UNIVERSITY of LOUISVILLE

dare to be great

BRAAN2 Users Guide for Principal Investigators and Research Teams

TABLE OF CONTENTS

CHAPTER 1. OVERVIEW

1.1 *BRAAN2 Overview*

The Biomedical Research and Assurance Network 2 (BRAAN2), is an electronic system for submission and routing of human research protocols. BRAAN2 allows the protocol submission and review process to be more efficient since protocols are stored in a central database for easy retrieval. This allows protocols to be reviewed and processed by required personnel - **all on-line** from work, from home, or on the road. BRAAN2 is the online system for protocol creation, routing, signing, review, and tracking. Before completing your research protocol, please read this entire manual and use the HSPPO website as a source of information and a resource to help answer any questions you may have. The HSPPO website can be found at the following link: http://research.louisville.edu/UHSC/index.htm

1.2 *Introduction*

The purpose of this manual is to walk users through the routing of a "typical" human subjects research protocol (or Emergency Use protocol) from creation and submission.

It is not the intent to present a thorough discussion of every possible scenario within the review process. Rather to give users a general idea of how the BRAAN2 system functions to automate the IRB review process and how their role(s) fit into the system and review process.

All forms, memos, or other documents in BRAAN2 are comprised of various pages, clusters, and fields. These will be explained within this manual. Contextual Help is available within many documents by clicking 

.

The buttons in the upper left corner of every memo, form, or document in BRAAN2 are used to:

- 

all work before opening a SubDocument field, navigating to the next page, or Closing the window.
- 

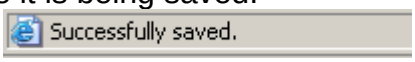
shows all questions that are required based on the answers you have provided.
- 

the window when you have finished input or need to leave your workstation.

1.3 *Saving*

While BRAAN2 is saving the protocol, the 

message will be displayed in the lower left corner of the browser window; please be patient and do not attempt to make changes in the document instance while it is being saved.

When the document has been saved by the system, the 

message will be displayed in the lower left corner of the browser window.

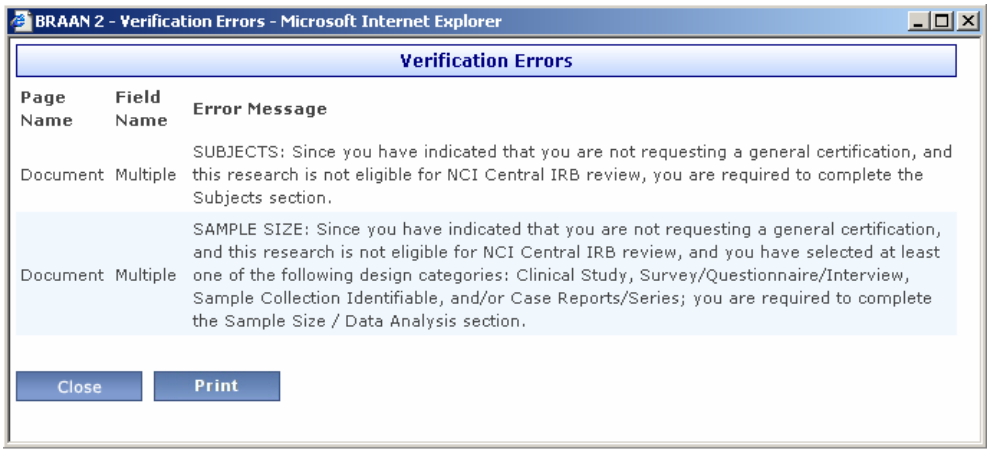
Always wait for the "Successfully saved" message to appear before making additional changes to the form or entering additional data to prevent the inadvertent loss of input data.

NOTE: Remember to 

every page of the protocol before closing the window. Saving work frequently and not leaving your workstation while working in BRAAN2 will prevent the inadvertent loss of input data.

1.4 *Verifying*

After it is saved, every document **must** be verified. Verifying the document helps to ensure that all required questions on the document have been answered. If any information is missing or inconsistent, a screen like this one will be displayed:



This information will help to uncover problems with the document before it is submitted or sent. After all of the corrections have been made, the document must be saved and verified again. For more complicated documents, such as the IRB Protocol form, the process of saving and verifying may take several attempts. Repeat until the document shows the message "No Errors Found":

NOTE: All documents (including protocols, memos, forms, etc.) must have no remaining errors in order to be submitted.

