

SUBMITTING A NEW PROTOCOL

- 1. Go to the Insight Research Portal: <u>https://insight.partners.org</u>
- 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

Last Modified
1

7. Click the 'Staff & Access' tab



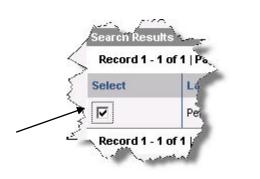
- 8. Click the Add Study Staff button to build the study staff list. Note: You will not be able to add a staff name to a Non-intervention/Interaction protocol submission if the person has not completed CITI within 3 years.
- 9. If the submitter also has a study-related role on the protcol, click the add submitter to staff button to move the submitter name from the Non-Study Staff Access to the Study Staff grid.



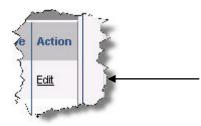
10. To search, enter a few letters of the last and first name <u>or</u> enter the user name only and click the **Search** button



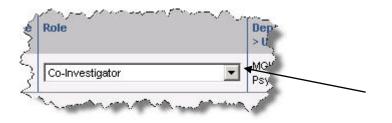
11. In the Search Results, check the box next to the name of the correct person and click the Add to Selected Results button



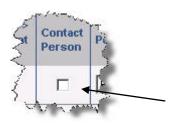
- 12. Repeat the steps above until all staff are in the 'Selected Results' grid. When complete, click the Next button
- 13. The next question "Do you need to add a non-Partners person to the study staff?" <u>REMINDER</u>: Do not add Non-Partners collaborators unless they are engaged in the conduct of 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 <u>continue</u> button, and enter the person information. If no, click the <u>continue</u> 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.



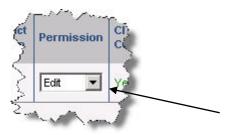
15. Select a study related role from the 'Role' pull down as close to the person's actual study responsibilities.



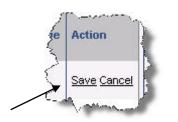
16. Indicate if the person should receive IRB correspondence by checking the 'Contact Person' check box.



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.

Attachment Type	Title	Attachment Mode	File Name	Forms ID	Attach / Edit	Delete Row	Version
Protocol Summary 🍀	Protocol Summary			IR	A	×	Add Version
etailed Protocol **	Detailed Protocol_01			IR		×	Add Version

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

Add Attachment	
Attachment Type:	Device Brochure
Title:	Device Brochure_01
Attachment Mode:	Select 💌
save cancel	Select Electronic
	Hardcopy Included In Detailed Protocol

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

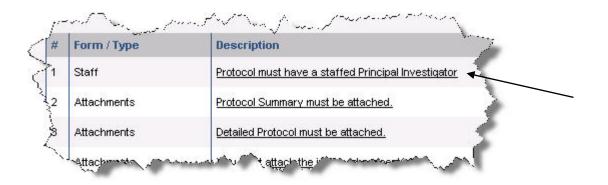
Add Attachment	
Attachment Type:	Device Brochure
Title:	Device Brochure_01
Attachment Mode:	Electronic 💌
Select File:	Browse
save cancel	

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

24. Click 'Submission' tab



25. 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.



- 26. 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.
- 27. Once all errors have been corrected, click the **Run Application Review** button for the application to check that all errors have been corrected.
- 28. If there are no errors, click the **Submit** button.