



Harvard University eCOMS Unofficial Guide

Contents

Committee on Microbiological Safety (COMS) Registration Requirements.....	2
New COMS Protocol Creation	2
<i>New Protocol Statuses</i>	<i>4</i>
<i>Prerequisites for COMS Protocol Approval</i>	<i>5</i>
PI Designees.....	5
<i>Adding PI Designees.....</i>	<i>5</i>
Annual Renewals	6
<i>Submitting Annual Renewals</i>	<i>6</i>
Amendments	7
<i>Creating Study Amendments.....</i>	<i>7</i>
Copying a COMS Protocol	9
Withdrawing Protocols (Pre-Approval)	12
COMS Protocol Inactivation Requests.....	13

For more information, please contact Harvard University Environmental Health & Safety Biosafety at
biosafety@harvard.edu.



Committee on Microbiological Safety (COMS) Registration Requirements

Laboratories are required to obtain [Committee on Microbiological Safety \(COMS\)](#) approval before purchase, receipt, storage, initiation, or modification of any and all research involving COMS-regulated materials (CRM) at Harvard University. The following materials are subject to COMS oversight:

- Recombinant or synthetic nucleic acids as defined in the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#)
- Human or non-human primate blood, cells, tissues, fluids, and secretions
- Biological toxins subject to the [National Select Agent Registry](#)
- Bacteria, virus, fungi, yeast, parasites, and prions

Principal Investigators (PIs) or their designees can create a new COMS protocol to register their research by logging in to the [eCOMS platform](#) using their HarvardKey.

New COMS Protocol Creation

1. Navigate to the eCOMS homepage and select “New COMS Study” (left menu).

The screenshot shows the eCOMS platform interface. At the top left is the Harvard Medical School logo. The user's name 'Angela Reid' and navigation links 'My Inbox | Projects | Logoff' are in the top right. Below the logo are navigation tabs: 'IACUC', 'COMS', 'Committees', and 'Support'. A breadcrumb trail reads 'Page for Angela Reid'. A 'Create...' menu is open, with 'New COMS Study' circled in blue. Other options include 'New Animal Study', 'New Reportable Event', and 'Create Safety Protocol...'. Below the menu are tabs for 'Inbox', 'My Reviews', 'My COMS', 'My IACUC', 'My Amendments', 'My Annual Renewals', 'My Reportable Events', and 'Upcoming Meetings'. A 'Filter by ID' dropdown is present with 'Go', 'Clear', and 'Advanced' buttons. The main content area shows 'No data to display.' and a pagination bar at the bottom indicating 'page 1' of 25.

2. Proceed through the pages as prompted.



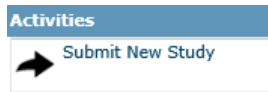
The application must be completed in order and sections cannot be skipped. However, each page may be saved using the “Save” option and returned to later.

To accessed unsubmitted applications, navigate to the study by selecting the project title on the homepage (“Inbox” tab). On the main study page, select “Edit Project” (upper left menu).

3. Enter the required information in each field.

Select “Save” or “Continue” to ensure each page’s information is saved and to proceed.

Select “Finish” on the last page to return to the main study page. Select “Submit New Study” to submit the study for review.



The protocol will remain in “Pre-Submission” state with a warning box until the study is submitted.

IMPORTANT

This study has not yet been submitted to COMS.
To submit this study, you must execute the “Submit New Study” activity on the left side of this page.



Only persons listed as PIs or PI designees can edit COMS protocols. Only the PI of the project can submit a new protocol/scientific amendment.

New Protocol Statuses

The status of a protocol is listed next to the project title under the eCOMS homepage (“Inbox” tab) and on the main study page (upper left corner).

BSO Review Status

“BSO Review” status indicates the protocol is currently being reviewed by the biosafety officer. This is the status assigned immediately after the PI selects “Submit New Study”.

Changes Requested by BSO Status

In the protocol review process, the BSO may determine edits are necessary prior to final protocol review by COMS. When the project is sent back to the PI/designee for adjustments, this triggers the “Changes Requested by BSO” status.