1.5 *System Requirements*

You will need an up-to-date browser. For PC users, Microsoft Internet Explorer 6.0, Netscape 7.0 and Firefox 1.0 are supported. For Mac users running MAC OS 10.4, Netscape 7.1 and Safari 2.0 are supported. For MAC OS 10.3 Netscape 7.1 and Safari 1.2. are supported and for Mac OS 9.2 Netscape 7.1 is supported.

Additionally, Adobe® Acrobat Reader® 6.0 or higher is required.

You may need to change your pop-up blocker settings in order for BRAAN2 to run properly on your computer.

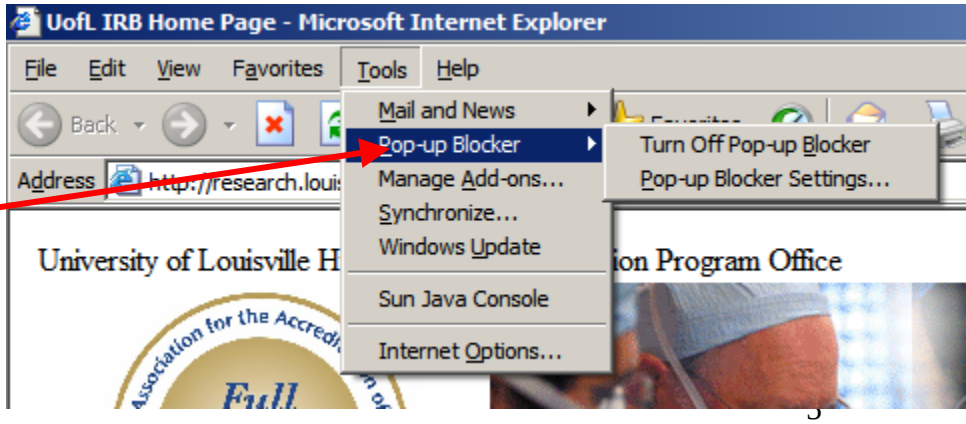
1.6 *Pop Up Blocker*

To change Pop-up Blocker settings:

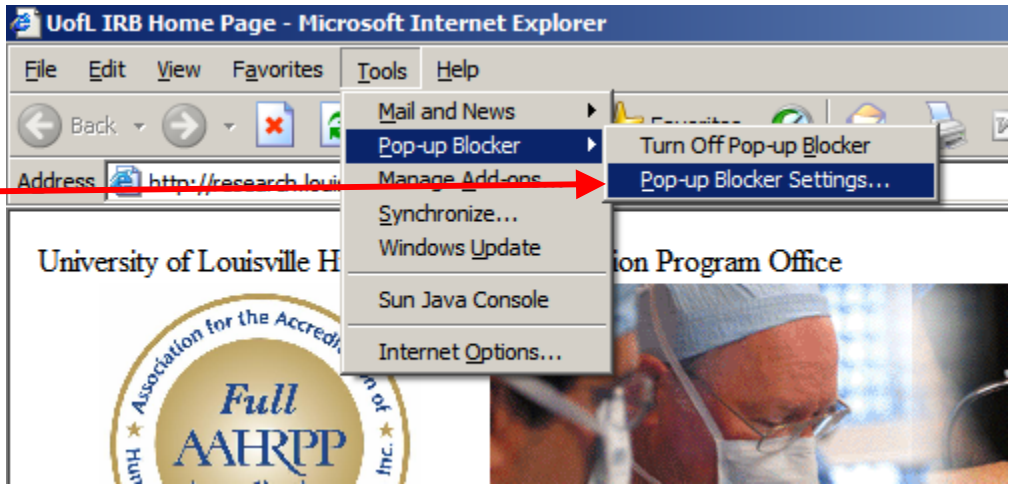
1. Click on this Icon on your desktop to open Internet Explorer.

