SUBMITTING A NEW PROTOCOL

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

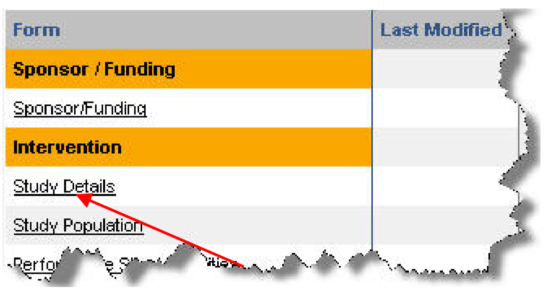
2. Enter your Partners user name and password to login to Humans/eIRB

3. Click on the **go to Humans** button

4. Click the **Create New Protocol** button

5. Answer the New Protocol Application configuration questions, then click the **Save** button

6. Click each form name to complete the questions, then click the **Save** button

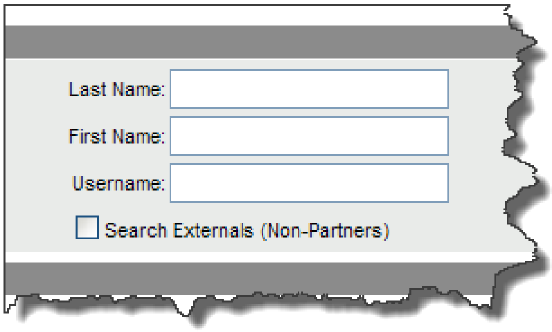


7. Click the 'Staff & Access' tab

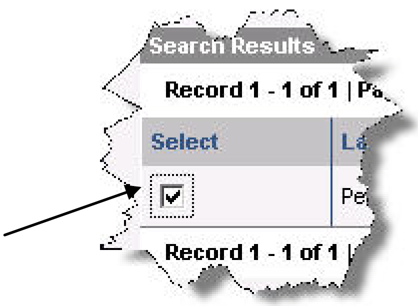
8. Click the **Add Study Staff** button to build the study staff list

9. If the submitter also has a study-related role on the protcol, click the **add submitter to staff** button to move the submitter name from the Non-Study Staff Access to the Study Staff grid.

10. To search, enter a few letters of the last and first name <u>or</u> enter the user name only and click the **Search** button



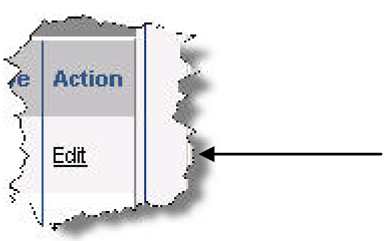
11. In the Search Results, check the box next to the name of the correct person and click the **Add to Selected Results** button



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

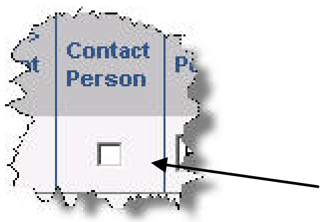
13. The next question "Do you need to add a non-Partners person to the study staff?" <u>REMINDER:</u> Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan to rely on the Partners IRB, and not their own IRB. If you are unsure, contact the IRB office before proceeding. If you know you need to add these people, answer 'yes,' click the **continue** button, and enter the person information. If no, click the **continue** button to proceed to the Staff & Access page.

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.

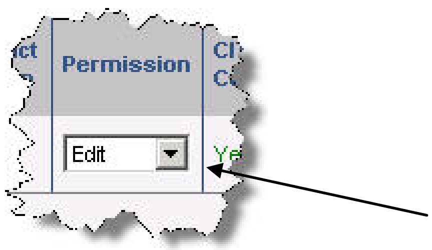


15. Select a study related role from the ‘Role’ pull down as close to the person’s actual study responsibilities.

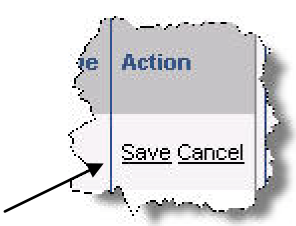
16. Indicate if the person should receive IRB correspondence by checking the ‘Contact Person’ check box.



17. Select the person’s permission for the submission: View=read only; Edit=can make forms changes; Manage=can change others permissions.

