this page to indicate the types of Regulated Medical Waste (RMW) generated by this protocol and how it will be treated and/or disposed of by your laboratory. Please refer to the RU Policy for the Disposal of Biological Waste http://rehs.rutgers.edu/pdf_files/biowaste_policy_10-07-13e.pdf, if necessary.

1. My laboratory will produce the following types of "Solids (non-glass)" biomedical waste (check appropriate boxes)

Types	How Treated/Disposed
<input type="checkbox"/> Culture plates/dishes	<input type="checkbox"/> Chemical treatment with 10% bleach - dispose in RMW box
<input type="checkbox"/> Flasks	<input type="checkbox"/> Autoclave - dispose in RMW box
<input type="checkbox"/> Serological pipettes	<input type="checkbox"/> Collect untreated directly into RMW box (BSL-1 waste only)
<input type="checkbox"/> Pipette tips	<input type="checkbox"/> Autoclave in clear autoclave bag - dispose in dumpster (Permitted in non-RBHS laboratories that conduct only BSL-1 work)
<input type="checkbox"/> Falcon tubes	
<input type="checkbox"/> Microfuge tubes	
<input type="checkbox"/> Loops	

Other:

2. My laboratory will produce the following types of "Liquids" biomedical waste (check appropriate boxes)

Types	How Treated/Disposed
<input type="checkbox"/> Waste from disinfection traps	<input type="checkbox"/> Chemical treatment with 10% bleach - dispose down drain
<input type="checkbox"/> Effluent from processing	<input type="checkbox"/> Autoclave - dispose down drain
<input type="checkbox"/> None Generated	<input type="checkbox"/> Collect in leak-proof container and place in RMW box

Other:

Create a New Protocol

13. Accidental Exposure: Read and acknowledge this disclaimer.

Protocols ▾
Workers
Locations

Add Protocol

Protocol Title: **Protocol Example (#19-019)**
 Principal Investigator: **Jessica McCormick-Ell**

Save Progress
 Check Progress
 Submit Protocol

Addendums
 File Cabinet

- Intro
- PI Information
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Accidental Exposure
 Add Comment

In case of an exposure incident, my laboratory personnel; whether students, faculty, staff, or visitors; have been instructed to contact Rutgers Occupational Health (New Brunswick) , Robert Wood Johnson Employee Health (New Brunswick/Piscataway), or New Jersey Medical School Occupational Medicine (Newark) as soon as possible for consultation and/or treatment at a Rutgers designated healthcare facility. I must complete an Accident Report on <http://myrehs.rutgers.edu> on the day of the incident. The contact numbers for Occupational/Employee Health are:

- Rutgers employees: Occupational Health - 848-932-8254
- RBHS (legacy UMDNJ) employees in New Brunswick/Piscataway: RWJMS Employee Health - 848-445-0123
- RBHS (legacy UMDNJ) employees in Newark: NJMS Occupational Medicine Service - 973-972-2900

Compliance with the NIH Guidelines for Recombinant DNA requires that Rutgers University, as a recipient of NIH funds, "reports any significant problems, violations of the NIH Guidelines or any significant research-related accidents or illnesses (Sections IV-B-1-j, -2-b-(7), -3-c-(2), -7-a-(3)). Compliance with the New Jersey Public Employee Occupational Safety and Health Act's General Duty Clause that requires that Rutgers provide "a place of employment which [is] free from recognized hazards that are causing or are likely to cause death or serious physical harm to [its] employees" (Sec. 5 Duties).

Reportable Incident: Any accident that leads to personal injury or illness. Any breach of containment. Any violation of the NIH Guidelines. Examples of reportable incidents include, but are not limited to, spills of recombinant materials outside of the biosafety cabinet, needlesticks, animal bites from infected animals, unprotected skin exposures to biological agents, and the escape or improper disposal of animals used in research. Appearance of symptoms indicative of laboratory acquired illness with a microorganism handled in your laboratory.

My staff has been informed that ALL WORK RELATED INJURIES AND ACCIDENTAL EXPOSURES (NEEDLESTICKS, EXPOSURE TO INFECTIOUS AGENTS or RDNA, CUTS or PUNCTURES, ASPIRATION OF AEROSOLIZED MATERIAL, ETC.) SHALL BE REPORTED via the On-line Accident and Incident Reporting System available at MyREHS website or <https://myrehs.rutgers.edu>.

By checking this box, I acknowledge that the above statement is true and I confirm that all persons involved with this protocol will comply with all applicable laws, rules, and regulations.



Create a New Protocol

14. Transportation:

Describe how you will be transporting biological material. .

Protocols	Workers	Locations
-----------	---------	-----------

Add Protocol

Protocol Title: **Protocol Example (#19-019)**
 Principal Investigator: **Jessica McCormick-Ell**

- Intro
- PI Information
- Materials Used
- Employees/Workers
- Locations of Study
- Project Description
- PPE
- Waste/Disinfectants
- Accidental Exposure
- Transportation**
- Dual Use
- Risk Assessment
- Questions

Transportation/Shipping (includes 'hand-carrying' specimens) Add Comment

If you are involved in shipping hazardous materials and/or dangerous goods, please read the information provided at: http://rehs.rutgers.edu/lsenv_dot.html. Materials being hand-carried between facilities must be stored in leak-proof secondary containment surrounded by absorbent material. Ensure that a biological spill kit is readily available in the event of an accidental release.

1. Will materials be transported outside of the laboratory in which they are being used?

Yes
 No

2. Will materials be carried by hand?

Yes
 No

If "Yes", please describe the hand transport procedures. Be sure to include the origin and destination of the shipment.

3. Will materials be transported by vehicle?

Yes
 No

4. Will materials be shipped to another university/ entity?



Reviewing a Protocol

15. Dual Use

Taken directly from the NIH website...

“Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.” <https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research>

It is the responsibility of the PI to assess their research for its DURC potential and the questions in the BPMS help do this. If any question is checked, then the research will need to be further assessed by the IBC working with the PI to conduct an ongoing assessment. If the research is DURC, the IBC must work with the PI to develop and implement a risk management plan, to which the research findings must adhere to.

Protocol Title: **Protocol Example (#19-019)**
Principal Investigator: **Jessica McCormick-Ell**

- Save Progress
- Check Progress
- Submit Protocol
- Addendums
- File Cabinet

- Intro
- PI Information
- Materials Used
- Employees/Workers
- Locations of Study
- Project Description
- PPE
- Waste/Disinfectants
- Accidental Exposure
- Transportation
- Dual Use
- Risk Assessment
- Questions
- Comments
- REHS Admin

Dual Use Research Add Comment

Check any categories below the apply to your project

- Renders a useful vaccine ineffective
- Enhances pathogen virulence
- Widens a pathogen's host range
- Weaponization (e.g. environmental stabilization of pathogens)
- Add antibiotic resistance affecting response to a clinically useful drug
- Increases pathogen transmissibility
- Lets a pathogen evade diagnostic or detection modalities
- Generating a novel pathogenic agent or toxin, or reconstitute an eradicated biological agent
- None of the above apply

1. Please describe how your research fits the above classification:

2. Please address additional risks to the workers, the environment and/ or public health that this research could present.



Create a New Protocol

16. Risk Assessment:

Please describe in detail the hazards associated with the biological materials you will be working with.

- Please do not write “no risk” when working with human cells. Human cell lines always have a risk of blood borne pathogens (even established cell lines).
- Acknowledge the risk of gene expression in a lab worker that would be accidentally exposed to recombinant/gene editing technologies (viral vectors, CRISPR, etc)
- If you are working with Sharps, as would be mentioned in the Waste section, please describe the risks associated with Sharps in this section as well.

Protocols	Workers	Locations
-----------	---------	-----------

Add Protocol

Protocol Title: **Protocol Example (#19-019)**

Principal Investigator: **Jessica McCormick-Ell**

- Intro
- PI Information
- Materials Used
- Employees/Workers
- Locations of Study
- Project Description
- PPE
- Waste/Disinfectants
- Accidental Exposure
- Transportation
- Dual Use
- Risk Assessment
- Questions

Risk Assessment Add Comment

0. Does this study involve the administration of rDNA/synthetic nucleic acid molecules to human subjects?

Yes (You will only have to answer Questions 8 through 21)
 No (You will only have to answer Questions 1 through 7 and 20 and 21)

20. Will work in protocol involve the use of sharps?

Yes
 No

21. Identify and describe the risk(s) to humans/ animals/ plants associated with the materials used in the experiment and methods that will be taken to prevent exposure to persons and/or the environment.

a. 1. Increased risk of exposure may be associated with generation of splashes, sprays, or aerosols from centrifugation, sonication, homogenization, use of sharps (needles, glass, or syringes), cage cleaning of infected animals, animal surgeries, etc. Management of these risks should be addressed in this section.

b. 2. Identify known/suspected signs and symptoms of exposure for each agent involved, as applicable.