2. Click on Tools.

3. In the Tools dropdown menu click on Pop-up Blocker.



4. Click on
Pop-up Blocker Settings:

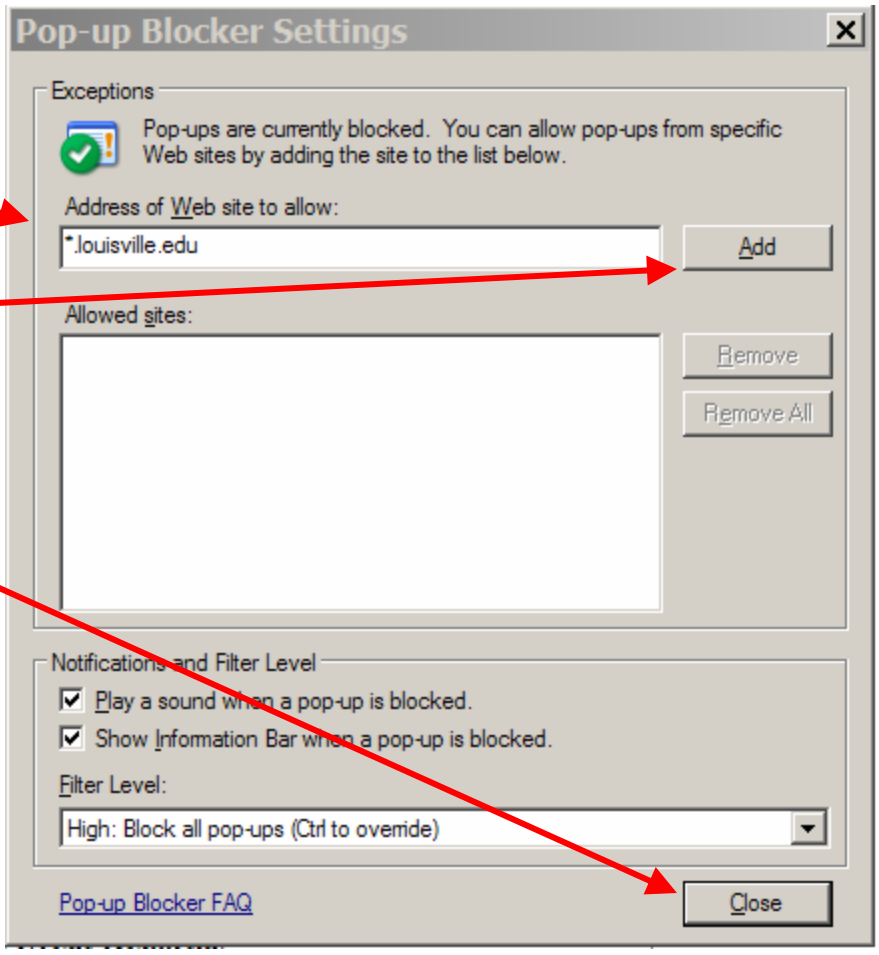


5.

a. Type: *.louisville.edu

b. Click: Add

c. Click: Close



1.7 *Log In*

Access the BRAAN2 system through the URL https://braanprod.louisville.edu by using your GroupWise email username and GroupWise password (you must have a GroupWise email account to utilize BRAAN2). If you do not already have a GroupWise email account, you will need to obtain one. To request a GroupWise account to gain access to BRAAN 2, please follow the procedure below:

To request a UofL ID number in order to gain access to BRAAN2 please contact your appropriate Research Office:

1. **Norton Employees:**
   Email: NHRO@nortonhealthcare.org

2. **Jewish Hospital & St. Mary's HealthCare Employees:**
   Email: research.office@jhsmh.org

3. **University of Louisville Hospital Employees:**
   Email: ULHRIO@ulh.org

   You will need to provide the following 9 pieces of information:

   1. First Name (as shown on Social Security Card)
   2. Middle Name, or Middle Initial *(as shown on Social Security Card)*
   3. Last Name of Individual (include applicable suffixes) *(as shown on Social Security Card)*
   4. Start Date
   5. End Date
   6. Social Security Number, or National ID number *(as shown on Social Security Card)*
   7. Gender
   8. Date of Birth
   9. Home Address

****If you are not affiliated with any of the above research offices, you will need to go to the HSPPO Office and provide the above 9 pieces of information to request a U of L ID**

1.8 *ID and Password*

Log into BRAAN2 using your GroupWise username and GroupWise password. If you don't remember your password, please contact IT at 502-852-7997 or at helpdesk@louisville.edu. When you change your GroupWise password, your BRAAN password will automatically change.

