



Creating a New Protocol in BPMS

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. In “My Protocols”, click on “Create a new Protocol”
2. Verify that a similar protocol does not already exist in the “Existing Protocols” panel
3. Click “no” if there is no similar existing protocols
4. 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 Principal Investigator / Protocol Information Principal Investigator <input type="text"/> <i>Once you select a PI the four locked fields (grey color) will unlock and become editable</i> Protocol Title <input type="text"/> Biosafety Level <input type="text"/> PI Title <input type="text"/> E-Mail Address <input type="text"/> Department <input type="text"/> Office Phone <input type="text"/> Emergency Phone (after hours) # <input type="text"/>
Employees/Workers	
Locations of Study	
PPE	
Biomedical Waste	
Disinfectants	
Accidental Exposure	
Transportation	
Dual Use	
Risk Assessment	
Project Description	
Materials Used	
	

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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)*

Protocols Workers Locations

Add Protocol

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

1 Save Progress 2 Check Progress 3 Submit Protocol 4 Addendums 5 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

Introduction Add Comment

Protocol Summary

Authoree: Jessica McCormick-Ell
 Creator: Anthony Gresko
 Department: IPO-Envir. Health & Safety
 Title: UNIV BIOSAFETY OFFICER
 Biosafety Level: BSL2
 Protocol: Protocol Example
 Location(s):
 Endorsements:
 Organisms:

Materials Used

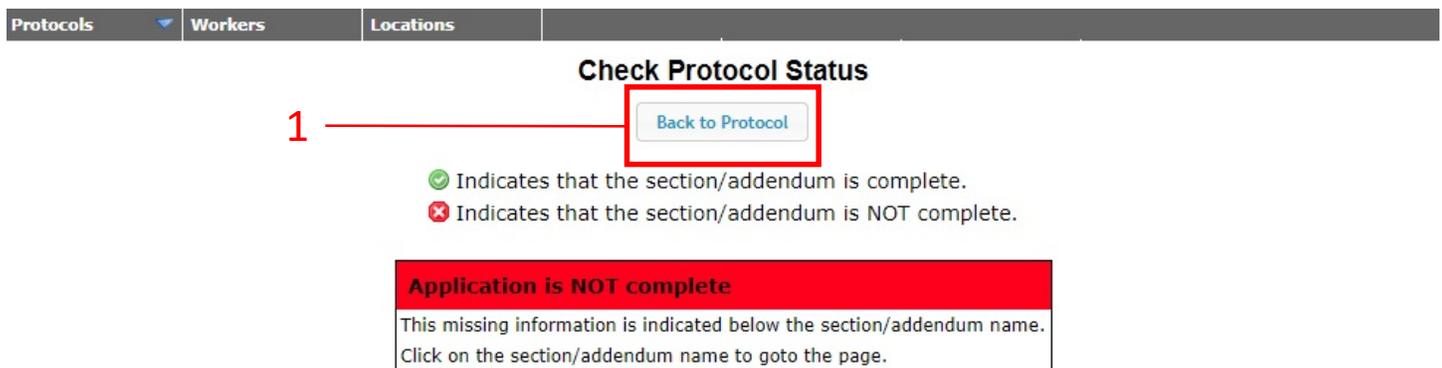
6

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

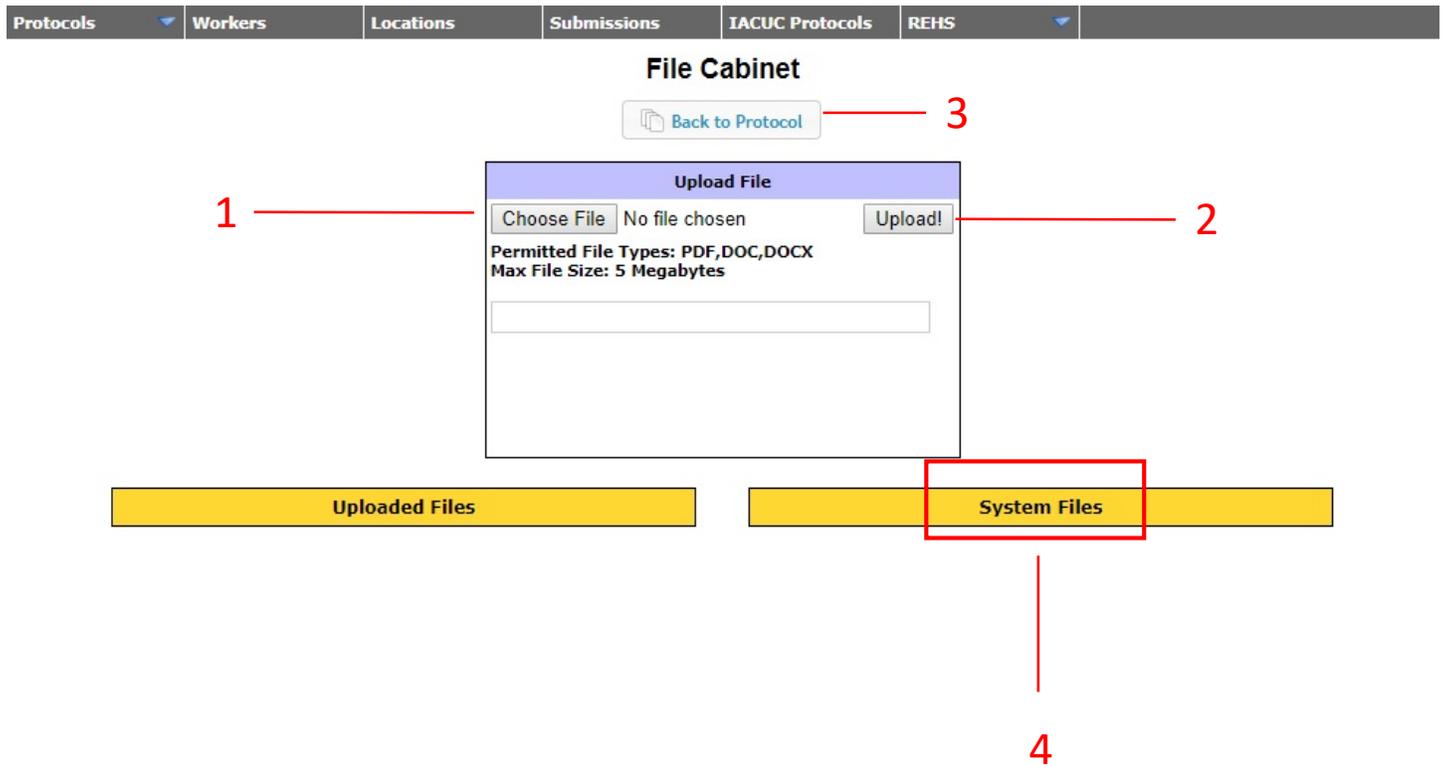
- ✘ **PI Information** 2
 - You must provide the US Government Agency(ies) and grant number(s)
 - You must provide the Non-US Government Agency(ies) and grant number(s)
 - You must provide the Agency(ies) which have issued permits
- ✘ **Employees/Workers**
 - You must check the Supervisor
- ✘ **Locations 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

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- 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.

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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.

1. 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.

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

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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 including the 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"/>	rDNA administration to human subjects	H
<input checked="" type="radio"/>	<input type="radio"/>	Cell Sorting and/or Flow Cytometry	I

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Create a New Protocol

8. Employees/Workers:

Follow the directions displayed to Add Workers to the protocol.

** 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)

Protocols **Workers** Locations

Add Protocol

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Principal Investigator: **Jessica McCormick-Ell**

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Employees/Workers Section

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



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.

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
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- Locations of Study**
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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

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

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

Add Protocol

Protocol Title: Protocol Example (#19-019)

Principal Investigator: Jessica McCormick-Ell

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PI Information
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Employees/Workers
Locations of Study
Project Description
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Accidental Exposure
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Dual Use
Risk Assessment
Questions

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

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

1

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.

2

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. 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

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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 <input type="text"/>	
<i>--Respirators require fit testing--</i>	

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 <input type="text"/>	
<i>--Respirators require fit testing--</i>	

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

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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

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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
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Add Protocol

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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?



Create a New Protocol

15. Dual Use:

Check any box that may apply to your research. If none apply, check "None of the above apply". Please contact Biosafety if you need help determining whether research could be Dual Use.

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Add Protocol

Protocol Title: **Protocol Example (#19-019)**
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Save Progress	Check Progress	Submit Protocol	Addendums	File Cabinet
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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



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
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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"

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Protocols Workers Locations

Addendums

Save Progress Check Progress Submit Protocol Protocol File Cabinet

- Addendum A
- 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 A Add Comment

Recombinant and Synthetic Nucleic Acids Questionnaire

Please answer each by clicking on the "Yes" or "No" button next to the question.

- 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 *red and italicized* 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.

Non-Exemption Questions - All these questions must be answered

#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.

#2) Does the recombinant or synthetic nucleic acids contain genes coding for molecules toxic to vertebrates (LD50 <100 nanograms / kg body wt)?