Create a New Protocol

17. Addendums:

1. Follow the directions and answer each Yes/No question by clicking on either "Yes" or "No".
2. Once all questions for Addendum A have been answered, proceed to Addendum "A-1" by clicking on the red tab to the left of the screen entitled "Addendum A-1". Complete ALL Addendums that are present. Keep in mind, you only have Addendum tabs to which you checked "yes" to in the "Materials Used" tab from the Protocol.
3. For a sample response to these questions, please see the attached document "Biosafety Protocol Template"

2

Protocols Workers Locations

Addendums

Addendum A	<div style="text-align: right; color: white;"><input type="button" value="Add Comment"/></div> <p>Recombinant and Synthetic Nucleic Acids Questionnaire</p> <p>Please answer each by clicking on the "Yes" or "No" button next to the question.</p> <ul style="list-style-type: none"> • The button will turn an orange color to indicate your answer. • If you click on the question, more information about that question will appear (the question will be <i>red and italicized</i> once you place the mouse cursor over the question). • Answering "Yes" to certain questions will cause more questions to appear which must be answered. • If all the Non-Exemption questions are answered "No", then the Exemption questions (scroll down to view the tan-colored boxes) must also be answered. <p>Non-Exemption Questions - All these questions must be answered</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Yes No #1) Does the work involve transfer of a drug resistance trait to an organism that does not acquire it normally, which could compromise the use of the drug to control the disease in humans, veterinary medicine or agriculture? Note: this does not refer to resistance used for selectable markers. </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Yes No #2) Does the recombinant or synthetic nucleic acids contain genes coding for molecules toxic to vertebrates (LD50 <100 nanograms / kg body wt)? </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Yes No #3) Is the proposed experiment is equivalent to an experiment that has previously been approved by the NIH Director as a Major Action? </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Yes No #4) Does the work involve administration of recombinant or synthetic nucleic acid molecules to human subjects? </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Yes No #5) Are any human or animal pathogens used either as the host organism or as a vector? </div> <div style="border: 1px solid #ccc; padding: 5px;"> Yes No #6) Is any DNA from Risk Group 2, 3, or 4 agents or restricted organisms cloned into non- </div>
Addendum A-1	
Addendum A-2	
Addendum A-3	
Addendum B	
Addendum C	
Addendum C-1	
Addendum D	
Addendum E	
Addendum F	
Addendum G	
Addendum H	
Addendum I	

Addendum C-1 is The use of Embryonic Stem Cells (including Somatic Cells [to be used for SCNT], Fetal Tissue/Cells, Embryos, Sperm, Oocytes)

Create a New Protocol

17. Addendum A and A-1 Helpful Hints:

Addendums A and A-1 are often a source of difficulty when creating a protocol. Here are some hints to think about when/if you are required to complete these addendums. Also, the IBC Protocol Example is a great resource to show you an example of responses to the questions in these addendums.

Addendum A

This section is to determine how rDNA will be used.

1. Where does the research fall under the NIH guidelines?
2. What/how rDNA is being used?
3. What/how viral vectors are being used?
4. Do genes of interest (rDNA) pose an increased risk? (oncogenic, immunosuppressive)
5. What are the viral vector concerns?
 - a) Competent vs Incompetent
 - b) Recombination potential
 - c) Residual viral gene expression
 - d) Method of vector construction/propagation
 - e) Integration potential

If the research includes CRISPR or viral vectors, make sure you read/sign the CRISPR guidesheet or viral vector factsheets and upload to the **File Cabinet**.

Addendum A-1

This section is to further determine the risk of rDNA and vectors.

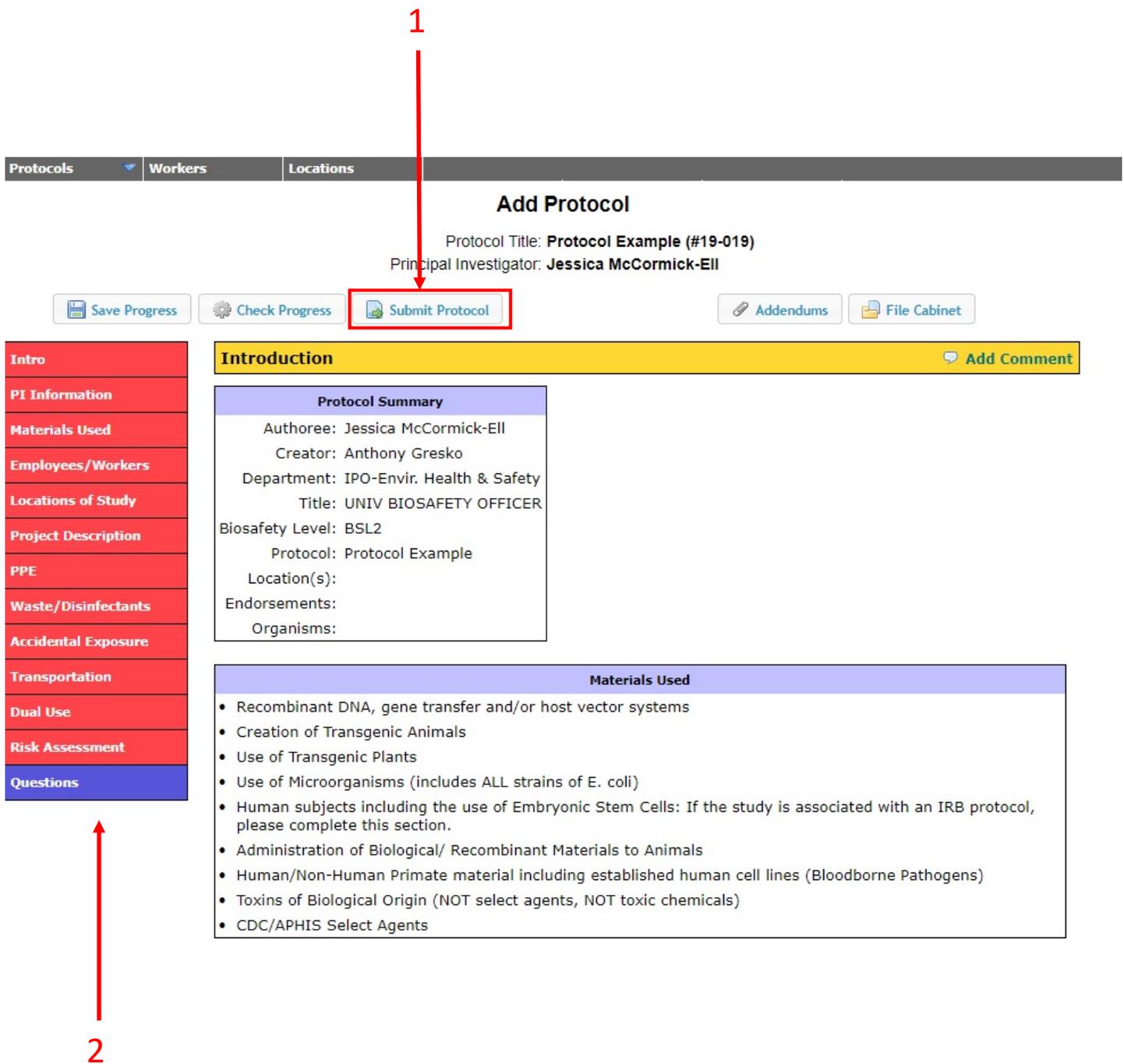
1. Do the vectors/strains/gene targets present any hazards?
 - a) Are the gene targets oncogenic?
 - b) Does putting the vector into the host present additional risks?
2. Is the viral vector contaminated with replication competent virus?

E.coli must be mentioned here. You also need to ensure all plasmids are listed, including the transfer **AND** packaging plasmids. Plasmid maps should be uploaded into the **File Cabinet**, and should relate to the vectors in the chart here.

Create a New Protocol

18. Submit Protocol:

1. Click on the “Submit Protocol” button to submit a finished protocol.
2. When the protocol is being reviewed by Biosafety, the PI will need to answer questions in the questions tab. When reviewers ask for more information through a question, please provide the information **in the requested sections of the protocol.**



The screenshot displays the 'Add Protocol' interface. At the top, there are navigation tabs for 'Protocols', 'Workers', and 'Locations'. Below these, the title 'Add Protocol' is centered, followed by the protocol details: 'Protocol Title: Protocol Example (#19-019)' and 'Principal Investigator: Jessica McCormick-Ell'. A row of buttons includes 'Save Progress', 'Check Progress', 'Submit Protocol' (highlighted with a red box and a red arrow labeled '1'), 'Addendums', and 'File Cabinet'. On the left, a vertical sidebar contains red tabs for 'Intro', 'PI Information', 'Materials Used', 'Employees/Workers', 'Locations of Study', 'Project Description', 'PPE', 'Waste/Disinfectants', 'Accidental Exposure', 'Transportation', 'Dual Use', 'Risk Assessment', and 'Questions' (highlighted in blue with a red arrow labeled '2'). The main content area shows the 'Introduction' section with a yellow header and an 'Add Comment' button. Below this is a 'Protocol Summary' box containing fields for Author, Creator, Department, Title, Biosafety Level, Protocol Name, Location(s), Endorsements, and Organisms. The 'Materials Used' section follows, listing various biological materials and agents.



Adding a Worker

To add a worker to a protocol:

1. In “My Protocols”, click on “View Protocol/Add Workers to an existing Protocol”
2. Click on the protocol you wish to add a worker to.

Protocols	Workers	Locations
-----------	---------	-----------

My Protocols

Please select from the listing below to Create, View/Add Workers, Renew, Terminate or Amend a protocol with the Institutional Biosafety Committee. Please contact biosafety@rutgers.edu with any questions regarding this protocol registration system.