Because usernames and passwords are an integral part of the electronic records and electronic signatures in BRAAN2 it is imperative that users **NOT SHARE** usernames and passwords for BRAAN2 accounts! You will be held responsible for the use of your ID and password.

1.9 *Important Information to Remember*

BRAAN2 is a **web-based** application. As with all web-based systems, the following conventions should be observed:

- Click links, icons, and buttons only once; **DO NOT** double-click.
- **DO NOT** use browser toolbar buttons to navigate from page to page.
- **DO NOT** use the ☒ in the upper, right corner of windows to close the windows.
- Web browser should be set to **NOT** cache pages; pages should be pulled fresh from the server each time they are accessed. (Consult your local Help Desk for more information.)

NEVER log into more than one session of BRAAN2 simultaneously on the same computer.

Always save and verify documents and subdocuments before closing!

1.10 *Definitions*

Version/Status
There are a couple of terms that describe and define work passing through the BRAAN application. *What* an item is, is its version. Common versions include: Amendment, Renewal, and New. *Where* an item is, is its status. Common statuses include: Draft, Submitted, and Approved. Version and status interact as protocols move through the process and you will often see them listed together. For the full list of protocol versions and their definitions, see Appendix A. For the full list of protocol statuses and their definitions, see Appendix B.

User
There are various user groups that access the BRAAN system. Many individuals will have multiple roles within BRAAN and will access protocols under different user roles, each of which will allow different access and privileges. Examples of different user groups include: Board Member, Investigator, Research Team and Reviewer.

Action
There are many actions that may be performed within BRAAN. Who can do what, to what, and under what conditions, is determined by your system administrator via an internal table called workflow. Examples of actions that may be performed within BRAAN include: submit, sign, amend, close, and approve.

Roles
Users are assigned one or more roles in the system. The role(s) of the user determine what actions the user may take in the system and the level of access that the user has within the system after he/she has logged in.

CHAPTER 2. DATA CONVERSION

Beginning June 4, 2007, all protocols that are currently active will start being converted from the old paper system to the new BRAAN2 system. Any protocol that was closed, expired or exempt prior to June 4, 2007 will remain in the HSPPO database. Pending protocols will remain in the HSPPO database until they have completed their review process via the old paper system and are fully approved. Once they are approved they will be automatically imported into BRAAN2.

Only approved protocols were automatically imported into BRAAN2 from the old HSPPO database. Since there is not a 1-to-1 correspondence between variables in the old IRB database and the new database (BRAAN2), investigators will find their imported protocols are incomplete. Administrative data will have been imported into BRAAN2 (PI name, protocol title, etc.) but experimental descriptions and consent forms must be re-entered by the investigator. The system will not process incomplete protocols. Therefore, all existing protocols will have to be completed in BRAAN2 before they can be renewed or amended. You can report SAEs, deviations and exceptions on protocols that have been imported into the new system but have not yet been converted.

Putting the science of your study into BRAAN2 is easy. If you have an electronic version of your approved protocol, you can copy the data directly from that file and paste it into BRAAN2.

You may choose to complete the conversion of an existing protocol into BRAAN2 immediately, or you may choose to wait until you need to amend or renew the protocol. When completing your "BRAAN2 Conversion," either as an amendment or a renewal, enter the data **EXACTLY** as is appears in your currently approved protocol. If you wish to introduce any new changes, they must be **clearly outlined** in the description box within the amendment form or within the general summary of the renewal form.

Once a protocol is entered into the system, it never needs to be re-entered again, even for renewals. Allow sufficient time to convert your protocols before you try to renew or amend for the first time.

Every conversion will be reviewed by the HSPPO staff to ensure the protocol was entered into the BRAAN2 system correctly.

Friday, August 10, 2007 will be the last day to submit anything to the HSPPO on paper.

Beginning Monday, August 13, 2007 the HSPPO will no longer accept any paper.

