

Introduction

The Staff section of the Humans module presents a list of Study Staff and Non-Study Staff members. It provides users the ability to add new staff members to the protocol or remove existing staff when creating a Protocol, Amendment, Staff Update or a Continuing Review. Before making changes to the staff section, it is important to understand when an Amendment is needed and when a Staff Update is needed.

When to submit an Amendment to change staff:

- * When the Principal Investigator is being changed
- * When a Site Responsible Investigator is changed or added

When to submit a Staff Update:

- * Adding/Removing study staff
- * Adding/Removing non-study staff
- * Updating study staff permissions, staff institution, contact person, staff role
- * Updating Financial Delegate

**Staff Updates are limited to staff changes and cannot be used to update protocol documents or forms. Staff Updates will be processed administratively with CITI training verification, completion of the Conflict of Interest questionnaire and Study Staff Certification and will be triaged to an IRB reviewer as needed.

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STEPS

1. The Staff page consists of two grids, one for listing the Study Staff members and the other for Non-study Staff members. It also lists the Financial Delegates when applicable
2. Within a transaction (Initial Review, Amendment, Staff Update, Continuing Review), click the **Staff** section on left navigation panel. Note that it gets unlocked when Initial Review, Amendment, Staff Update or Continuing Review request is created
3. You can add new study staff members by clicking on **+ New Study Staff** link on the top right corner of the Study Staff grid

Name	Degree	Organization	Role	Permission	Process	DCR	eCOI	CITI Expires	Staff Cert.	Contact
Daly, Mark J	Ph.D	Broad Institute	Co-Investigator	Manage	IR	<input checked="" type="checkbox"/>		12/13/19		<input type="checkbox"/>
Eggen, Kevin Carl		Broad Institute > Central Administration	Principal Investigator	Manage	IR	<input checked="" type="checkbox"/>		01/12/21		<input checked="" type="checkbox"/>

4. Upon clicking **+ New Study Staff** link, a drop-down box is displayed

Name	Degree	Organization	Role	Permission	Process	DCR	eCOI	CITI Expires	Staff Cert.	Contact
Daly, Mark J	Ph.D	Broad Institute	Co-Investigator	Manage	IR	<input checked="" type="checkbox"/>		12/13/19		<input type="checkbox"/>
Eggen, Kevin Carl		Broad Institute > Central Administration	Principal Investigator	Manage	IR	<input checked="" type="checkbox"/>		01/12/21		<input checked="" type="checkbox"/>

5. You can enter the staff name or username in the search field and search for the staff from the drop-down list and select the person you would like to add
6. Click **Add** to add the selected person to your registration, you can see a confirmation message in green to the right corner of the page
7. Selected person is successfully added to the Staff page. You can also add multiple staff simultaneously
8. You can select the role for the newly added staff member from the drop-down field for the staff line that has been created, designate permissions and contact person if applicable

Name	Degree	Organization	Role	Permission	Process	DCR	eCOI	CITI Expires	Staff Cert.	Contact
Daly, Mark J	Ph.D	Broad Institute	Co-Investigator	Manage	IR	<input checked="" type="checkbox"/>		12/13/19		<input type="checkbox"/>
Eggen, Kevin Carl		Broad Institute > Central Administration	Principal Investigator	Manage	IR	<input checked="" type="checkbox"/>		01/12/21		<input checked="" type="checkbox"/>

- The eCOI status remains **In Review** until the IRB eCOI form is approved
- If the added Staff member is CITI certified, an expiration date is displayed otherwise, a **Not Certified** status would be displayed

Dedi, Brixhilda	MGH > Neurology > Neuro Clinical Research - ALS	Research Coordinator/Ma...	Manage	AME5	<input checked="" type="checkbox"/>	06/07/20		<input type="checkbox"/>	
Fang, Ton	Partners	Intern/Student	Manage	AME13	<input checked="" type="checkbox"/>	Not Certified		<input type="checkbox"/>	
Fleisher, Emma	MGH > Neurology > Neuro Clinical Research - ALS	Intern/Student	View	AME5	<input type="checkbox"/>	07/02/21		<input type="checkbox"/>	
Gelevski, Dario	MGH > Neurology > Neuro Clinical Research - ALS	Research Coordinator/Ma...	Manage	AME9	<input checked="" type="checkbox"/>	Review Not Needed	09/05/21		<input type="checkbox"/>

- Upon submission of the Staff Update, the staff being added will receive a notification to sign off on the submission (staff certification)
- After the Staff Certification is complete, a PDF copy is available under the **Staff Cert** column for the added staff member
- There is a icon next to some of the staff member names which represents a POI (Person of Interest) status (see screenshot above)
- To add external study staff, click on the **+ New Study Staff** link

Name	Degree	Organization	Role	Permission	Process	DCR	eCOI	CITI Expires	Staff Cert.	Contact
Daly, Mark J	Ph.D	Broad Institute	Co-Investigator	Manage	IR	<input checked="" type="checkbox"/>		12/13/19		<input type="checkbox"/>
Eggen, Kevin Carl		Broad Institute > Central Administration	Principal Investigator	Manage	IR	<input checked="" type="checkbox"/>		01/12/21		<input checked="" type="checkbox"/>

- Note that a link **+ Add External Staff** appears at the top right corner of the study staff grid

Name	Degree	Organization	Role	Permission	Process	DCR	eCOI	CITI Expires	Staff Cert.	Contact
Daly, Mark J	Ph.D	Broad Institute	Co-Investigator	Manage	IR	<input checked="" type="checkbox"/>		12/13/19		<input type="checkbox"/>
Eggen, Kevin Carl		Broad Institute > Central Administration	Principal Investigator	Manage	IR	<input checked="" type="checkbox"/>		01/12/21		<input checked="" type="checkbox"/>