Adding personnel who will work with **Human Materials** (e.g., established human cell lines) will require that an Amendment be submitted as changes must also be made to Addendum E for the respective worker(s) added.

Make sure to click on the "Save Progress" button as you populate/edit each tab. Click on "Submit Protocol" to indicate the protocol is ready for pre-review (does not go out to entire committee). Protocols created by non-PIs will require PI Assurance to be submitted by PI.

1 ———

Please select an action to perform

Create a new Protocol

View Protocol/Add Workers to an Existing Protocol

Renew an Existing Protocol

Terminate an Existing Protocol(s)

Amend an Existing Protocol

Click on the title of the protocol to access that protocol

Existing Protocols					
Code	Title	Authoree	Status	BSL	Expiration Date
17-034	dfs	McCormick-Ell Jessica	New	BSL1	
19-019	Protocol Example	McCormick-Ell Jessica	Amending	BSL3	09/20/2021

2

Adding a Worker

To add a worker to a Protocol:

3. Click on “Employees/Workers” tab
4. Click on “Add Worker” button

3

The screenshot shows the 'Add Protocol' interface. At the top, there are tabs for 'Protocols', 'Workers', and 'Locations'. Below the tabs, the protocol title is 'Protocol Example (#19-019)' and the principal investigator is 'Jessica McCormick-Ell'. There are buttons for 'Save Progress', 'Check Progress', and 'Submit Protocol', along with 'Addendums' and 'File Cabinet' options. On the left, a vertical menu lists various sections: 'Intro', 'PI Information', 'Materials Used', 'Employees/Workers', 'Locations of Study', 'Project Description', 'PPE', 'Waste/Disinfectants', 'Accidental Exposure', 'Transportation', 'Dual Use', 'Risk Assessment', and 'Questions'. The 'Employees/Workers' tab is highlighted in red, and a red box is drawn around it. A red line connects this box to the number '3' on the left. The main content area shows the 'Introduction' section with a 'Protocol Summary' box containing details like 'Author: Jessica McCormick-Ell', 'Creator: Anthony Gresko', 'Department: IPO-Envir. Health & Safety', 'Title: UNIV BIOSAFETY OFFICER', 'Biosafety Level: BSL2', 'Protocol: Protocol Example', 'Location(s):', 'Endorsements:', and 'Organisms:'. Below this is the 'Materials Used' section with a list of items such as 'Recombinant DNA, gene transfer and/or host vector systems', 'Creation of Transgenic Animals', 'Use of Transgenic Plants', 'Use of Microorganisms (includes ALL strains of E. coli)', 'Human subjects including the use of Embryonic Stem Cells: If the study is associated with an IRB protocol, please complete this section.', 'Administration of Biological/ Recombinant Materials to Animals', 'Human/Non-Human Primate material including established human cell lines (Bloodborne Pathogens)', 'Toxins of Biological Origin (NOT select agents, NOT toxic chemicals)', and 'CDC/APHIS Select Agents'.

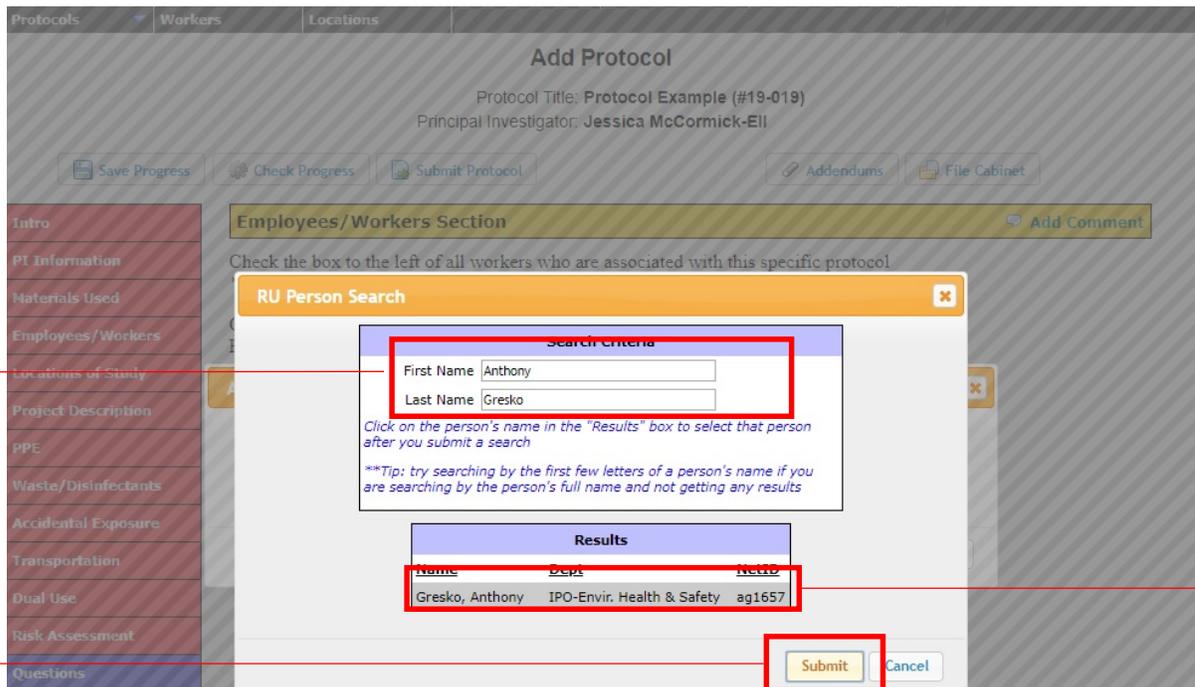
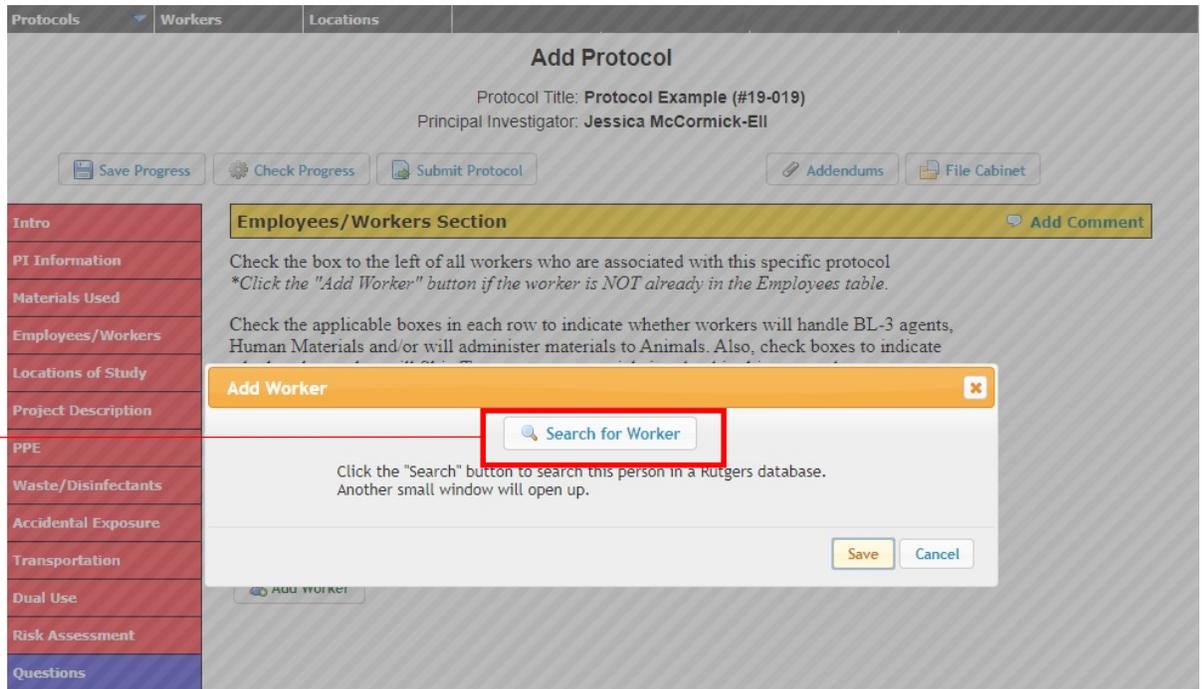
4

The screenshot shows the 'Add Protocol' interface, similar to the previous one, but with the 'Employees/Workers' section expanded. The 'Employees/Workers Section' header is highlighted in yellow. Below the header, there is text: 'Check the box to the left of all workers who are associated with this specific protocol *Click the "Add Worker" button if the worker is NOT already in the Employees table.' and 'Check the applicable boxes in each row to indicate whether workers will handle BL-3 agents, Human Materials and/or will administer materials to Animals. Also, check boxes to indicate whether the worker will Ship/Transport any materials involved in this protocol.' Below this text is a table with columns: 'Name', 'Responsible', 'SL3', 'Human Materials', 'Animals', and 'Shipping / Transport'. The 'Add Worker' button is highlighted in red, and a red box is drawn around it. A red line connects this box to the number '4' on the right. The left sidebar menu is the same as in the previous screenshot.