CHAPTER 3. ROLES

Users are assigned one or more roles in the system. The role(s) of the user determine what actions the user may take in the system and the level of access that the user has within the system after he/she has logged in.

3.1 *Research Team (Key Personnel) Role*

All users involved in the research process are assigned the Research Team role. (This may include student researchers, nursing and clinical staff, and/or administrative assistants.) Functions that can be performed by users with the Research Team role include but are not limited to:

- Creating and editing protocols, copying or deleting protocols
- Requesting that a protocol be returned after submission
- Setting permissions for individual protocols
- Viewing protocols and protocol history
- Filtering for specific protocol(s)

3.2 *Principle Investigator (PI) Role*

The Principle Investigator (PI) role is a specialized subset of the Research Team (Key Personnel) role. Functions that can be performed by users with the PI role include all of the functions listed above for the Research Team role and include but are not limited to:

- Submitting (and resubmitting, if necessary) protocols
- Changing ownership of a protocol to another member of the research team

It is important to note that ***only*** users with the PI role can submit protocols in the BRAAN2 system.

3.3 *Signature Role*

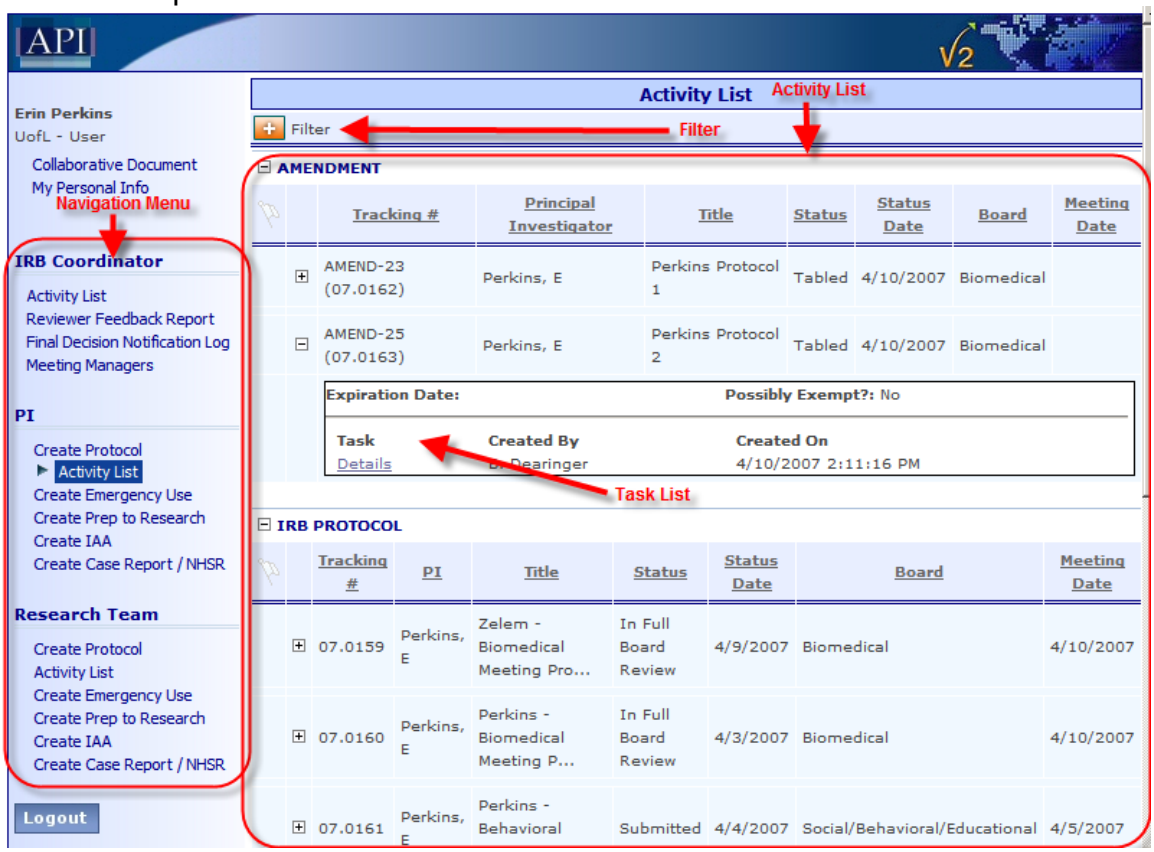
The signature of the Department Chair or Division Chief is required before the protocol is taken under consideration by the board. This individual is assigned the Signature role. Functions of this role include but are not limited to:

