SUBMITTING A NEW AMENDMENT

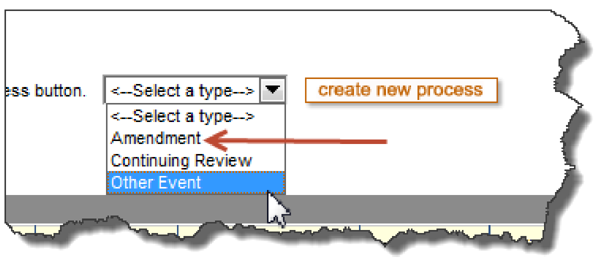
1. Go to the Insight Research Portal: https://insight.partners.org

3. Enter your Partners user name and password and click the Login button

2. Click on the go to Humans button

3. Click on the appropriate protocol title

4. Select ‘Amendment’ from the drop down list



5. Click the Create New Process button (see B. below).

6. The Amendment form will open. Complete the form and click the Save button. You are brought to the Forms page.

7. Click the Staff & Access tab

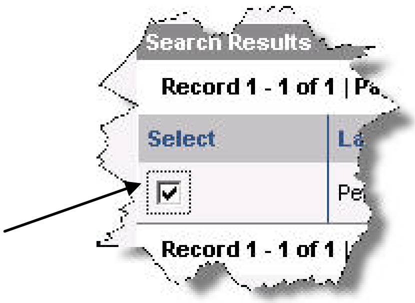
8. To add staff, proceed to step 9 and/or to delete staff proceed to step 21. NOTE: you can add and remove study staff with the same amendment. You can not however, combine a staff and non-staff amendment.

9. Click the Add Study Staff button below the Staff grid on the right

10. Enter person information and click the Search button. For best results, try searching on Partners user name only. If you do not know the user name, try last name and first initial. If the person has a hyphenated or apostrophe in their last name try the opposite.

Note: if the person you want to add does not have a Partners user name, click the 'Search Externals' checkbox. If no appropriate results return, click the **Next** button at the bottom of the screen and skip to step 15.

11. In the Search Results, check the box next to the name of the correct person and click the **Add to Selected Results** button. NOTE: You cannot select a name if the user is not listed as currently CITI certified

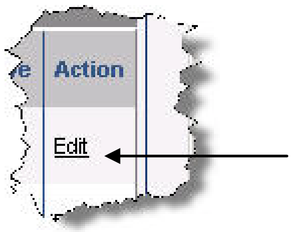


12. Repeat the steps above until all staff are in the 'Selected Results' grid. When complete, click the **Next** button

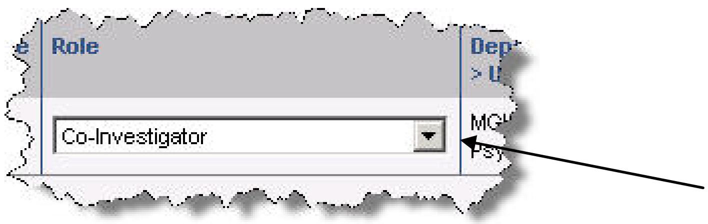
13. If you need to add a person that does not have a Partners user name to the study staff, and their name does not come up in the 'Search Externals' results, click 'Yes' and the **Continue** button. REMINDER: Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan.

14. Enter the person information and click the **Continue** button.

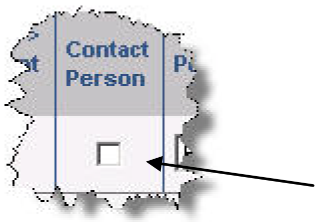
15. You are then brought back to the ‘Staff & Access’ main screen. Find the row with the name of the person you just added. In the ‘Action’ column of that row, click the ‘Edit’ link.



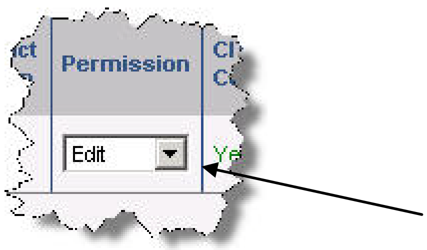
16. Select a study related role from the ‘Role’ pull down as close to the person’s actual study responsibilities.



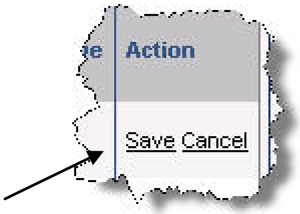
17. Indicate if the person should receive IRB correspondence by checking the ‘Contact Person’ check box.



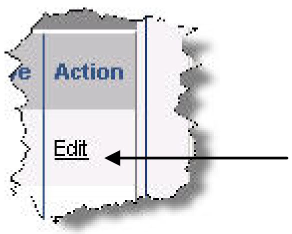
18. Select the person’s permission for the protocol record- View=read only; Edit=can make form changes; Manage=can change other’s permissions.



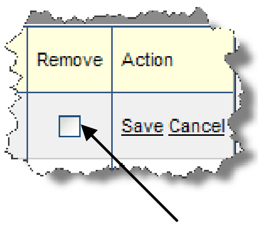
19. When complete, click the ‘Save’ link at the end of the row. Repeat for all people added.



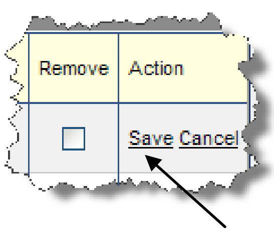
20. To delete study staff, find the row with the name of the person you need to remove. In the ‘Action’ column of that row, click the ‘Edit’ link.



21. Check the ‘Remove’ checkbox



22. Click the ‘Save’ link. Repeat steps 21-23 if others are to be removed.



23. Click the ‘Submission’ tab

24. If there are no errors, click the Submit button. If there are errors, click the error description to be brought to the form to correct the error.

25. Once you click the Submit button, the amendment is automatically routed for electronic sign off. You can track the progress of the sign off process by going to the Pending Applications page and clicking on the Workflow History icon in the row where the transaction appears.