COMS Review Status

After completing their review, the BSO submits the study to COMS, changing the study’s status to “COMS Review”.

Active Status

Once COMS approves a protocol, either administratively or at a committee meeting, the status changes to “Active”.

Original approval letters for “Active” studies can be found under the study’s main study page “Supporting Documents” tab. This is known as the “parent” protocol for future amendments.



Prerequisites for COMS Protocol Approval

PIs must complete [NIH Guidelines and COMS for the PI training](#) and have a laboratory inspection before COMS grants their protocol approval. Training and inspection frequencies occur in accordance with COMS policies.

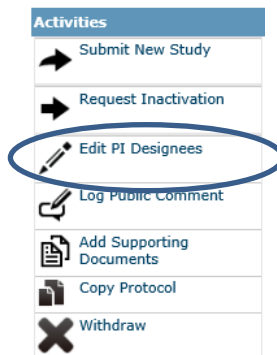
PI Designees

PIs can add PI designees to enable others to create new studies or amendments, edit their protocols, and submit annual renewals.

Adding PI Designees

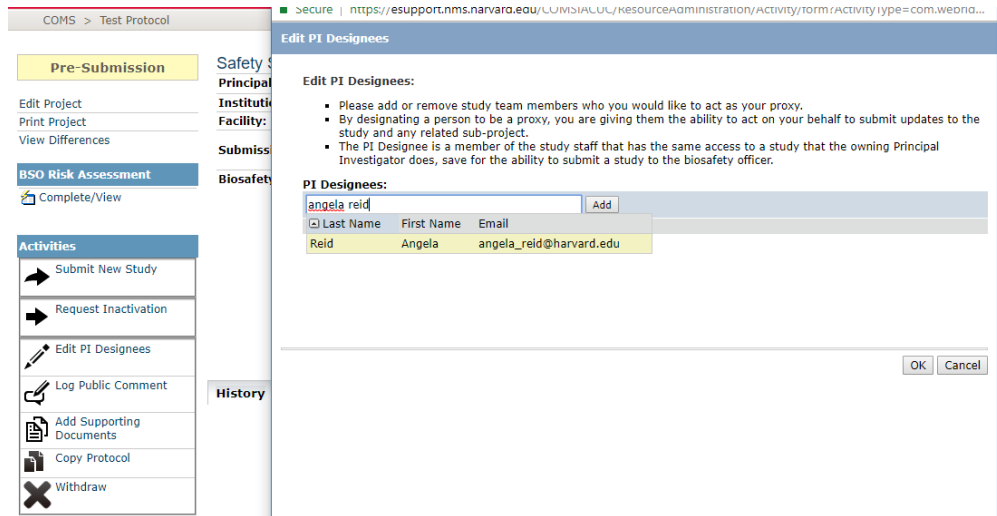
PIs, other PI designees, BSOs, or COMS administrators can update PI designees lists by:

1. Login to eCOMS. On the homepage, select the “My COMS” tab.
2. Select the title of the study.
3. Select “Edit PI Designees” (left-hand navigation bar).



4. Enter the desired designee’s name or Harvard email address, select their name, and select “OK”.

Updating PI designees may not be used as a substitute for amending protocols to include new personnel. Only people listed as study staff are allowed to perform the work described in the approved protocol.



Annual Renewals

PIs must annually confirm that their COMS registration remains consistent with their research.

The first annual renewal date is one year following formal approval in eCOMS. PIs or their designees can submit annual renewals.

Unrenewed studies may be inactivated. Laboratories may not continue work on inactivated protocols.

PIs and designees should receive email notices to submit their annual renewal at 90 days, 60 days, 30 days, and 10 days before it is due. Early submission does not reset the renewal date. PIs and designees can submit their review anytime within the 90-day renewal window.

The annual renewal process should take about five minutes.

Submitting Annual Renewals

Select “Submit Annual Renewal” under “Activities” (left study menu) to open a window where PIs or designees can add or drop personnel and verify that all research remains the same. PIs will be prompted to submit a COMS amendment if changes to the research or differences in the location of the research are noted during the renewal process.



Amendments

PIs may make changes or additions to “Active” status COMS protocols (protocols already approved by COMS and not expired) through amendments.

