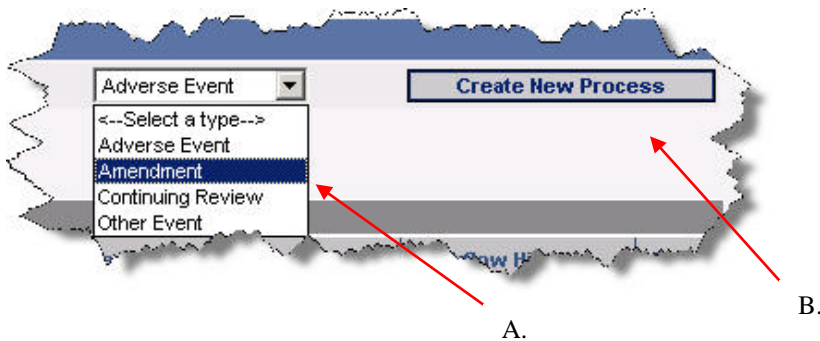


SUBMITTING A NEW AMENDMENT

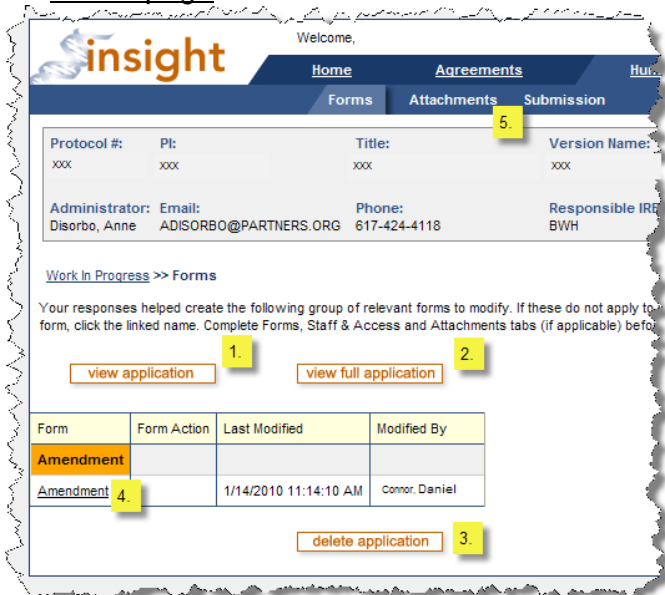
NOTE: You cannot submit an amendment that involves attachments, if one is already pending that involves attachments.

1. Go to the Insight Research Portal:
<https://insight.partners.org>
3. Enter your Partners user name and password and click the **Login** button
2. Click on the **go to Humans** button
3. Click on the appropriate protocol title
4. Select 'Amendment' from the drop down list (see A. below), then click the **Create New Process** button (see B. below).



5. The Amendment form will open. Complete the form and click the **Save** button. You are brought to the Forms page.

Forms page



Form	Form Action	Last Modified	Modified By
Amendment			
Amendment		1/14/2010 11:14:10 AM	Conor, Daniel

1=View application displays the questions and your answers in pdf format.

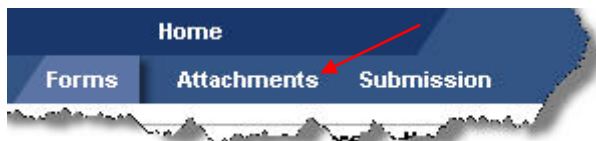
2=View FULL application displays the questions/answers and includes any documents attached from the Attachments page, all in one pdf.

3=Delete application will delete the submission.

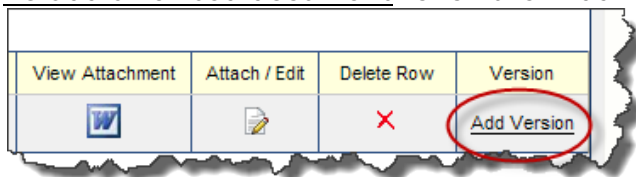
4=The hyperlink 'Amendment' opens the amendment form you just completed

5= 'Attachments' is where you attach documents to the submission. 'Submission' is where you complete the process to submit the amendment.

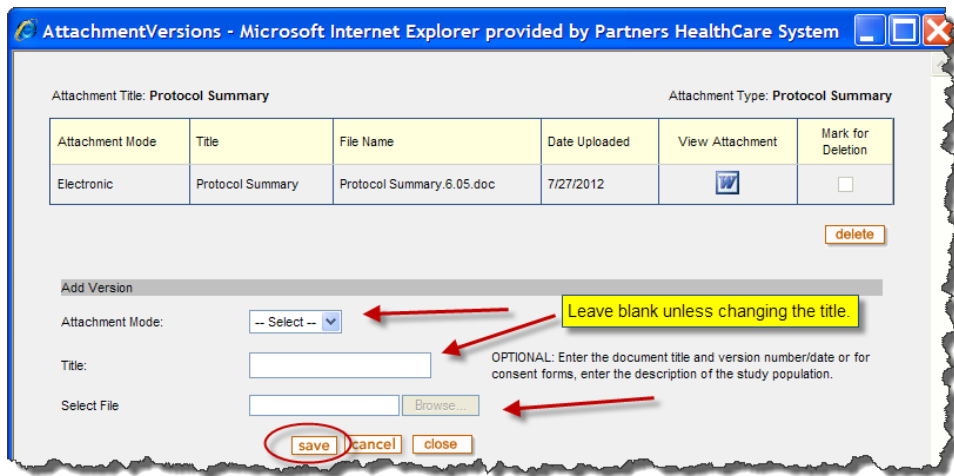
- If you have new/updated documents to submit with the amendment, click on the 'Attachments' tab and upload/version any attachments that have been changed/added. Make sure you have answered the question "Are you submitting new or revised study-related documents?" as 'yes' on the amendment form for the Attachments tab to be visible.



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



- 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.

- 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.

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

11. Select the Attachment Type from the drop down list

Add Attachment

Attachment Type: -- Select --

Title:

Attachment Mode: Electronic

Select File: **Browse...**

save **cancel**

12. 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

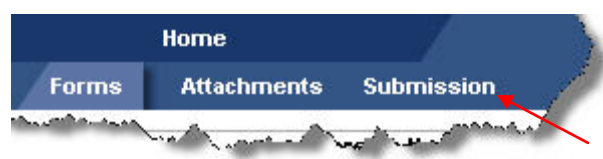
Attachment Mode: -- Select --

save **cancel**

13. Browse to select the file from where you have it saved and click the **save** button

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

15. Click the 'Submission' tab



16. 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

17. 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.
18. Once all errors have been corrected, click the **Run Application Review** button for the application to check that all errors have been corrected.
19. If there are no errors, click the **Submit** button.