- Signing protocols to indicate departmental, scientific merit, and/or other approval
- Returning protocols to the Principal Investigator for necessary revisions prior to signing
- Assigning a proxy
- Viewing protocols and protocol history (limited to protocols in the Awaiting Signature status)

CHAPTER 4. NAVIGATION

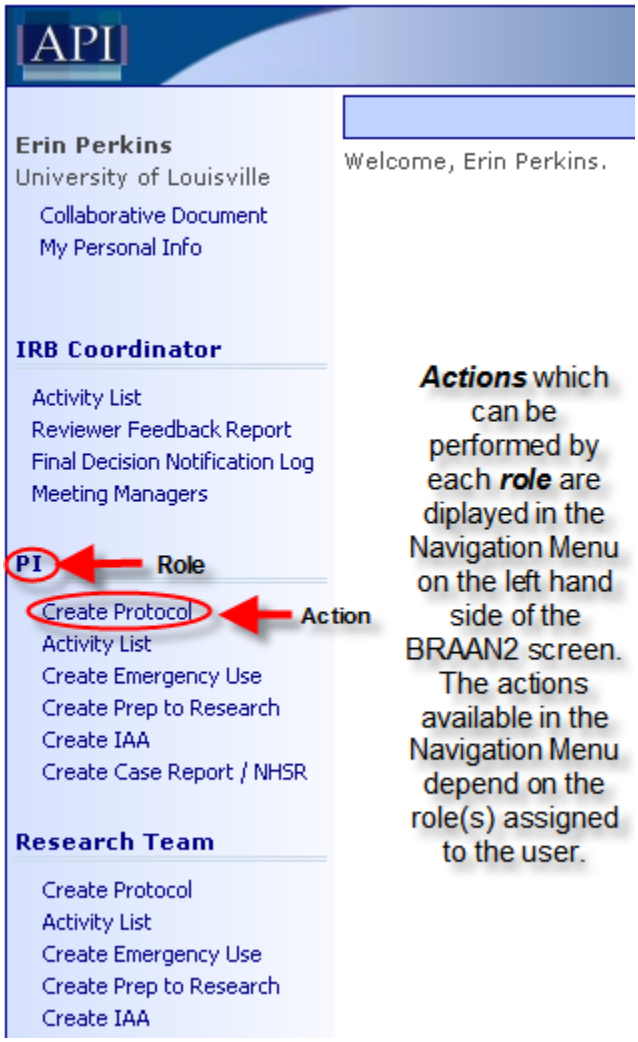
4.1 *Navigating in BRAAN2*

This is a map of the main screen in BRAAN2:



Each of these areas will be discussed in more detail on the following pages.

4.2 *Navigation Menu*

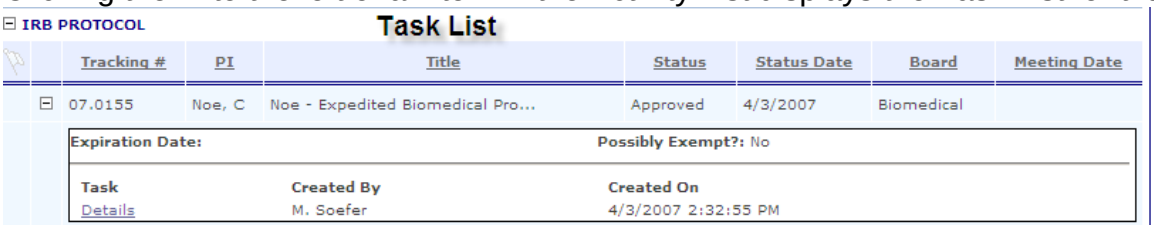


4.3 *Activity List*

Selecting “Activity List” from the Navigation Menu (see example above) opens the Activity List. This is the standard working screen in BRAAN2. The Activity List displays a list of active protocols ands other work and the status of each.