There are two types of changes:

- **Administrative:** Personnel changes
- **Scientific:** All other changes (ex. rooms, biological agents, etc.)

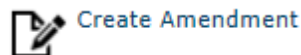
Administrative change amendments are immediately active after amendment submission, while scientific changes need further review prior to amendment approval.

Administrative change amendments do not generate a new approval letter due to automatic processing. Scientific change amendments generate new approval letters, which are under the amendment’s “Supporting Documents” tab after COMS approves the updates.

For both administrative and scientific amendments, the expiration date is the same as the “parent” protocol (i.e., the original study being amended).

Creating Study Amendments

1. Login to eCOMS. On the homepage, select “My COMS” tab.
2. Select the study to amend.
3. Select “Create an Amendment” (left menu).



A new study will be created similar to the original study except for the protocol number. The new study’s protocol number is the “parent” protocol number with “-AXX” for the amendment number. All of the information from the “parent” protocol is copied into the amendment.



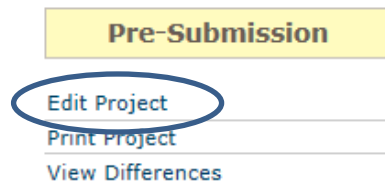
Do not delete anything from the amendment, and only add new information (rooms and personnel are exceptions). The “parent” protocol is connected to the amendment and any changes made will affect the “parent” protocol once approved.

In the newly generated amendment page, select “Edit Project” (upper left menu) and complete the necessary changes to update the protocol.

Update the “Amendment Summary” page with the list of changes you plan to make. The “Amendment Summary” page is the only place to delete information from past amendments, as it will not be shown in the “parent” protocol.

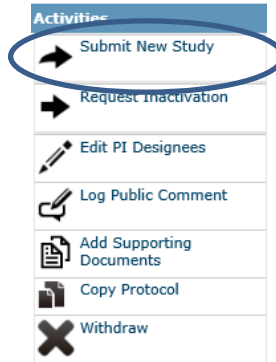
Do not delete anything from the body of the protocol (i.e., anything beyond the “Amendment Summary” page). Deleting content from the body of the protocol will remove your approval for these items.

Select “Save” or “Continue” to ensure each page’s information is saved and to proceed.



4. Once the edits are complete, select “Submit New Study” (left menu) to submit the amendment.

Depending on if the amendment changes are administrative or scientific, the amendment will change to “Active” status (administrative) or “BSO Review” status (scientific).

