THE UNOFFICIAL GUIDE TO NAVIGATING HARVARD UNIVERSITY eCOMS
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Creating a New COMS Protocol

When working with certain biological materials at Harvard University, you will be required to submit a protocol to the Committee on Microbiological Safety (COMS) for review of your research. The following 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 by logging in to the eCOMS platform using their HarvardKey at https://esupport.hms.harvard.edu/COMSIACUC

Once on the homepage, on the left-hand side, there will be a button to create a “New COMS Study.”

After clicking this button, proceed through the pages as prompted. Please note you will not be able to skip sections when completing the application. The application must be filled out in order. However, you can save each page using the “Save” button and log back in later to pick up where you left off.

When you log back in, navigate to the study by clicking the project title on the homepage. It should be listed under the “Inbox” tab above. From the study main page, click “Edit Project” in the upper part of the left navigation panel.

Submit your study for review
Enter all of the information required in each field. You will need to hit the “Save” button or use the “Continue” button to ensure information on each page is saved and to allow you to proceed. On the last page, clicking “Finish” will bring you back to the main page for the study. Once you are ready to submit the study for review, click “Submit New Study”.

Until the study is submitted, the protocol will remain in the Pre-Submission state, with the warning box below.

**Note: ONLY PERSONS LISTED AS PIs OR PI DESIGNEES CAN EDIT COMS PROTOCOLS. The listed PI on a project is the only one who can submit a new protocol/amendment and the only one who can inactivate/withdraw a protocol.**

The yellow box in the upper left corner indicates the protocol status. After submission, the project will go to BSO Review, and this will be reflected in the status. If the BSO requests edits be made to the project prior to submission to the committed, the project may be sent back to the PI/designee for adjustments and the status will indicate Changes Requested by BSO. Upon completing their review, the BSO submits the study to COMS, where the status changes to COMS Review. Once COMS approves a protocol, either administratively or at a committee meeting, the status of the project is switched to Active. Original approval letters for Active studies can be found under the study’s “Supporting Documents” tab on the study main page.

This project will be the one you amend, if you wish to change or add anything to this project. It is referred to as the “parent” protocol.

Adding PI Designees

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

To update the PI designees list, the PI, other PI designee, Biosafety Officer (BSO), or COMS administrator can login to eCOMS, and click on the My COMS tab from the homepage, and then click on the study you wish to edit.

Under the study, in the left-hand navigation bar, click the button to “Edit PI Designees.”
Type in the name or Harvard email of the individual you wish to add as a designee, select their name, and click OK. Do not use this as a substitute for amending a protocol to include new personnel. Only people listed as study staff will be allowed to perform work described in the approved protocol.

Creating an Amendment

Amendments are used to make changes or additions to COMS protocols with an “Active” status (the protocol has already been approved by the Committee and is not expired). There are two types of changes: administrative (ONLY changes to personnel are possible) and scientific (anything else—changes to rooms, biological agents, etc.). Administrative changes are immediately active after amendment submission, while scientific changes need further review prior to the amendment approval. Because of its automatic processing, no new approval letter will be generated with the submission of an administrative change. New approval letters will be generated for amendments with scientific changes, and the letters can be found under the “Supporting Documents” tab of that amendment once COMS has approved the updates. For both types of amendments, the date of expiration will be the same as the “parent” protocol (the original study you are amending).

To create an amendment, you can login to eCOMS, and click on the My COMS tab from the homepage, and then click on the study you wish to amend.

Under the study, in the left-hand navigation bar, click the button to create an amendment to the study.

Create Amendment

A new study page should pop up, that looks like the original, with the exception of the protocol number. It should be the parent protocol number with a “-AXX” for the amendment number. All information from the parent protocol will be copied into the amendment. DO NOT DELETE anything in the amendment, only add in the new information (rooms and personnel are the exceptions to this). The parent protocol is connected to the amendment, and any changes made here will affect the parent once approved.

Click “Edit Project” in the upper left corner. Complete the necessary changes to update the protocol. You should update the Amendment Summary page with the list of changes you plan to make—this is the only place you can delete information from past amendments, as it will not be shown in the parent protocol. Again, NO deleting in the body of
the protocol (anything beyond the Amendment Summary page). Deleting content from the body of the protocol will remove your approval for these items. Make sure to save each page before moving to the next you need to edit.

Once done making edits, submit the amendment by clicking “Submit New Study” on the left-hand navigational panel. Depending on if the amendment changes are administrative or scientific, it’s status will change to Active (administrative) or BSO Review (scientific).

Copying a COMS Protocol
Whenever a study is about to expire or is up for its five-year rewrite, you can copy the data from the current COMS into a new protocol, if you wish the study to continue. All of the information should transfer if the protocol was originally written in the new COMS system.

To copy a protocol, login to eCOMS, and click on the My COMS tab from the homepage, and then click on the appropriate parent study.

In the left-hand navigation bar, click the button to copy the protocol. You can change the name or keep it the same. The protocol number is automatically updated and what will be used to distinguish the new project.
Once in the copied protocol, please edit the protocol by clicking “Edit Project” (upper left corner of the new page, under Protocol Status (Pre-submission):

Under the General Information page, please update Anticipated Start date to be the meeting date for when you anticipate approval (or the expiration date of the protocol this will replace). Update personnel listed by adding or deleting. Select Yes or No for 10 and 11, if not already selected. See below for these steps.

Change Start Date

Change Personnel (you can search by last name by clicking the 3 dots, entering the name, and click OK)

“Advanced” search will let you search by First Name, Last Name or Email address.
Check Yes or No for number 10 and 11 on this page.

9. * Does this project involve the use of animals?:  
   Yes  No

10. * Does this project involve the use of plants?:  
    Yes  No

11. * Is this a clinical trial?:  
    Yes  No

Click the continue button on the upper or lower right of the page to save your work and move to the next page (verify all remaining information in the protocol is correct by doing this).

Once you have reviewed/modified all necessary pages, please click Finish on the last page of the protocol, which will return you to the main protocol page.
To submit this project for Biosafety Review, the study PI must click the “Submit New Study” button under “Activities”.

### Withdrawing a Protocol (pre-approval)

Sometimes a PI will decide not to go through with a study or a BSO will determine the contents of the application do not fall under COMS purview. In these and other scenarios where a protocol has not been approved by COMS, but is no longer necessary or desired, it should be withdrawn.

To withdraw a study, you can login to eCOMS, and click on the My COMS tab from the homepage, and then click on the study you wish to withdraw from submission.

Under the study, in the left-hand navigation bar, there is a button to withdraw the study. Click the button and follow the prompts. Upon submission and review by the COMS Office, the status box will show *Withdrawn*.

### Requesting COMS Protocol Inactivation

Whenever a study has been replaced with a new protocol, a PI is leaving the university, or the work is otherwise no longer active, it should be inactivated in the eCOMS system.

To request inactivation, you can login to eCOMS, and click on the My COMS tab from the homepage, and then click on the study you wish to inactivate.

Under the study, in the left-hand navigation bar, there is a button to request inactivation. Click the button and follow the prompts to inactivate the study. Status will show the protocol as *Inactive*.  

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**NOTE: Studies that pass their expiration date will now be automatically switched to *Expired* status. You may NOT continue work on an expired protocol—you must submit a rewrite (see Copying a COMS Protocol section), if you wish the work to continue.