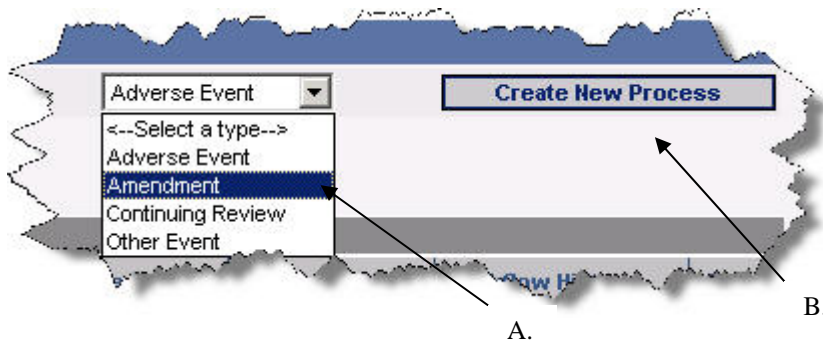


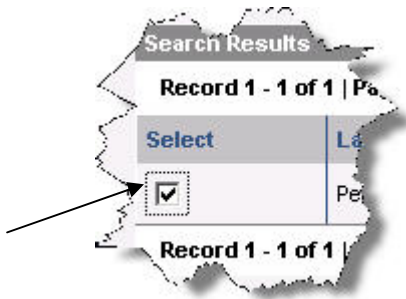
SUBMITTING A NEW AMENDMENT

1. Login to the Partners network
2. Go to the following web page: <http://insight.partners.org>
3. Enter your Partners user name and password to login to Humans/eIRB
4. Click on the **go to Humans** button
5. Click on the appropriate protocol title
6. Click the type of submission you would like to complete for the protocol (see A. below), then click the **Create New Process** button (see B. below).



7. Complete the form and click the **Save** button.
8. For study staff amendments, go to the 'Staff & Access' tab to add or remove the staff from the study list (Proceed to #9 below). For any other amendment, go to the 'Attachments' tab and upload any attachments that have been changed/added (Skip to #20).
9. Click the **Add Study Staff** button
10. Enter person information and click the **Search** button. For best results, try searching on last/first name alone, without entering institution/department etc.

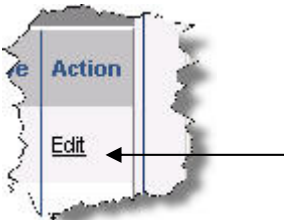
11. In the Search Results, check the box next to the name of the correct person and click the **Add to Selected Results** button



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

13. Answer 'Yes' to the next question, "Do you need to add any people that do not belong to a Partners Institution that you did not find in the search results?" if there are Partners staff that do not have a Partners user name, or collaborators that will be working independently from their non-Partners institutional/academic appointment that need to be added to the study staff list. If not, then click the **Continue** button.

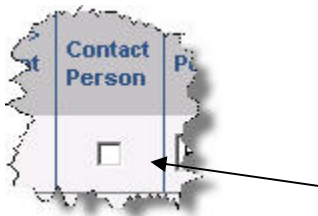
14. You are then brought back to the 'Staff & Access' main screen. Find the row with the name of the person you just added. In the 'Action' column of that row, click the 'Edit' link.



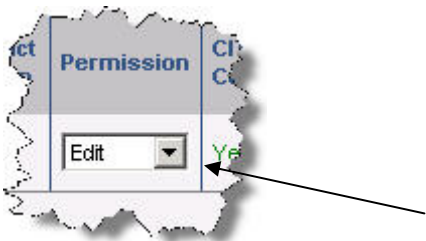
15. Select a study related role from the 'Role' pull down as close to the person's actual study responsibilities.



16. Indicate if the person should receive IRB correspondence by checking the 'Contact Person' check box.



17. Select the person's permission for the submission- View=read only; Edit=can make forms changes; Manage=can change other's permissions.