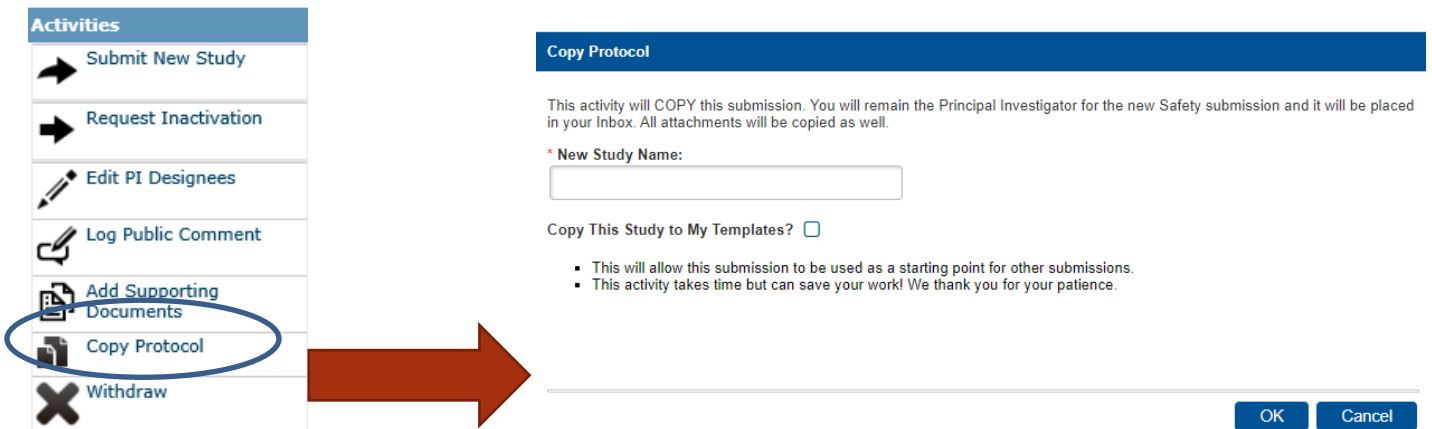


Copying a COMS Protocol

COMS protocols are approved for 5 years, after which, they are required to be rewritten. When a study is expiring, data can be copied from the current COMS into a new protocol.

1. Login to eCOMS. On the homepage, select the “My COMS” tab.
2. Select the title of the appropriate parent study.
3. On the main page of the protocol, select “Copy Protocol” (left menu).

Protocol titles can be changed or kept the same. The protocol number automatically updates and distinguishes the new project.





- The new protocol will appear on a separate page, once generated. Edit the copied protocol by selecting “Edit Project” under “Protocol Status” (upper left, new page).

Pre-Submission

[Edit Project](#)

[Print Project](#)

[View Differences](#)

- On the “General Information” page, update the “Anticipated Start” date with the meeting date for when you anticipate approval (or the expiration date of the protocol this will replace).

HARVARD MEDICAL SCHOOL Edit: Safety - 18-207

You Are Here: Test protocol

« Back Save Exit Hide/Show Errors Print Jump To - Continue »

General Information

Please provide the following general information.

- Project Title:** Test protocol
- Anticipated Starting Date:** 9/4/2020
- Principal Investigator:** Angela Reid
- PI Designees:** [Empty field]

Person	Organization
Marissa Cardwell	Harvard University
Eric Rouse	Harvard University

- Study Staff with HUIDs:** [Empty field]

2. **Anticipated Starting Date:** 10/4/2020

3. [Calendar dropdown]

4. [Calendar grid showing Oct 2020]

5. [Now Done buttons]

Organization: Harvard University



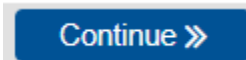
- Update the personnel listed by adding or deleting personnel. Search by last name by selecting the ellipsis dots, entering a name, and selecting “OK”.

5. **Study Staff with HUIDs** ⓘ:

“Advanced” search enables searching by first name, last name, or email address.

Last Name	First Name	Email
<input type="checkbox"/>		contact@hanbertrand.com
<input type="checkbox"/>		NULL
<input type="checkbox"/>		NULL
<input type="checkbox"/>		NULL
<input type="checkbox"/>		NULL
<input type="checkbox"/>		NULL
<input type="checkbox"/>		mamie_polidor@gse.harvard.edu

- Select “Continue” (upper or lower right-side of the page) to save and move to the next page, which also verifies that all the remaining information in the protocol is correct.



- After reviewing/modifying all the necessary pages, select “Finish” on the last page of the protocol to return to the main protocol page.



You Are Here: Transformation of Drosophila

Navigation bar with buttons: Back, Exit, Hide/Show Errors, Print, Jump To, Finish

You have reached the end of the COMS application. Click "finish" to save and exit. This study will need to be submitted to your Biosafety Officer (BSO) before it can be reviewed. In order to submit the study, the project Principal Investigator must click "submit" on the left-hand menu of the project workspace.

Please take this opportunity to review the information you have provided. It is very important that the responses be thorough and specific. Failure to respond to all requested items, submit all required documents, or complete all personnel requirements will result in a delay in the review of this study and may result in the study being returned to the investigator for correction or completion.

Thank you for completing this application.

*****PLEASE NOTE*****

- Clicking the "Finish" button on this page will NOT submit this study.
- To submit this study, you must execute the "Submit Study" activity in the study workspace.
- Once your study has been submitted, it will transition to the "BSO Review" or "Awaiting BSO Assignment" state.