- Click **+ Add External Staff**
- An internal window pops-up where you can search for an external staff (see below)
- Clicking on **Search** button presents a list of external staff members
- Clicking on **Load more** button and scrolling down loads more external staff members
- If there are no existing records for the external staff you are trying to add, you can create an external record to add a new person by clicking on **+ Add External Staff** link at the bottom left corner of the window

Name	Email	External Institution Affiliation	Start typing to initiate search	Search	Clear Selections
Name	Email	Institution	The search criteria yielded no results.		
+ Add External Staff		Add staff	Cancel		

- Another internal window pops up where you can enter the name, email, institution details of the external staff being added
- Enter all required fields and click **Add** button (see below)

Add
Cancel

23. The external person also gets added to the grid like with **POI** status next to the name
24. Once the external staff has been added to the staff grid, there will be an option to upload the external staff's CITI certificate and the External Study Staff Certification at the end of the study staff grid. Please do not upload these documents in the attachments page

Study Staff (24) + New study Staff											
Name	Degree	Organization	Role	Permission	Process	DCR	eCOI	CITI Expires	Staff Cert.	Contact	
Alishkho, Mohamad J.	MD, MA	MGH > Neurology	Co-Investigator	Manage	AME1	<input checked="" type="checkbox"/>	Review Not Needed	10/29/20		<input type="checkbox"/>	<input type="checkbox"/>
Andrea, Pousada		BIDMC	Select...	View	Draft Staff Updates 1	<input type="checkbox"/>		Not Certified		<input type="checkbox"/>	Added <input type="checkbox"/>
Anez Bruzual, Isabel		MGH > Psychiatry > Neuroscience and Neuroimaging	Research Coordinator/Ma...	Manage	AME15	<input type="checkbox"/>		11/21/21		<input type="checkbox"/>	<input type="checkbox"/>
Arabasz, Grae E.		MGH > Radiology > Nuclear Medicine	Laboratory Technician/Te...	Manage	AME1	<input type="checkbox"/>		06/14/22		<input type="checkbox"/>	<input type="checkbox"/>
Babu, Suma	MBBS, MPH	MGH > Neurology	Principal Investigator	Manage	AME11	<input checked="" type="checkbox"/>	Review Not Needed	06/08/22		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Butterfield, Regan I.		MGH > Radiology	Laboratory Technician/Te...	Manage	AME1	<input type="checkbox"/>		06/17/22		<input type="checkbox"/>	<input type="checkbox"/>
Chew, Sheena		MGH > Medical Services > General Internal Medicine	Co-Investigator	Manage	AME7	<input checked="" type="checkbox"/>	Review Not Needed	08/04/20		<input type="checkbox"/>	<input type="checkbox"/>
Dedi, Brixhilda		MGH > Neurology > Neuro Clinical Research - ALS	Research Coordinator/Ma...	Manage	AME5	<input type="checkbox"/>		06/07/20		<input type="checkbox"/>	<input type="checkbox"/>
CITI Training Cert.	Select...										
Study Staff Cert.	Select...										

25. You can add new non-study staff members by clicking on **+ New non-study Staff** link on the top right corner of the Non-study Staff grid
26. You can select the organization and permission values from the drop-down fields

Non-study Staff (2) + New non-study Staff				
Name	Organization	Permission	Comments	Contact
Mahmood, Umar	MGH > Radiology > Martinos Center	Manage	<input type="text"/>	<input type="checkbox"/>
Walker, Daniela Grasso	MGH > Neurology > Neuro Clinical Research - ALS	View	<input type="text"/>	<input type="checkbox"/>

27. To remove a staff member, click on the **X** icon at the end of the staff record
28. Click **OK** to confirm staff deletion

Anez Bruzual, Isabel	MGH > Psychiatry > Neuroscience and Neuroimaging	Research Coordinator/Ma...	Manage	AME15	<input type="checkbox"/>	11/21/21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Arabasz, Grae E.	MGH > Radiology > Nuclear Medicine	Laboratory Technician/Te...	Manage	AME1	<input type="checkbox"/>	06/14/22		<input type="checkbox"/>	<input checked="" type="checkbox"/>

29. After the staff deletion, you can see the deleted staff member stroked off and in red text
30. You can undo the staff deletion by clicking on the **Undo** button
31. Staff deletion can be successfully restored after clicking Undo, you can find a confirmation message to the top right corner of the page

Babu, Suma	MBBS, MPH	MGH > Neurology	Principal Investigator	Manage	AME11	<input checked="" type="checkbox"/>	Review Not Needed	06/08/22		<input checked="" type="checkbox"/>	
Butterfield, Regan+		MGH > Radiology	Laboratory Technician/Te...	Manage	Draft Staff Updates-1	<input type="checkbox"/>		06/17/22		<input type="checkbox"/>	Deleted
Chew, Sheena		MGH > Medical Services > General Internal Medicine	Co-Investigator	Manage	AME7	<input checked="" type="checkbox"/>	Review Not Needed	08/04/20		<input type="checkbox"/>	

32. Financial Delegates can be updated in the corresponding section located at the bottom of the Staff page by clicking on the drop-down option for each designated delegate.

Financial Delegate		
Fund #232478	Select a financial delegate	
Fund #229495	Select a financial delegate	
Fund #231772	Select a financial delegate	
Fund #224793	Select a financial delegate	
Fund #225820	Select a financial delegate	