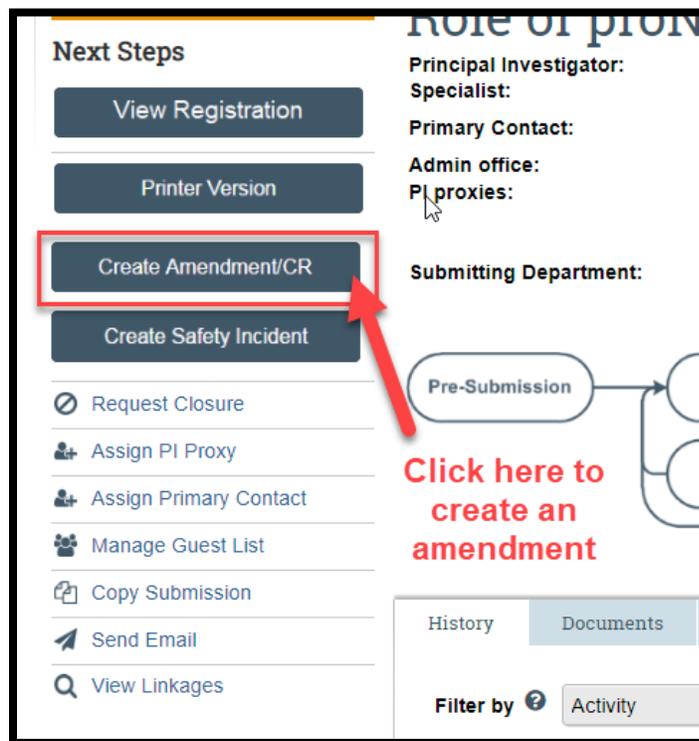


How to Submit an Amendment

PLEASE NOTE: Only one amendment can be active at a time. You cannot make changes to the registration materials or methods at the same time as a key personnel change.

Step 1

Click the Create Amendment/CR button



NOTE: If you do not see the Amendment button, it means there is an outstanding amendment on this lab registration that has not yet been approved. It must go through the approval process first before another amendment can be started and submitted.

Step 2

Choose “Amendment” and “Other parts of the protocol” in the initial form.

Amendment / Continuing Review

*** Type of Submission:**

- Amendment
- Amendment/CR
- Continuing Review

[Clear](#)

To change the PI, select "Other parts of the protocol." When changing team members, select both amendment types if team members must be added or removed as handlers of materials.

*** Amendment type:**

- Protocol team member information
- Other parts of the protocol

Step 3

Fill out page 1 of the Amendment Form. Ensure that the changes made to the registration are clearly listed on the form. Clicking “Continue” will open the entire registration for changes.

Editing: SAMEND202200000002

Amendment Introduction

1. * **Amendment short title:**

Amendment for REG202200013

This title can be changed or left as-is

2. * **Describe the changes:**

Adding a new cell line to the registration- HeLa
Adding a new room (Given D405) to the registration.
Adding a new funding source to the registration. Grants Office ID #FP20176

List the details of each change you are making to the registration.

3. * **Describe the rationale for the changes:**

We received a new JIT notice from the NIH and wish to add the new cell line and corresponding grant to our registration.
We have new lab space and would like to add it to the registration.

Provide clear justification for these changes.

4. * **If this is an IBC registration, I confirm that all study team members have reviewed this master protocol registration and all associated SOP and BARs listed under Supporting Documents/Registrations. If this is a DEA Documentation Registration, I confirm that all authorized users have taken the required training and have reviewed the DEA registration.**

Clicking "Continue" will allow you to make your changes directly to the pages of your registration

Exit Save Continue

As indicated on the form, the following changes need to be made:

Step 4:

Adding new materials: If the new materials are in a category not currently used on the

registration you will need to visit the Biosafety Summary page to check the box to add that specific page to the registration. Click "Continue" at the bottom of the page- this will add the new sections to the registration.

Biosafety Summary

1. * Select any items involved in the lab registration. Note, unchecking any items will cause you to lose data associated with the page(s).

Please choose "Human Research Participants" if your research involves Gene Therapy.
Please choose "Select Agents or Toxins" only if your research involves those Select Agents or Select Toxins listed on the CDC Federal Select Agents List.
Please choose "Other" if your research involves Toxins that are not on the CDC list, and then describe in the box below.