Navigation bar with buttons: Back, Exit, Hide/Show Errors, Print, Jump To, Finish

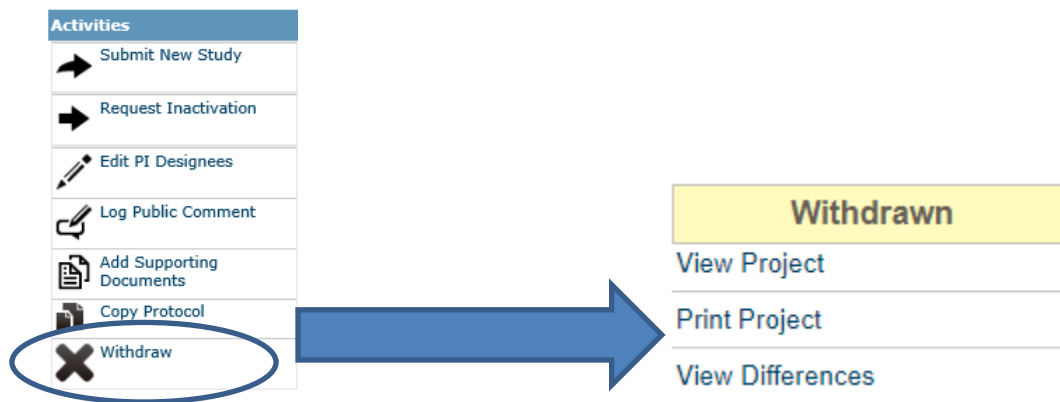
9. The study PI selects "Submit New Study" under "Activities" to submit the project for Biosafety Review.

Withdrawing Protocols (Pre-Approval)

Sometimes a PI decides not to go through with a study or a BSO determines that the contents of the application do not fall under COMS purview. In these and other scenarios where a protocol is not approved by COMS but is no longer necessary or desired, the protocol should be withdrawn. **PI designees can submit withdrawal requests in the eCOMS system, but only the PI can give final consent to the COMS office to withdraw a protocol.**



1. Login to eCOMS. On the homepage, select the “My COMS” tab.
2. Select the study to withdraw from submission.
3. Select “Withdraw” (left menu) and follow the prompts to withdraw the study.
4. The study will change to “Withdrawn” status upon submission and review by COMS.



COMS Protocol Inactivation Requests

When a new protocol replaces a study, a PI leaves the University, or the work is otherwise no longer active the study should be inactivated. **PI designees can submit inactivation requests in the eCOMS system, but only the PI can give final consent to the COMS office to inactivate a protocol.**

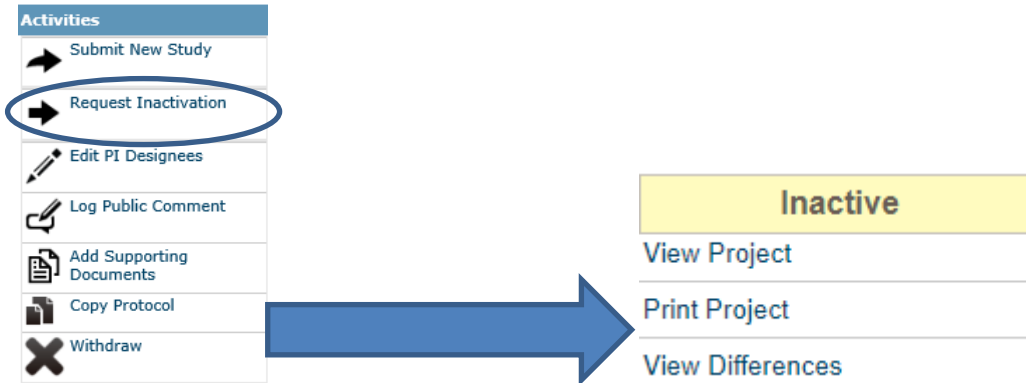
1. Login to eCOMS. On the homepage, select the “My COMS” tab.
2. Select the study to inactivate.
3. Select “Request Inactivation” (left menu) and follow the prompts to inactivate the study. The protocol’s status changes to “Inactive”.



HARVARD

Campus Services

ENVIRONMENTAL HEALTH & SAFETY



Studies that pass their expiration date automatically change to “Expired” status. You may not continue work on an expired protocol. You must submit a rewrite to continue the work (see [Copying a COMS Protocol](#)).