#3) Is the proposed experiment is equivalent to an experiment that has previously been approved by the NIH Director as a Major Action?

#4) Does the work involve administration of recombinant or synthetic nucleic acid molecules to human subjects?

#5) Are any human or animal pathogens used either as the host organism or as a vector?

#6) Is any DNA from Risk Group 2, 3, or 4 agents or restricted organisms cloned into non-

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.

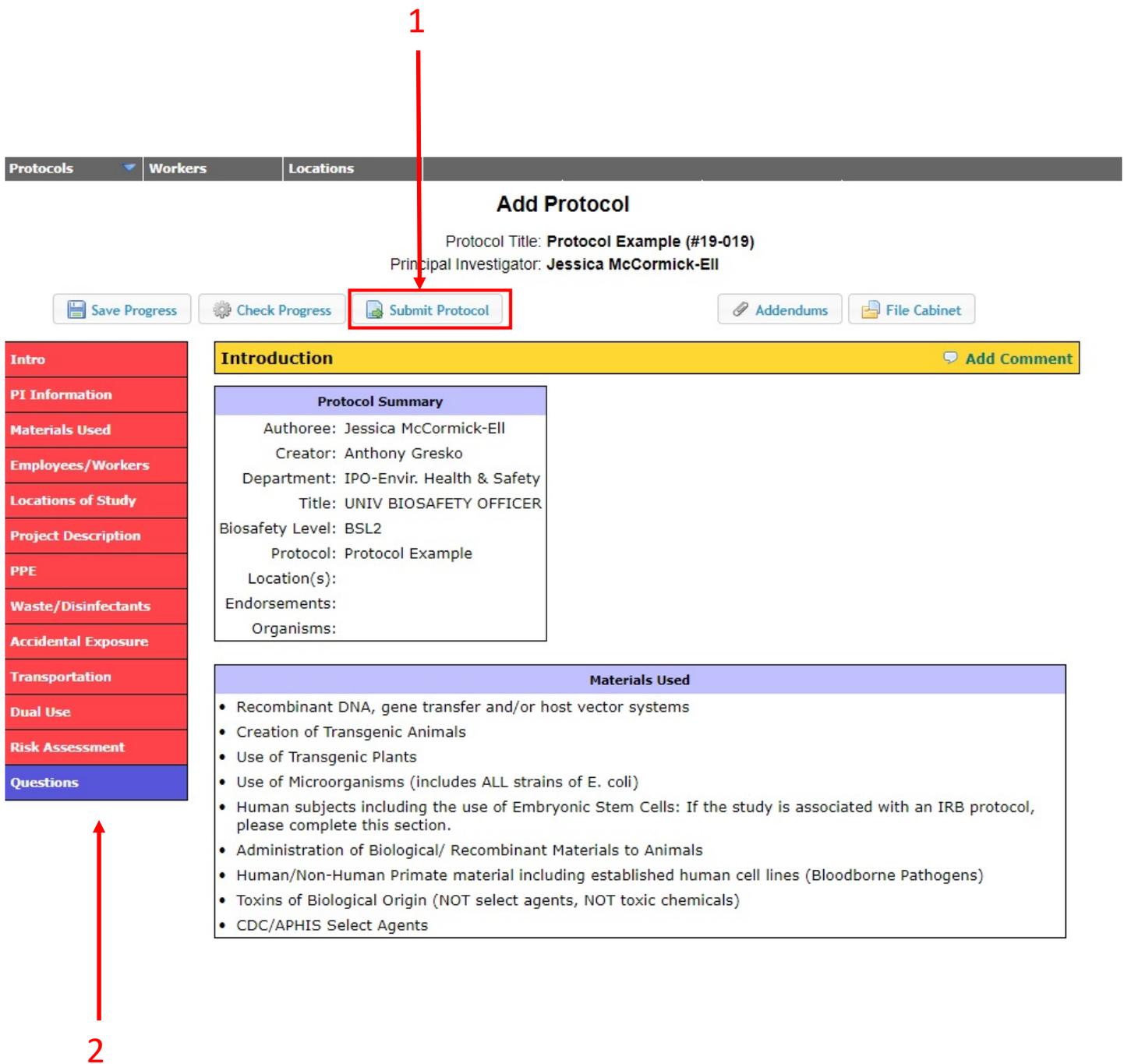
1. Do the vectors/strains/gene targets present any hazards?
 - a) Are the gene targets oncogenic?
 - b) Does putting the vector into the host present additional risks?
2. Is the viral vector contaminated with replication competent virus?

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.

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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.