- Tissues, Blood, or Body Fluids
- Primary Cells or Cell Lines
- Bacteria, Yeasts, Fungi, or Parasites
- Viruses or Prions
- Select Agents or Toxins
- Recombinant or Synthetic Nucleic Acids
- Human Research Participants
- Animals
- Genetically Modified Animals
- Plant Pathogens
- Other

Once the new section has been added, use the left side index to jump to the section of the registration you need to change.

Click "Add" to add a new agent to the registration. Complete the form with all required information. When complete, click "Ok" at the bottom.

Add Biological Agent Information

Editing: SAF00000003

Primary Cells or Cell Lines

1. * Identify the source of all primary cells or cell lines

+ Add

Agent Biocontainment

There are no items to display

2. List other mammalian species

3. List other non-mammalian species

4. Identify cultures in volumes over 100 ml

1. * Agent:

HeLa

You can either start typing your new agent in the text box or use the "..." to search.

Name	Type	Usage Order
HeLa-ACE2	Cell Line	
HeLa-S3	Cell Line	
HELA	Cell Line	

2. HELA Cell Line

BSL-1

BSL-2

BSL-3

Clear

3. * Describe the use of the agent:

4. * Where are you obtaining the material from?

5. * Storage Locations: ?

You can either type the room number (not the building) in the text box or use the "..." to search.

Facility	Building	Usage
There are no items to display		

6. * Usage Locations: ?

Facility	Building	Usage
There are no items to display		

* Required

OK OK and Add Another Cancel

Adding/Removing Rooms:

Room numbers are noted within all Biological Agent pop up windows. An easy way to identify which sections need the room numbers adjusted is to look at the [Biohazards page](#). Each agent listed on the form should have a room for storage and usage- rooms can be found here.

Biohazards												
1. Summary of each agent, toxin, or microorganism that will be used in this protocol:												
Agent	BSL	Type	Select Agent	Storage Locations	Usage Locations	Supplier	Qty.	Handlers	ECX	Recombinant	Used in Animals	Used in Humans
HELA	BSL-2	Cell Line	no	D405	D405	Collaborators	1		1	no	no	no
Mucus Membrane Tissue	BSL-2	Tissue	no	120	120	hospital	1		1	no	no	no

Room numbers are displayed here and you can identify which sections need to have room numbers adjusted.

Once the section that needs to be changed is identified, it is easily edited:

Edit Biological Agent Information

Editing: SAF00000003

Tissues, Blood, or Body

1. * List type and source of all tissues

2. Describe any tissues transplanted

3. Describe the quantity of tissues

4. * Where are you obtaining the material from?
hospital

5. * Storage Locations: ?

Facility	Building	Usage
120	COLCHESTER RESEARCH FACILITY	

6. * Usage Locations: ?

Facility	Building	Usage
120	COLCHESTER RESEARCH FACILITY	

Start typing a room number (not building) or use the "..." to search
Remember to change both Storage and Usage locations if applicable.

Click the "x" to remove a room

Changes to funding and materials can be added in this same way.

When submitting changes to materials, please note that additional changes to the registration

may apply, such as:

1. Risk Group or Containment Practices
2. Exposure Assessment or Protective Equipment
3. Waste Management
4. Protocols/Registrations
5. Supporting Documents, such as SOPs or BARs.

Step 5

When all changes have been made, click “Save” and then “Exit” at the bottom of the screen. Click “submit” activity to submit the amendment to the Safety Office and start the review process.

The screenshot displays a web application interface for submitting an amendment. The top left corner features a yellow 'Pre-Submission' header. Below it, the 'Amendment' section includes a 'Next Steps' list with buttons for 'Edit Amendment', 'Printer Version', and 'Submit' (highlighted with a red box and arrow). Other options include 'Manage Guest List', 'Manage Ancillary Reviews', 'Add Comment', 'Discard', and 'Send Email'. The main content area shows the amendment ID 'SAMEND20220000001' and the title 'Amendment for REG2022000'. It lists the Principal Investigator as Margaret Vizzard, the Specialist, Primary Contact, Admin office (Safety), PI proxies (Aubrie Clas), and Submitting Department. The Amendment Type is 'Protocol team member information' and the Registration is 'New Registration'. A flowchart on the right illustrates the review process: Pre-Submission leads to Specialist Review, which can lead to Committee Review or Clarification Requested. Committee Review can lead to Clarification Requested, which then loops back to Specialist Review. At the bottom, there are tabs for 'History', 'Documents', 'Reviews', 'Contacts', and 'CITI Training'.