Adding a Worker

To add a worker to a Protocol:

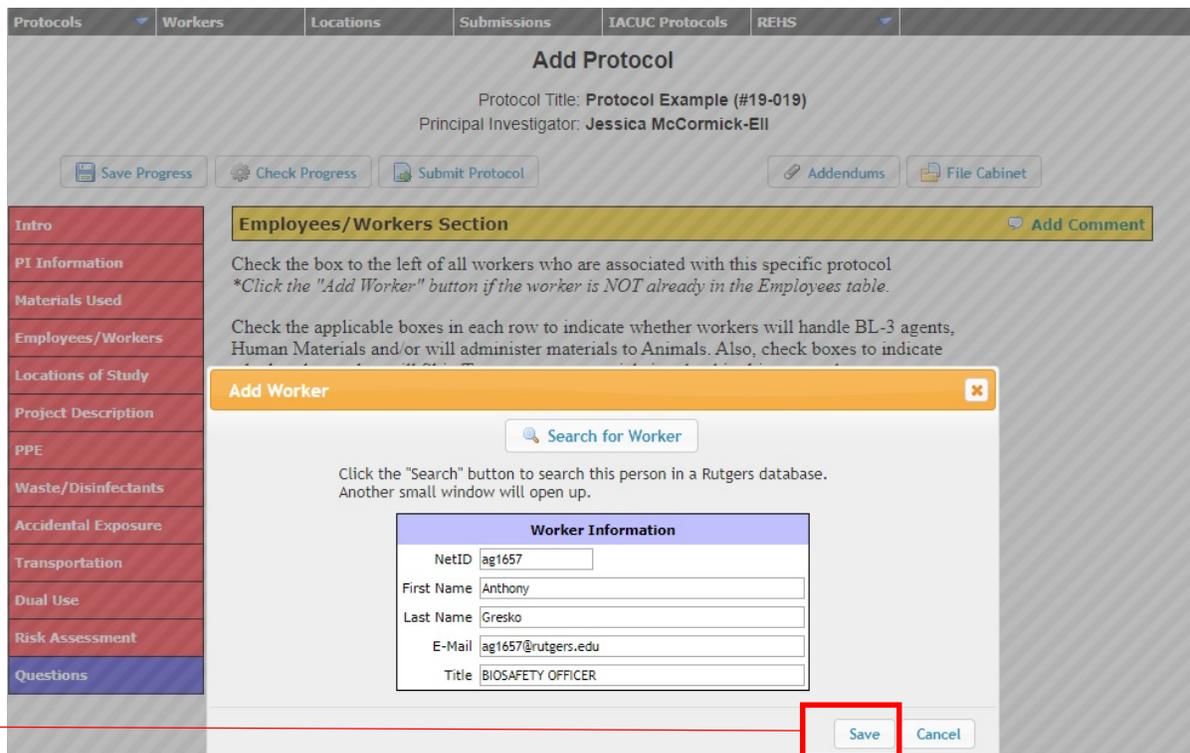
5. Click on “**Search for Worker**” button
6. Type in the workers name and click “**Submit**” button
7. In the Results box, click on the name of the desired worker.



Adding a Worker

To add a worker to a Protocol:

8. Verify the worker information is correct and click **“Save”** button
9. Check on the role(s) that the worker will have in the laboratory. Note: Human Materials includes use of established cell lines (HEK, Vero, etc). **Additional windows MAY appear, which must be completed.**
10. Click **“Save Progress”** button



Protocols Workers Locations Submissions IACUC Protocols REHS

Add Protocol

Protocol Title: Protocol Example (#19-019)
Principal Investigator: Jessica McCormick-Ell

Save Progress Check Progress Submit Protocol Addendums File Cabinet

Employees/Workers Section Add Comment

Check the box to the left of all workers who are associated with this specific protocol
**Click the "Add Worker" button if the worker is NOT already in the Employees table.*

Check the applicable boxes in each row to indicate whether workers will handle BL-3 agents, Human Materials and/or will administer materials to Animals. Also, check boxes to indicate whether the worker will Ship/Transport any materials involved in this protocol.

All listed workers must be up to date with required Laboratory Safety/Biosafety training, Online Viral Vector Training, online Plant Pathogen Training and/or Shipping Training, as applicable. Training status may be checked by floating over each name and clicking.

Add Worker

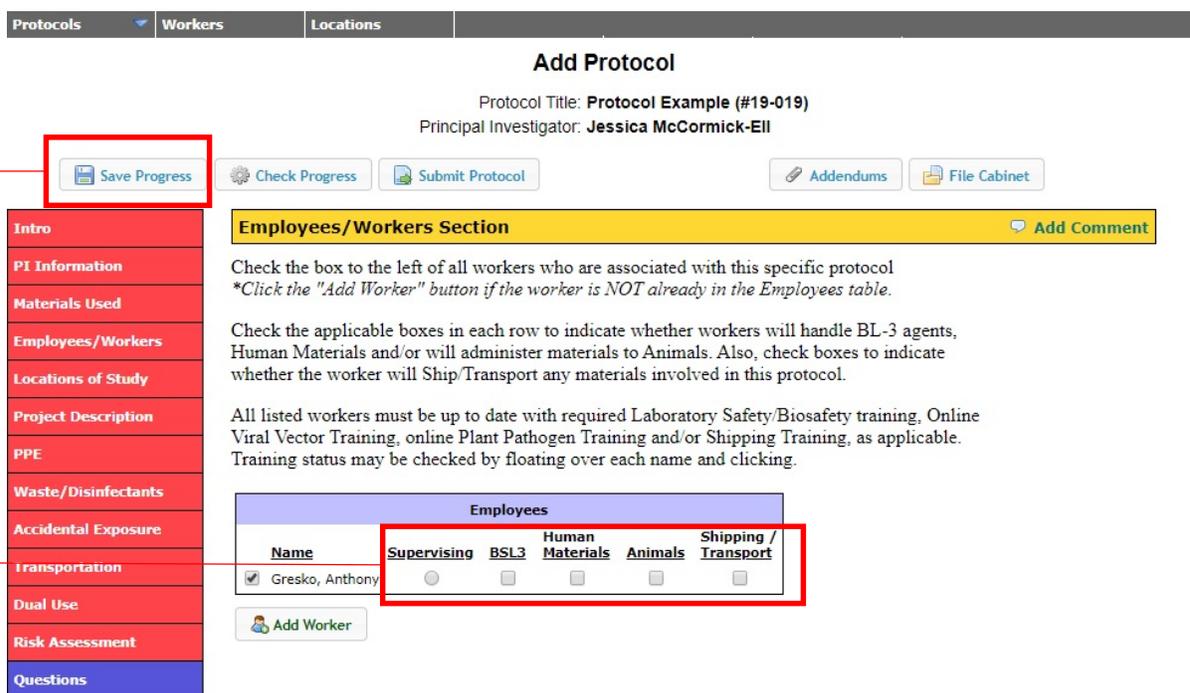
Search for Worker

Click the "Search" button to search this person in a Rutgers database. Another small window will open up.

Worker Information	
NetID	ag1657
First Name	Anthony
Last Name	Gresko
E-Mail	ag1657@rutgers.edu
Title	BIO SAFETY OFFICER

Save Cancel

8



Protocols Workers Locations

Add Protocol

Protocol Title: Protocol Example (#19-019)
Principal Investigator: Jessica McCormick-Ell

Save Progress Check Progress Submit Protocol Addendums File Cabinet

Employees/Workers Section Add Comment

Check the box to the left of all workers who are associated with this specific protocol
**Click the "Add Worker" button if the worker is NOT already in the Employees table.*

Check the applicable boxes in each row to indicate whether workers will handle BL-3 agents, Human Materials and/or will administer materials to Animals. Also, check boxes to indicate whether the worker will Ship/Transport any materials involved in this protocol.

All listed workers must be up to date with required Laboratory Safety/Biosafety training, Online Viral Vector Training, online Plant Pathogen Training and/or Shipping Training, as applicable. Training status may be checked by floating over each name and clicking.

Employees					
Name	Supervising	BSL3	Human Materials	Animals	Shipping / Transport
<input checked="" type="checkbox"/> Gresko, Anthony	<input type="checkbox"/>				

Add Worker

10

9



Removing a Worker

To remove a worker to a protocol:

1. In "My Protocols", click on "View Protocol/Add Workers to an existing Protocol"
2. Click on the protocol you wish to remove a worker from.

Protocols	Workers	Locations
-----------	---------	-----------

My Protocols

Please select from the listing below to Create, View/Add Workers, Renew, Terminate or Amend a protocol with the Institutional Biosafety Committee. Please contact biosafety@rutgers.edu with any questions regarding this protocol registration system.

Adding personnel who will work with **Human Materials** (e.g., established human cell lines) will require that an Amendment be submitted as changes must also be made to Addendum E for the respective worker(s) added.

Make sure to click on the "Save Progress" button as you populate/edit each tab. Click on "Submit Protocol" to indicate the protocol is ready for pre-review (does not go out to entire committee). Protocols created by non-PIs will require PI Assurance to be submitted by PI.

