



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.

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



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



- 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







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



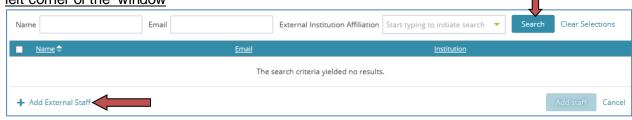
- **11.** Upon submission of the Staff Update, the staff being added will receive a notification to sign off on the submission (staff certification)
- **12.** After the Staff Certification is complete, a PDF copy is available under the **Staff Cert** column for the added staff member
- **13.** There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



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



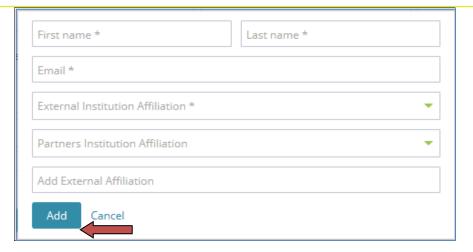
- 16. Click + Add External Staff
- **17.** An internal window pops-up where you can search for an external staff (see below)
- 18. Clicking on Search button presents a list of external staff members
- 19. Clicking on Load more button and scrolling down loads more external staff members
- **20.** If there 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 <u>bottom</u> left corner of the window



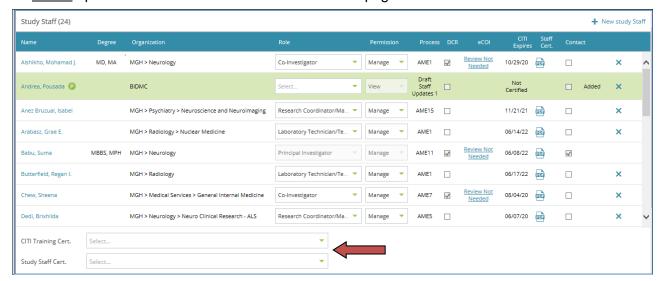
- **21.** Another internal window pops up where you can enter the name, email, institution details of the external staff being added
- 22. Enter all required fields and click Add button (see below)



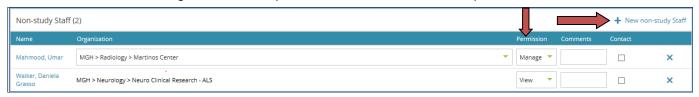




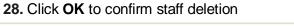
- 23. The external person also gets added to the grid like with POI status next to the name
- 24. Once the external staff has been added to the staff grid, there will be an option to upload the external staff's CITI certificate and the External Study Staff Certification at the end of the study staff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



- 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



27. To remove a staff member, click on the X icon at the end of the staff record





- 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





Insight 4.0 – Humans Staff



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.