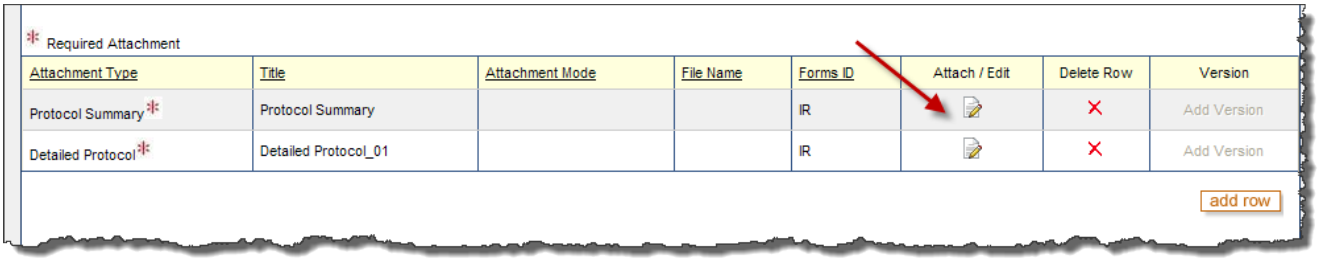


18. When complete click the Save link at the end of the row. Repeat for all people added.

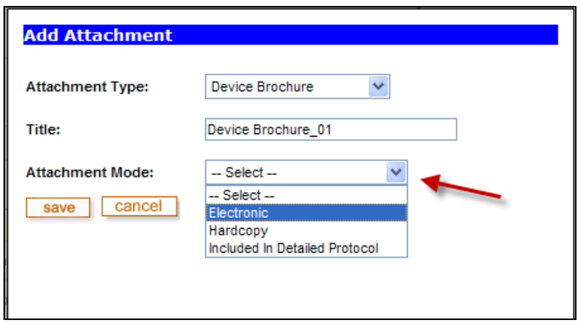


19. Click the ‘Attachments’ tab

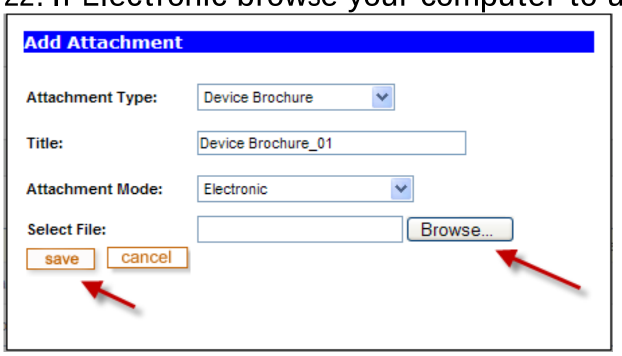
20. A list of required documents is displayed based on the answers given on form questions. To attach click the Attach/Edit icon.



21. Click Electronic if you have a file to upload, Hardcopy to fax into the IRB office, or Include With Detailed Protocol if the document is part of the Detailed Protocol.



22. If Electronic browse your computer to upload the file and click the save button.

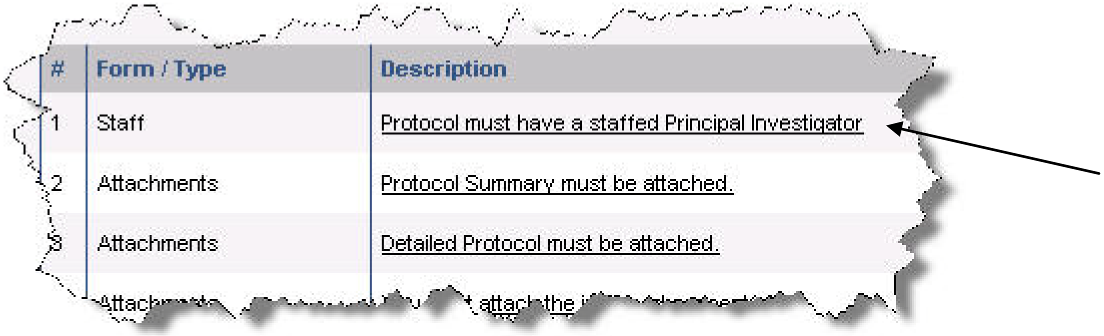


23. Repeat the above steps until all files have been uploaded

24. Click 'Submission' tab

25. Click Run Application Review to check for errors and validate that all required fields contain data, and that all required attachments have been uploaded or checked as being sent by 'Hardcopy.'

26. 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	Staff	Protocol must have a staffed Principal Investigator
2	Attachments	Protocol Summary must be attached.
3	Attachments	Detailed Protocol must be attached.
	Attach	attach the

27. 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.

28. Once all errors have been corrected, click the **Run Application Review** button for the application to check that all errors have been corrected.

29. If there are no errors, click the **Submit** button.