



## Responding to IRB Review

1. Go to the following web page: <https://insight.partners.org/>
2. Enter your Partners user name, password and click the **Login** button
3. Click on the **go to Humans** button
4. Click the 'Pending Applications' tab



5. Click on the Protocol Title of the submission to open. Note: there will be an entry for each board reviewing the submission. If there is more than one, click any of them. It makes no different which one you click.

Selected Protocol #: 2013p000044

To create a new protocol application click the Create New Protocol button. [create new protocol](#) [cede review](#)

1 Pending Applications [Download to Excel](#) [Download to PDF](#)

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Protocol #	PI Name	Title	Sponsor Name	Forms ID	Date Received	Board	Pending	Review Type	Meeting Date	Review Status	Approval Expires	Lock Status	Workflow History
2013P000044	Name	A Phase 2 Double Blind...	None	IR	01/07/2013	IRB	Submitter Review	Expedited		Deferred			

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6. Make any applicable form changes and/or attach new/revised study-related documents.

### FORMS

To make a change to a form from the Forms page:

7. Click the name of the form to open
8. Update the questions needed
9. Click the  button

Welcome, Daniel Connor 4/4/2013 4:45:03 PM [Fund # Lookup](#) [Train](#)

**insight**

Agreements Humans Meeting Management

Protocol Details Forms Staff & Access Attachments Submission Protoc

Protocol #: 2013P000681 PI: Connor, Daniel Title: test Version Name: Version date: Sponsor: SUNDRY ... Overall Status: A  
 Administrator: Kea, Laura Email: LKEA@PARTNERS.ORG Phone: 617-424-4106 Institution: MGH Last Modified: 04/04/2013 Proposal Number: 2009A056678 104833 ... Ha

[Add/Update Attachments](#)

[Pending Applications >> Forms](#)

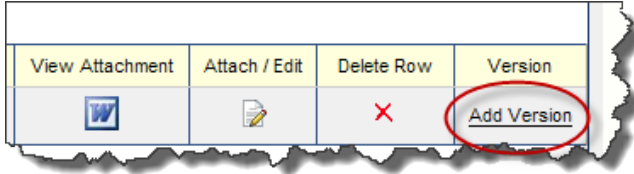
Your responses helped create the following group of relevant application forms. If these do not apply to your protocol, you can add or delete forms as on the linked name. Complete the Forms, Staff & Access, and Attachments tabs before Submission.

Edit: [Full title or Sponsor protocol designation/number](#)

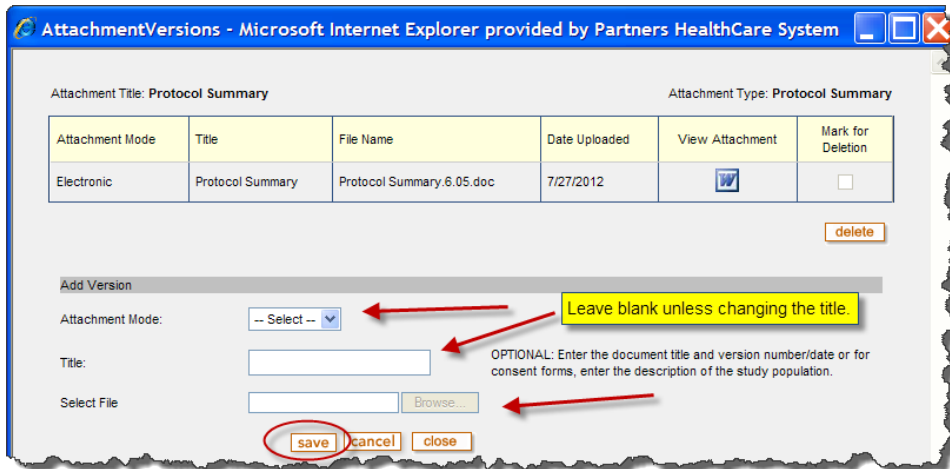
Form	Last Modified	Modified By
<b>Response to Review</b>		
<a href="#">Response to Review 1</a>	4/4/2013 4:4	
<b>Sponsor / Funding</b>		
SUNDRY	4/4/2013 4:36:41 PM	Connor, Daniel
<a href="#">Cleveland Clinic Foundation</a>	4/4/2013 4:37:18 PM	Connor, Daniel
<a href="#">Add Sponsor/Funding</a>		
<b>Health/Medical Information</b>		
<a href="#">Health / Medical Records</a>	4/4/2013 4:37:36 PM	Connor, Daniel

## ATTACHMENTS

10. To add a revised document: click the 'Add Version' hyperlink on the document row.



11. 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.



NOTE: If you are submitting an updated version of a document you will need to attach two copies. One 'revised/marked' version and one 'clean/unmarked' version. If the document is protected you will not be able to use the Tracked Changes function in Word, use Bold/Underline/Strikethrough to indicate what words you are deleting and what words you are adding.

The file name should be used to indicate which version is marked and which is clean. Do not rename the Attachment Title in Insight with those words. Only enter an Attachment Title if you need to change the current Title.

12. If Electronic browse your computer to upload the file and click the **save** button. Always attach the marked version first and then the clean. By versioning the clean version last, it will render in the 'view full application' pdf for printing and saving for your records.

13. To attach a new document, click the **Add Row** button. If you have no new documents to attach skip to step 20.

14. Select the Attachment Type from the drop down list

**Add Attachment**

Attachment Type: -- Select --

Title:

Attachment Mode: Electronic

Select File:

15. 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.

**Add Attachment**

Attachment Type: Device Brochure

Title: Device Brochure\_01

Attachment Mode: -- Select --

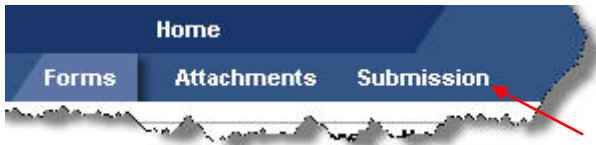
- Select --
- Select --
- Electronic
- Hardcopy
- Included In Detailed Protocol

16. Browse to select the file from where you have it saved and click the  button

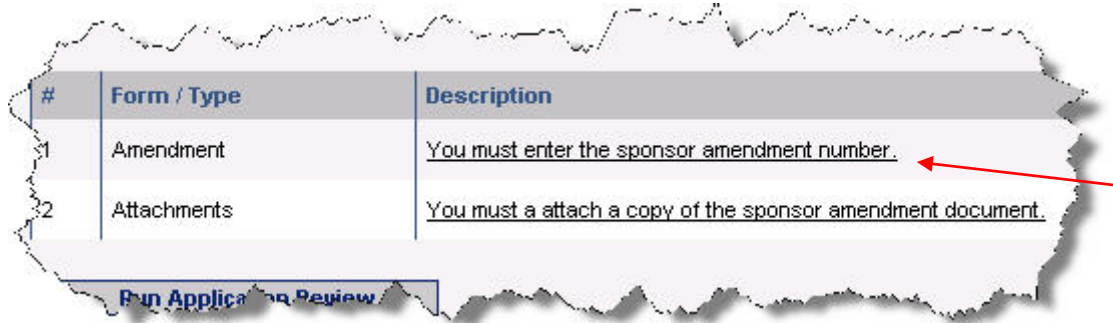
17. Repeat the above steps until all files have been uploaded

## SUBMISSION

18. Click the 'Submission' tab



19. If there are no errors listed, 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**

20. 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.

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

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