18. When complete, click the 'Save' link at the end of the row. Repeat for all people added.

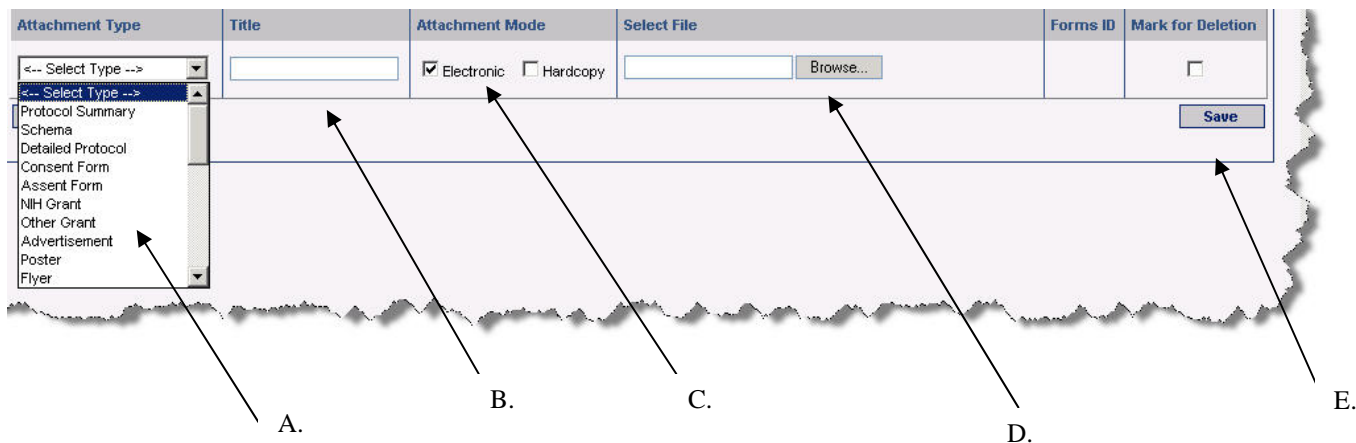


19. To complete the study staff amendment, skip to #28.

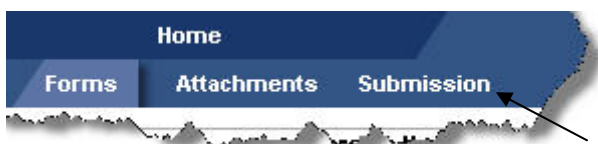
20. If you have any study-related documents to attach proceed to #21, if not, skip to #28.

21. To upload, click the **Add Row** button

22. Select the type of file you are uploading from the drop down list (see A. below).



23. Enter a title for the document, i.e., Study Ad for Healthy Subjects (see B. above). For best results, do not use symbols in the title, i.e., apostrophe, parenthesis, etc.
24. Check off 'Electronic' to upload the file (see C. above). For any hard copy files, check 'Hardcopy' and fax or mail to the Human Research Office.
25. Browse on your computer/SFA/memory stick for the file to upload (see D. above).
26. Repeat the above steps until all files have been uploaded
27. When complete, click the **Save** button (see E. above). NOTE: depending on the number and size of the files - this could take several minutes.
28. Click the 'Submission' tab



29. Click the **Run Application Review** button to validate that all required fields contain data and that all required attachments have been uploaded or checked as being sent by 'Hardcopy.'
30. 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.

#	Form / Type	Description
1	Amendment	<u>You must enter the sponsor amendment number.</u>
2	Attachments	<u>You must a attach a copy of the sponsor amendment document.</u>

Run Application Review

31. When brought to the form, correct the error and click the **Save** button to be brought back to the Submission screen. Repeat steps above to correct all errors.
32. Once all errors have been corrected, click the **Run Application Review** button for the application to check that all errors have been corrected.
33. If there are no errors, click the **Submit** button.