1 —

Please select an action to perform

Create a new Protocol

View Protocol/Add Workers to an Existing Protocol

Renew an Existing Protocol

Terminate an Existing Protocol(s)

Amend an Existing Protocol

Click on the title of the protocol to access that protocol

Existing Protocols					
Code	Title	Authoree	Status	BSL	Expiration Date
17-034	Jfs	McCormick-Ell Jessica	New	BSL1	
19-019	Protocol Example	McCormick-Ell Jessica	Amending	BSL3	09/20/2021

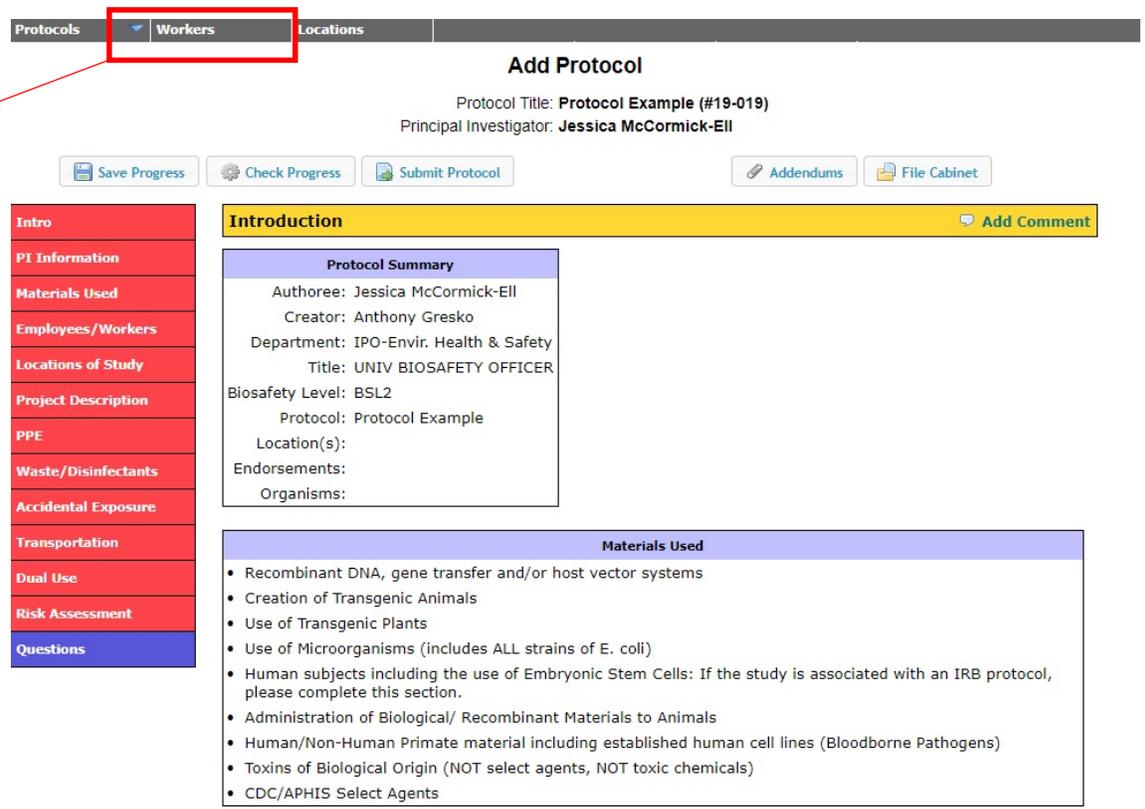
2 —

Remove a Worker

To remove a worker to a Protocol:

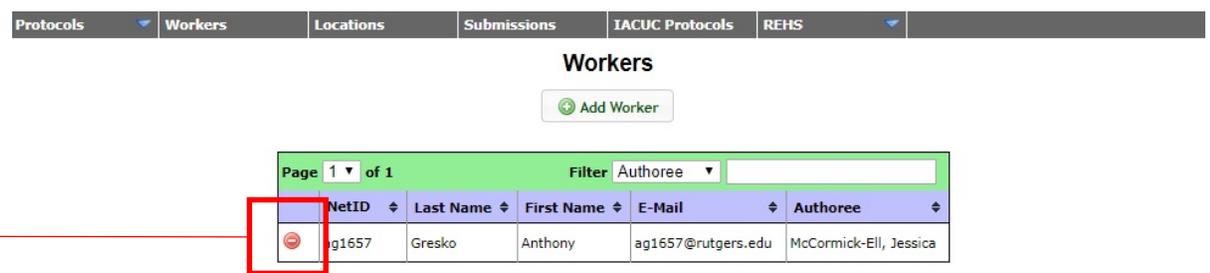
3. Click on “**Workers**” tab at the top in gray
4. Click on the red button next to the name of the worker you would like to remove from the protocol.

3



The screenshot shows the 'Add Protocol' interface. At the top, there are navigation tabs: 'Protocols', 'Workers', and 'Locations'. The 'Workers' tab is highlighted with a red box. Below the tabs, the page title is 'Add Protocol'. The protocol title is 'Protocol Example (#19-019)' and the principal investigator is 'Jessica McCormick-Ell'. There are buttons for 'Save Progress', 'Check Progress', 'Submit Protocol', 'Addendums', and 'File Cabinet'. On the left, there is a vertical menu with various sections: 'Intro', 'PI Information', 'Materials Used', 'Employees/Workers', 'Locations of Study', 'Project Description', 'PPE', 'Waste/Disinfectants', 'Accidental Exposure', 'Transportation', 'Dual Use', 'Risk Assessment', and 'Questions'. The main content area is titled 'Introduction' and contains a 'Protocol Summary' box and a 'Materials Used' box. The 'Protocol Summary' box lists: Author: Jessica McCormick-Ell, Creator: Anthony Gresko, Department: IPO-Envir. Health & Safety, Title: UNIV BIOSAFETY OFFICER, Biosafety Level: BSL2, Protocol: Protocol Example, Location(s):, Endorsements:, and Organisms:.

4



The screenshot shows the 'Workers' page. At the top, there are navigation tabs: 'Protocols', 'Workers', 'Locations', 'Submissions', 'IACUC Protocols', and 'REHS'. The 'Workers' tab is highlighted. Below the tabs, there is an 'Add Worker' button. Below that, there is a table with columns: 'NetID', 'Last Name', 'First Name', 'E-Mail', and 'Authoree'. The table contains one row with the following data: NetID: ag1657, Last Name: Gresko, First Name: Anthony, E-Mail: ag1657@rutgers.edu, Authoree: McCormick-Ell, Jessica. A red box highlights a red minus sign button next to the first row of the table.

NetID	Last Name	First Name	E-Mail	Authoree
ag1657	Gresko	Anthony	ag1657@rutgers.edu	McCormick-Ell, Jessica



Remove a Worker

To remove a worker to a Protocol:

5. Type "DELETE" in all capital letters to confirm your intention to remove the worker from the protocol.

The screenshot shows the user interface for removing a worker. At the top left is the Rutgers logo and navigation tabs for 'Protocols', 'Workers', and 'Log'. A confirmation dialog box is open, displaying the message 'myrehs.rutgers.edu says' and 'Type "DELETE" (all Capital Letters) to confirm deletion'. A text input field contains 'DELETE', and there are 'OK' and 'Cancel' buttons. Below the dialog is a 'Person Search' form with fields for First Name, Last Name, Authoree (containing 'mccor'), NetID, and E-Mail, along with a 'Search' button. At the bottom is a table with the following data:

Page	1	of 1	Filter	Authoree	
	NetID	Last Name	First Name	E-Mail	Authoree
	ag1657	Gresko	Anthony	ag1657@rutgers.edu	McCormick-Ell, Jessica



Adding a Location

To add a location to a protocol:

1. In “My Protocols”, click on “Amend an Existing Protocol”
2. Click on the protocol that you wish to amend.
3. Click on the “Click to begin Amendment Process” button

Protocols Workers Locations

My Protocols

Please select from the listing below to Create, View/Add Workers, Renew, Terminate or Amend a protocol with the Institutional Biosafety Committee. Please contact biosafety@rutgers.edu with any questions regarding this protocol registration system.

Adding personnel who will work with **Human Materials** (e.g., established human cell lines) will require that an Amendment be submitted as changes must also be made to Addendum E for the respective worker(s) added.

Make sure to click on the "Save Progress" button as you populate/edit each tab. Click on "Submit Protocol" to indicate the protocol is ready for pre-review (does not go out to entire committee). Protocols created by non-PIs will require PI Assurance to be submitted by PI.

Please select an action to perform

- Create a new Protocol
- View Protocol/Add Workers to an Existing Protocol
- Renew an Existing Protocol
- Terminate an Existing Protocol(s)
- Amend an Existing Protocol

1

Check the radio button next to the protocol code of the protocol you wish to amend

Note: Expired Protocols Or Protocols within 3 months of expiration date CANNOT be amended, they must be renewed

Existing Protocols					
Code	Title	Authoree	Status	BSL	Expiration Date
17-034	dfs	McCormick-Ell Jessica	New	BSL1	
<input checked="" type="checkbox"/> 19-019	Protocol Example	McCormick-Ell Jessica	Approved	BSL3	09/20/2021

2

3

Adding a Location

To add a location to a protocol:

4. Type into the dialogue box the location you wish to add and what the location will be used for.
5. As you will need to add it in the protocol itself, click **“I still need to make changes to my protocol”**.
6. Once all boxes have been appropriately checked and/or answered, click on the **“Save Amendment”** button.

Amend Protocol

All Sections/Addendums Complete

Describe your changes here

I wish to add a location to the protocol (Building A, Room 1234). This room will be used for (animal work, virus work, tissue culture, etc.)

