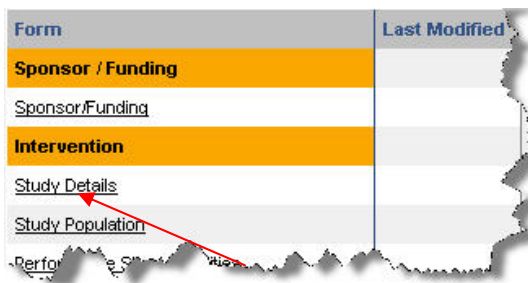


## SUBMITTING A NEW PROTOCOL

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 the **Create New Protocol** button
6. Answer the New Protocol Application configuration questions, then click the **Save** button
7. Click each form name to complete the questions, then click the **Save** button



Form	Last Modified
<b>Sponsor / Funding</b>	
Sponsor/Funding	
<b>Intervention</b>	
Study Details	
Study Population	
Performance Study	

8. Click the 'Staff & Access' tab

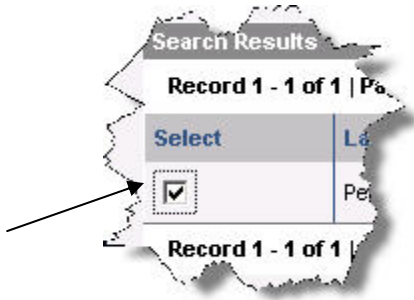


9. If the submitter also has a study-related role on the protocol, click the **Add Submitter to Staff** button to move the submitter name from the Non-Study Staff Access to the Study Staff grid.



10. Click the **Add Study Staff** button to build the protocol staff list
11. Enter person information and click the **Search** button

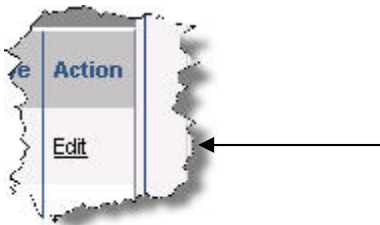
12. In the Search Results, check the box next to the name of the correct person and click the **Add to Selected Results** button



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

14. 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.

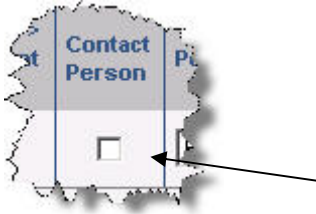
15. You are then brought back to the 'Staff & Access' main screen. Find the row with the name of the person you just added. In the 'Action' column of that row, click the 'Edit' link.



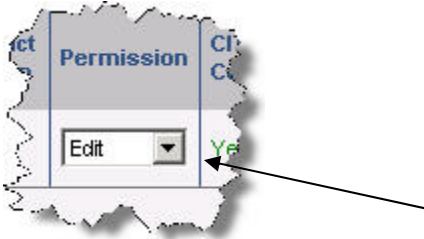
16. Select a study related role from the 'Role' pull down as close to the person's actual study responsibilities.



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



18. Select the person's permission for the submission: View=read only; Edit=can make forms 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. Click the 'Attachments' tab



21. A list of required documents is displayed based on the answers given on form questions.

Attachment Type	Title	Attachment Mode	Select File
Detailed Protocol	<input type="text" value="Detailed Protocol"/>	<input checked="" type="checkbox"/> Electronic <input type="checkbox"/> Hardcopy	<input type="text"/> <input type="button" value="Browse..."/>
Protocol Summary	<input type="text" value="Protocol Summary"/>	<input type="checkbox"/> Electronic <input type="checkbox"/> Hardcopy	
Consent Form	<input type="text" value="Consent Form 1"/>	<input type="checkbox"/> Electronic <input type="checkbox"/> Hardcopy	

1. points to the Title field of the first row.  
2. points to the Electronic checkbox of the first row.  
3. points to the Browse... button of the first row.

22. You can keep the default document title or change it (see 1 above). To change it, click in the field and enter your text, i.e., Detailed Protocol-Stent Study.

23. Check off Electronic to upload the file (see 2 above). For any hard copy files, check 'Hardcopy' and fax or mail to the Human Research Office.

24. Browse on your computer, SFA, memory stick for the file to upload (see 3 above)

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

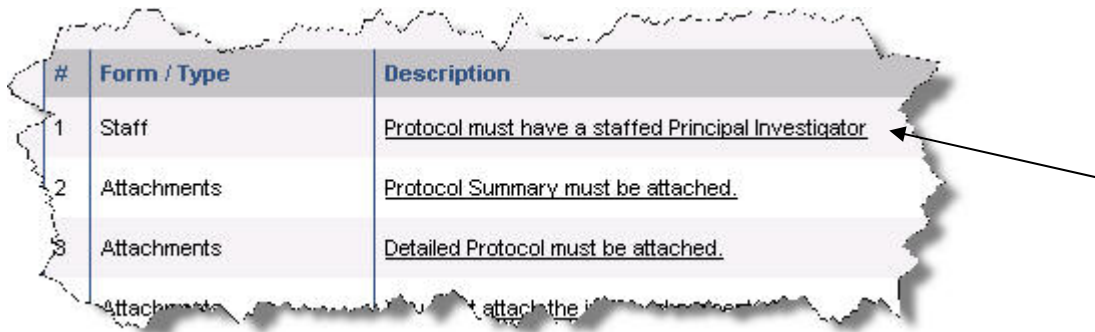
26. When complete, click the  button. NOTE: depending on the number and size of the files - this could take several minutes.

27. Click 'Submission' tab



28. Click  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.'

29. 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	<u>Protocol must have a staffed Principal Investigator</u>
2	Attachments	<u>Protocol Summary must be attached.</u>
3	Attachments	<u>Detailed Protocol must be attached.</u>
4	Attachments	<u>attach the i</u>

30. 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.

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

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