4

Please ensure you have updated your protocol to reflect the above mentioned changes.

- I still need to make changes to my protocol (You will be taken to your protocol when you click the "Save Amendment" button)
- I have completed all changes to my protocol

5

Save Amendment

6

Adding a Location

To add a location to a protocol:

7. Click on the **Locations of Study** tab.

Protocols Workers **Locations**

Edit Protocol

Protocol Title: **Protocol Example (#19-019)**
Principal Investigator: **Jessica McCormick-Ell**

Save Progress Check Progress Submit Protocol Addendums File Cabinet

Intro	<h4>Introduction Add Comment</h4> <h5>Protocol Summary</h5> <p>Authoree: Jessica McCormick-Ell Creator: Anthony Gresko Department: IPO-Envir. Health & Safety Title: UNIV BIOSAFETY OFFICER Biosafety Level: BSL3 Protocol: Protocol Example Location(s): International Center For Public Health IcpH 1190 (Rutgers Health Sciences Campus at Newark Campus) Endorsements: Organisms: E. coli, Examplevirus 2, Examplevirus 1, Mouse Examplevirus, Plant Examplevirus, Lentivirs</p> <h5>Materials Used</h5> <ul style="list-style-type: none">• Recombinant DNA, gene transfer and/or host vector systems• Creation of Transgenic Animals• Use of Transgenic Plants• Use of Microorganisms (includes ALL strains of E. coli)• Administration of Biological/ Recombinant Materials to Animals• Human/Non-Human Primate material including established human cell lines (Bloodborne Pathogens) <h5>Pending Amendments</h5> <p><i>(Click on the highlighted grey row to view changes from the time the amendment was started to the current version)</i></p> <table border="1"><thead><tr><th>Date</th><th>Type</th><th>Renewal</th><th>Changes</th></tr></thead><tbody><tr><td>09/26/2019</td><td>Amendment</td><td></td><td>I wish to add a location to the protocol (Building A, Room 1234). This room will be used for (animal work, virus work, tissue culture, etc.)</td></tr></tbody></table>	Date	Type	Renewal	Changes	09/26/2019	Amendment		I wish to add a location to the protocol (Building A, Room 1234). This room will be used for (animal work, virus work, tissue culture, etc.)
Date		Type	Renewal	Changes					
09/26/2019		Amendment		I wish to add a location to the protocol (Building A, Room 1234). This room will be used for (animal work, virus work, tissue culture, etc.)					
PI Information									
Materials Used									
Employees/Workers									
Locations of Study									
Project Description									
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Waste/Disinfectants									
Accidental Exposure									
Transportation									
Dual Use									
Risk Assessment									
Questions									

Adding a Location

To add a location:

8. You can click or unclick a location that is already in the protocol
9. You can click on the **“Add Location”** button to add a new location to the protocol.

Protocols | **Workers** | **Locations**

Edit Protocol

Protocol Title: **Protocol Example (#19-019)**
Principal Investigator: **Jessica McCormick-Ell**

Intro	<div style="background-color: #fff; border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> Locations of Study Add Comment </div> <p>Check all locations which are used with this protocol. Make sure to include Vivarium Procedure Rooms, as applicable.</p> <p>If a location is not present, then click the "Add Location" button to add it to the table below.</p> <div style="background-color: #f0f0f0; border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p style="text-align: center; background-color: #f080f0; margin: 0;">Saved Locations</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20px;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">International Center for Public Health ICPH 1190</td> </tr> </table> <p>Shared Space: No Room Functions: Bench Work, Tissue Culture, Agent Storage Containment Control: Fume Hood, Biosafety Cabinet</p> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <input type="button" value="Add Location"/> </div>	<input checked="" type="checkbox"/>	International Center for Public Health ICPH 1190
<input checked="" type="checkbox"/>		International Center for Public Health ICPH 1190	

PI assurance

When a proxy under a PI submits a protocol, the PI must acknowledge that the proposed work in the submitted protocol is indeed correct. **Protocols will not be approved until the assurance is completed.**

To give PI assurance:

1. When the proxy submits a protocol, the PI will receive an email asking to provide assurance that they approved the submission of the protocol. An example of this email is shown below.

From: biosafety@rutgers.edu <biosafety@rutgers.edu>
 Sent: Thursday, September 19, 2019 10:24 AM
 To: Jessica McCormick-Ell <jessica.mccormickell@rutgers.edu>
 Subject: Rutgers Biosafety Protocol Management System - PI Assurance Required

Anthony Gresko has created, renewed or amended a biosafety protocol on your behalf.

Please use the link at the bottom of the email to access your protocol

Protocol Code: 19-019

Protocol Title: Protocol Example

Please review the protocol, and if all is accurate, click on the "PI Assurance" button to read and complete the agreement statement. Your protocol will be reviewed and processed but will not be finalized until you have taken this action. Please contact biosafety@rutgers.edu with any questions or concerns!

https://myrehs.rutgers.edu/index.php?bpms_protocol=XWlm55fyawWxRK47

2. The PI will need to click on the link sent to their email address which will bring them to the protocol in question. Click the **"PI Assurance"** button

2

Edit Protocol

Protocol Title: **Protocol Example (#19-019)**
 Principal Investigator: **Jessica McCormick-Ell**

PI Assurance
Addendums
File Cabinet

The Protocol is "Locked". Changes can only be made in the "Employees/Workers" section

Add Comment

Protocol Summary

Authoree: Jessica McCormick-Ell
 Creator: Anthony Gresko
 Department: IPO-Envir. Health & Safety
 Title: UNIV BIOSAFETY OFFICER
 Biosafety Level: BSL3
 Protocol: Protocol Example
 Location(s): International Center For Public Health IcpH 1190 (Rutgers Health Sciences Campus at Newark Campus)
 Endorsements:
 Organisms: E. coli, Examplevirus 2, Examplevirus 1, Mouse Examplevirus, Plant Examplevirus, Lentivurs

Materials Used

- Recombinant DNA gene transfer and/or host vector systems

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PPE
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Accidental Exposure
Transportation
Dual Use
Risk Assessment
Questions



PI assurance

To give PI assurance:

3. Read the PI assurances and click on "I agree with the above mentioned statements" to acknowledge and approve of the research proposed in the submitted protocol. Then click "Submit" button.

Protocols	Workers	Locations
-----------	---------	-----------

Submit Protocol

[Back to Protocol](#)

All Sections/Addendums Complete

Principal Investigator's Assurance

1. I confirm that all persons involved with this project (including my collaborators) have been adequately trained in good microbiological techniques, have received instruction on any specific hazards associated with the project and worksite, and are aware of any specific safety equipment, practices, and behaviors required while conducting project procedures and using these facilities. The IBC may review my records documenting this instruction.
2. I will immediately report to the University Biosafety Officer any accident, injury, spill of biohazardous material, equipment or facility failure (i.e., ventilation failure), and /or any breakdown in procedure that could result in potential exposure of laboratory personnel, staff, or the public to biohazardous or toxic material.
3. I confirm that any proposed changes to my work that would result in an increased level of biohazard will be reported to the IBC before the change is implemented.
4. I confirm that no work that requires IBC approval will be initiated or modified until approval is received and all sponsoring agency requirements have been met.
5. I will notify the IBC of new personnel on my protocol through the use of the "Add Workers" function on the BPMS.
6. I have read and understand my responsibilities as Principal Investigator outlined in Section IV-B-4 of the NIH Guidelines and agree to comply with these responsibilities.
7. I certify that the information provided within this application is accurate to the best of my knowledge. I also understand that, should I use the project described in this application as a basis for a funding proposal (either intramural or extramural), I am responsible for ensuring that the description of procedures in the funding proposal is identical in principle to that contained in this application.
8. I confirm that all persons involved with this protocol will comply with all applicable environmental laws and regulations and that this project does not significantly impact the environment.

(Check that you agree with the above mentioned statements and then click the "Submit" to finish the application)

I agree with all the above mentioned statements

Submit

3



Amending a Protocol

To amend a protocol:

1. In “My Protocols”, click on “Amend an Existing Protocol”
2. Click on the protocol that you wish to amend.
3. Click on the “Click to begin Amendment Process” button

Protocols Workers Locations

My Protocols

Please select from the listing below to Create, View/Add Workers, Renew, Terminate or Amend a protocol with the Institutional Biosafety Committee. Please contact biosafety@rutgers.edu with any questions regarding this protocol registration system.

Adding personnel who will work with **Human Materials** (e.g., established human cell lines) will require that an Amendment be submitted as changes must also be made to Addendum E for the respective worker(s) added.

Make sure to click on the "Save Progress" button as you populate/edit each tab. Click on "Submit Protocol" to indicate the protocol is ready for pre-review (does not go out to entire committee). Protocols created by non-PIs will require PI Assurance to be submitted by PI.

Please select an action to perform

- Create a new Protocol
- View Protocol/Add Workers to an Existing Protocol
- Renew an Existing Protocol
- Terminate an Existing Protocol(s)
- Amend an Existing Protocol

1

Check the radio button next to the protocol code of the protocol you wish to amend

Note: Expired Protocols Or Protocols within 3 months of expiration date CANNOT be amended, they must be renewed

Existing Protocols					
Code	Title	Authoree	Status	BSL	Expiration Date
17-034	dfs	McCormick-Ell Jessica	New	BSL1	
<input checked="" type="checkbox"/> 19-019	Protocol Example	McCormick-Ell Jessica	Approved	BSL3	09/20/2021

2

3

Amending a Protocol

To amend a protocol:

4. Type into the dialogue box a summary of what you intend to change with the amendment. This is referred to later in this guide as “Summary of Changes”.
5. Depending on your changes, you may need to go into the protocol and edit the necessary sections where the changes are (i.e. project description, risk assessment, addendums, etc.). If further changes must be made, click on the appropriate box.
6. Once all boxes have been appropriately checked and/or answered, click on the “**Save Amendment**” button.

Amend Protocol

All Sections/Addendums Complete

Describe your changes here

I wish to add the use of a viral vector (3rd generation lentivirus) for transduction of cells.
I wish to add cell sorting of non-fixed, transduced human cells to my protocol.

4

Please ensure you have updated your protocol to reflect the above mentioned changes.

- I still need to make changes to my protocol (You will be taken to your protocol when you click the "Save Amendment" button)
- I have completed all changes to my protocol

5

 Save Amendment

6



Amending a Protocol

To amend a protocol:

- Go into the Sections that need to be changed and make the necessary changes that you described in your "Summary of Changes" that was in Step 4. An example of making the changes is shown in step 8.

NOTE: You will ALWAYS need to update the Project Description and Risk Assessment sections.

Protocols Workers Locations

Edit Protocol

Protocol Title: **Protocol Example (#19-019)**
Principal Investigator: **Jessica McCormick-Ell**

Save Progress Check Progress Submit Protocol Addendums File Cabinet

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- Employees/Workers
- Locations of Study
- Project Description
- PPE
- Waste/Disinfectants
- Accidental Exposure
- Transportation
- Dual Use
- Risk Assessment
- Questions

Introduction Add Comment

Protocol Summary

Authoree: Jessica McCormick-Ell
 Creator: Anthony Gresko
 Department: IPO-Envir. Health & Safety
 Title: UNIV BIOSAFETY OFFICER
 Biosafety Level: BSL3
 Protocol: Protocol Example
 Location(s): International Center For Public Health Icph 1190 (Rutgers Health Sciences Campus at Newark Campus)
 Endorsements:
 Organisms: E. coli, Examplevirus 2, Examplevirus 1, Mouse Examplevirus, Plant Examplevirus, Lentivurs

Materials Used

- Recombinant DNA, gene transfer and/or host vector systems
- Creation of Transgenic Animals
- Use of Transgenic Plants
- Use of Microorganisms (Includes ALL strains of E. coli)
- Administration of Biological/ Recombinant Materials to Animals
- Human/Non-Human Primate material including established human cell lines (Bloodborne Pathogens)

Pending Amendments
(Click on the highlighted grey row to view changes from the time the amendment was started to the current version)

Date	Type	Renewal	Changes
09/26/2019	Amendment		I wish to add the use of a viral vector (3rd generation lentivirus) for transduction of cells. I wish to add cell sorting of non-fixed, transduced human cells to my protocol.

7

Amending a Protocol

To amend a protocol:

- 8. Example Amendment: In the project description, describe the changes you wish to make to the protocol. **It helps to mark the date of these changes to distinguish when this part of your research was added to your protocol.*

Pending Amendments			
<i>(Click on the highlighted grey row to view changes from the time the amendment was started to the current version)</i>			
Date	Type	Renewal	Changes
09/26/2019	Amendment		<p>I wish to add the use of a viral vector (3rd generation lentivirus) for transduction of cells.</p> <p>I wish to add cell sorting of non-fixed, transduced human cells to my protocol.</p>

2. Provide a step by step "walk-through" of your research methodology. Be sure to explain how and why specific agents are used. If there is a connection between this IBC protocol, IRB, ESCRO and/ or IACUC be sure to describe the links.

immunoregulatory in nature. Recombinant plants will be generated using CRISPR techonology. Recombinant cell lines will be generated using RNAi and lentiviral systems. Both siRNA and miRNA will be used for transient gene knockdown.

Amendment 9/20/2019
 A lentivirus containing CRISPR gRNA library will infect both cell types (Cell A and Cell B) to achieve stably knock-out and knock-in cell lines. The lentivirus packaging system (3rd generation, acquired from this company (website)) is split into 4 total plasmids. One plasmid encodes Rev, one encodes Gag and Pol, one encodes the envelope protein (VSV-G), and the last plasmid encodes the shRNA or cDNA for Cas9. This 4 plasmid system is replication incompetent and having 4 separate plasmids further decreases the possibility of recombination and creation of replication competent particles. Also, the 5' LTR region of the transfer plasmid contains self-inactivation mutations to further decrease possibility of replication competent particle generation.

Cell Sorting will also be performed to sort for stable knock-outs and knock-ins from the lentiviral transduction. Additional information is found in Addendum I.

8

******* NOTE: In addition to describing the changes in the Project Description, Addendums A, A-1, and B must be updated for the use of the Lentivirus, as well as creating an Addendum I for cell sorting. The Risk Assessment section will need to be updated to reflect any change.**



Amending a Protocol

To amend a protocol:

- When finished editing ALL sections needed, click “**Save Progress**” and “**Submit Protocol**”.

9

Protocols Workers Locations

Edit Protocol

Protocol Title: **Protocol Example (#19-019)**
Principal Investigator: **Jessica McCormick-Ell**

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Introduction Add Comment

Protocol Summary

Authoree: Jessica McCormick-Ell
 Creator: Anthony Gresko
 Department: IPO-Envir. Health & Safety
 Title: UNIV BIOSAFETY OFFICER
 Biosafety Level: BSL3
 Protocol: Protocol Example
 Location(s): International Center For Public Health IcpH 1190 (Rutgers Health Sciences Campus at Newark Campus)
 Endorsements:
 Organisms: E. coli, Examplevirus 2, Examplevirus 1, Mouse Examplevirus, Plant Examplevirus, Lentivirs

Materials Used

- Recombinant DNA, gene transfer and/or host vector systems
- Creation of Transgenic Animals
- Use of Transgenic Plants
- Use of Microorganisms (includes ALL strains of E. coli)
- Administration of Biological/ Recombinant Materials to Animals
- Human/Non-Human Primate material including established human cell lines (Bloodborne Pathogens)

Pending Amendments
(Click on the highlighted grey row to view changes from the time the amendment was started to the current version)

Date	Type	Renewal	Changes
09/27/2019	Renewal	Renew my protocol WITH changes	I wish to use a different viral vector (3rd generation lentivirus) for transduction of cells. I wish to add cell sorting of non-fixed, transduced human cells to my protocol

Renewing a Protocol

To renew a protocol:

1. In “**My Protocols**”, click on “**Renew an Existing Protocol**”
2. Click on the protocol that you wish to renew.
3. Click on the “**Click to begin Renewal Process**” button

My Protocols

Please select from the listing below to Create, View/Add Workers, Renew, Terminate or Amend a protocol with the Institutional Biosafety Committee. Please contact biosafety@rutgers.edu with any questions regarding this protocol registration system.

Adding personnel who will work with **Human Materials** (e.g., established human cell lines) will require that an Amendment be submitted as changes must also be made to Addendum E for the respective worker(s) added.

Make sure to click on the "Save Progress" button as you populate/edit each tab. Click on "Submit Protocol" to indicate the protocol is ready for pre-review (does not go out to entire committee). Protocols created by non-PIs will require PI Assurance to be submitted by PI.

Please select an action to perform

- Create a new Protocol
- View Protocol/Add Workers to an Existing Protocol
- Renew an Existing Protocol**
- Terminate an Existing Protocol(s)
- Amend an Existing Protocol

1

Check the radio button next to the protocol code of the protocol you wish to renew
Note: Protocols with an expiration date greater than six months from today CANNOT be renewed

Existing Protocols					
Code	Title	Authoree	Status	BSL	Expiration Date
17-034	dfs	McCormick-Ell Jessica	New	BSL1	
<input checked="" type="radio"/> 19-019	Protocol Example	McCormick-Ell Jessica	Approved	BSL3	09/20/2019

2

✔ Click to begin Renewal Process

3



Renewing a Protocol

To renew a protocol:

4. If you have no changes to your protocol, click “**Renew my protocol without making any changes**”. If you do not have changes and click “**Save Renewal**”, you will see the screen at the bottom and will NOT be able to make any changes in your protocol. **If you have changes, proceed to step 5 on the next page.**

Protocols	Workers	Locations
-----------	---------	-----------

Renew Protocol

All Sections/Addendums Complete

Renewal Options

Renew my protocol without making any changes

Renew my protocol WITH changes

Save Renewal

Protocols	Workers	Locations
-----------	---------	-----------

Protocol Renewal Submission Complete

Your protocol renewal has been submitted to REHS. Your protocol is currently "Locked" and no changes can be made. If changes need to be made, then you will need to contact REHS and request that the protocol be unlocked.

Renewing a Protocol

To renew a protocol:

5. If you have changes to your protocol, click **“Renew my protocol WITH changes”**.
6. Type into this dialog box a summary of what you intend to change with the renewal. This is referred to later in this guide as **“Summary of Changes”**
7. Depending on your changes, you may need to go into the protocol and edit the necessary sections where the changes are (i.e. project description, risk assessment, addendums, etc). If further changes must be made, click on the appropriate box.
8. Once all boxes have been appropriately checked and/or answered, click the **“Save Renewal”** button.

Renew Protocol

All Sections/Addendums Complete

Renewal Options

Renew my protocol without making any changes

Renew my protocol WITH changes

5

Describe your changes here

I wish to use a different viral vector (3rd generation lentivirus) for transduction of cells.

I wish to add cell sorting of non-fixed, transfected human cells to my protocol.

6

Please ensure you have updated your protocol to reflect the above mentioned changes.

I still need to make changes to my protocol (You will be taken to your protocol when you click the "Save Renewal" button)

I have completed all changes to my protocol

7

 Save Renewal

8



Renewing a Protocol

To renew a protocol:

- Go into the Sections that need to be changed and make the necessary changes that you described in your "Summary of Changes" that was in Step 6. An example of making the changes is shown in step 10.

NOTE: You will ALWAYS need to update the Project Description and Risk Assessment sections.

Protocols Workers Locations

Edit Protocol

Protocol Title: **Protocol Example (#19-019)**
Principal Investigator: **Jessica McCormick-Ell**

Save Progress Check Progress Submit Protocol Addendums File Cabinet

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Protocol Summary

Authoree: Jessica McCormick-Ell
 Creator: Anthony Gresko
 Department: IPO-Envir. Health & Safety
 Title: UNIV BIOSAFETY OFFICER
 Biosafety Level: BSL3
 Protocol: Protocol Example
 Location(s): International Center For Public Health IcpH 1190 (Rutgers Health Sciences Campus at Newark Campus)
 Endorsements:
 Organisms: E. coli, Examplevirus 2, Examplevirus 1, Mouse Examplevirus, Plant Examplevirus, Lentivirs

Materials Used

- Recombinant DNA, gene transfer and/or host vector systems
- Creation of Transgenic Animals
- Use of Transgenic Plants
- Use of Microorganisms (includes ALL strains of E. coli)
- Administration of Biological/ Recombinant Materials to Animals
- Human/Non-Human Primate material including established human cell lines (Bloodborne Pathogens)

Pending Amendments
(Click on the highlighted grey row to view changes from the time the amendment was started to the current version)

Date	Type	Renewal	Changes
09/27/2019	Renewal	Renew my protocol WITH changes	I wish to use a different viral vector (3rd generation lentivirus) for transduction of cells. I wish to add cell sorting of non-fixed, transduced human cells to my protocol

9

Renewing a Protocol

To renew a protocol:

- Example renewal/amendment: In the project description, describe the changes you wish to make to the protocol. ***It helps to mark the date of these changes to distinguish when this part of your research was added to your protocol.**

Pending Amendments			
<i>(Click on the highlighted grey row to view changes from the time the amendment was started to the current version)</i>			
Date	Type	Renewal	Changes
09/20/2019	Renewal	Renew my protocol WITH changes	<p>I wish to use a different viral vector (3rd generation lentivirus) for transduction of cells.</p> <p>I wish to add cell sorting of non-fixed, transfected human cells to my protocol.</p>

2. Provide a step by step "walk-through" of your research methodology. Be sure to explain how and why specific agents are used. If there is a connection between this IBC protocol, IRB, ESCRO and/ or IACUC be sure to describe the links.

neither of which are ONCOGENIC or IMMUNOREGULATORY in nature. RECOMBINANT plants will be generated using CRISPR TECHNOLOGY. RECOMBINANT cell lines will be generated using RNAi and lentiviral systems. Both siRNA and miRNA will be used for transient gene knockdown.

Renewal/Amendment 9/20/2019

A lentivirus containing CRISPR gRNA library will infect both cell types (Cell A and Cell B) to achieve stably knock-out and knock-in cell lines. The lentivirus packaging system (3rd generation, acquired from this company (website)) is split into 4 total plasmids. One plasmid encodes Rev, one encodes Gag and Pol, one encodes the envelope protein (VSV-G), and the last plasmid encodes the shRNA or cDNA for Cas9. This 4 plasmid system is replication incompetent and having 4 separate plasmids further decreases the possibility of recombination and creation of replication competent particles. Also, the 5' LTR region of the transfer plasmid contains self-inactivation mutations to further decrease possibility of replication competent particle generation.

Cell Sorting will also be performed to sort for stable knock-outs and knock-ins from the lentiviral transduction. Additional information is found in Addendum I.

10

******* NOTE: For this example, in addition to describing the changes in the Project Description, Addendums A, A-1, and B must be updated for the use of the Lentivirus, as well as creating an Addendum I for cell sorting. The Risk Assessment section will need to be updated to reflect any change.**



Renewing a Protocol

To renew a protocol:

- When finished editing ALL sections needed, click “**Save Progress**” and “**Submit Protocol**”.

11

Protocols Workers Locations

Edit Protocol

Protocol Title: **Protocol Example (#19-019)**
Principal Investigator: **Jessica McCormick-Ell**

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[Check Progress](#)
[Submit Protocol](#)
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Protocol Summary

Authoree: Jessica McCormick-Ell
 Creator: Anthony Gresko
 Department: IPO-Envir. Health & Safety
 Title: UNIV BIOSAFETY OFFICER
 Biosafety Level: BSL3
 Protocol: Protocol Example
 Location(s): International Center For Public Health IcpH 1190 (Rutgers Health Sciences Campus at Newark Campus)
 Endorsements:
 Organisms: E. coli, Examplevirus 2, Examplevirus 1, Mouse Examplevirus, Plant Examplevirus, Lentivirs

Materials Used

- Recombinant DNA, gene transfer and/or host vector systems
- Creation of Transgenic Animals
- Use of Transgenic Plants
- Use of Microorganisms (includes ALL strains of E. coli)
- Administration of Biological/ Recombinant Materials to Animals
- Human/Non-Human Primate material including established human cell lines (Bloodborne Pathogens)

Pending Amendments
(Click on the highlighted grey row to view changes from the time the amendment was started to the current version)

Date	Type	Renewal	Changes
09/27/2019	Renewal	Renew my protocol WITH changes	I wish to use a different viral vector (3rd generation lentivirus) for transduction of cells. I wish to add cell sorting of non-fixed, transduced human cells to my protocol

Terminating a Protocol

To terminate a protocol:

1. In “**My Protocols**”, click on “**Terminate an Existing Protocol(s)**”
2. Click on the protocol that you wish to terminate.
3. Click on the “**Click to send Terminate Protocol(s) request**” button

My Protocols

Please select from the listing below to Create, View/Add Workers, Renew, Terminate or Amend a protocol with the Institutional Biosafety Committee. Please contact biosafety@rutgers.edu with any questions regarding this protocol registration system.

Adding personnel who will work with **Human Materials** (e.g., established human cell lines) will require that an Amendment be submitted as changes must also be made to Addendum E for the respective worker(s) added.

Make sure to click on the "Save Progress" button as you populate/edit each tab. Click on "Submit Protocol" to indicate the protocol is ready for pre-review (does not go out to entire committee). Protocols created by non-PIs will require PI Assurance to be submitted by PI.

Please select an action to perform

- Create a new Protocol
- View Protocol/Add Workers to an Existing Protocol
- Renew an Existing Protocol
- Terminate an Existing Protocol(s)**
- Amend an Existing Protocol

1

Click the checkbox next to the protocol code of the protocol (or protocols, you may check more than one) you wish to terminate

Note: This will send an email to the Biosafety Officer (BSO) to terminate the selected protocol. The BSO will then terminate the protocol

Existing Protocols						
Code	Title	Authoree	Status	BSL	Expiration Date	
<input checked="" type="checkbox"/>	17-034	dfs	McCormick-Ell Jessica	New	BSL1	
<input type="checkbox"/>	19-019	Protocol Example	McCormick-Ell Jessica	Amending	BSL3	09/20/2021

2

✖ Click to send Terminate Protocol(s) request

3

Terminating a Protocol

To terminate a protocol:

4. If you are certain you wish to terminate the protocol, click OK to confirm.

Protocols
Workers
Locations

My Protocols

Please select from the listing below to Create, View/Add Workers, Renew, Terminate or Amend a protocol with the Institutional Biosafety Committee. Please contact biosafety@rutgers.edu with any questions regarding this protocol registration system.

Adding personnel who will work with **Human Materials** (e.g., established human cell lines) will require that an Amendment be submitted as changes must also be made to Addendum E for the respective worker(s) added.

Make sure to click on the "Save Progress" button as you populate/edit each tab. Click on "Submit Protocol" to indicate the protocol is ready for pre-review (does not go out to entire committee). Protocols created by non-PIs will require PI Assurance to be submitted by PI.

Please select an action to perform

Create a new Protocol

Confirm ✕

⚠ Are you sure you wish to submit a request to terminate protocol(s)?

OK

Cancel

Click the checkbox next to the protocol(s) you wish to terminate. (More than one) you wish to terminate the BSO will then terminate the protocol

Note: This will send an email to the Biosafety Office

Existing Protocols				
Code	Title	Authoree	Status	BSL
<input checked="" type="checkbox"/>	17-034 dfs	McCormick-Ell Jessica	New	BSL1
<input type="checkbox"/>	19-019 Protocol Example	McCormick-Ell Jessica	Amending	BSL3 09/20/2021

✕ Click to send Terminate Protocol(s) request