4.4 *Task List*

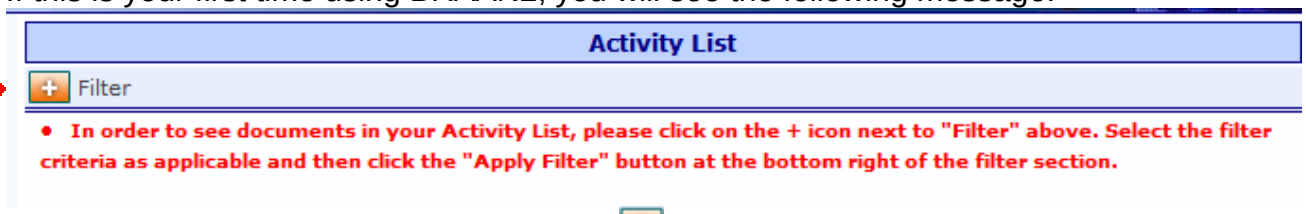
Clicking the ⊞ to the left of an item in the Activity List displays the Task List for that item:



This is a list of tasks that the user can perform associated with the item on the Activity List. The list of tasks varies depending on the role of the user and the document type and status of the item in the Activity List.

4.5 *Filter*

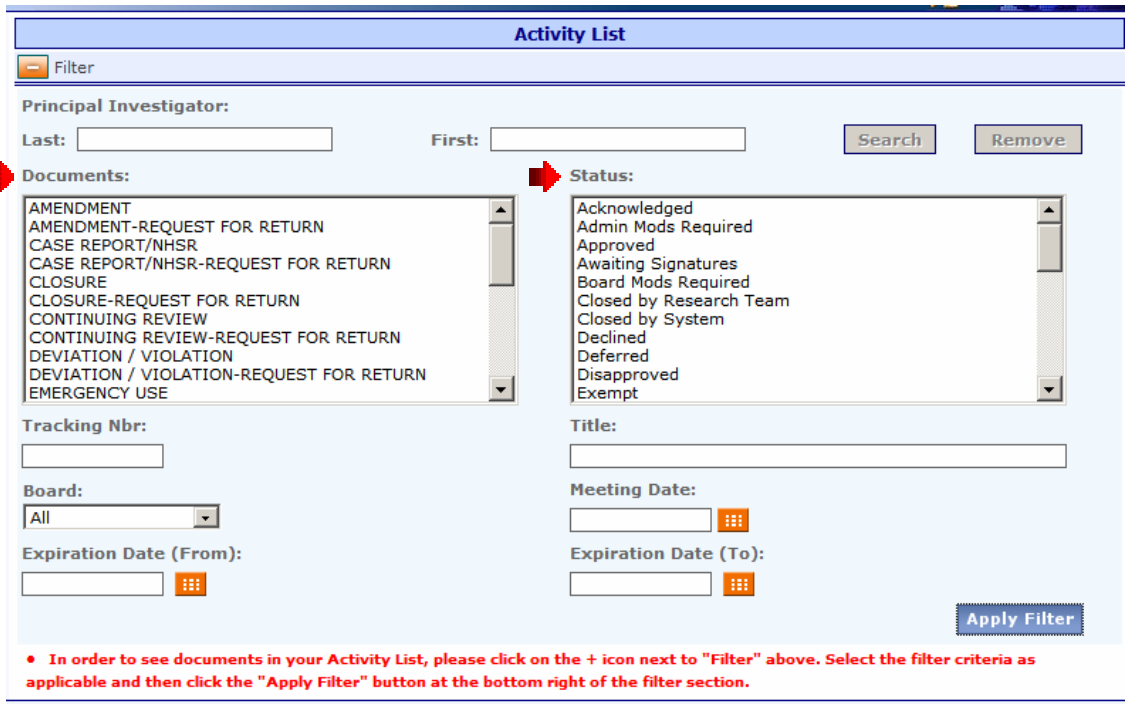
If this is your first time using BRAAN2, you will see the following message.



To filter your activity list please click on the ⊞ sign next to the word filter.

A screen will pop up showing you all the filter options available to you. There are two lists in the middle of the screen: Documents and Status.

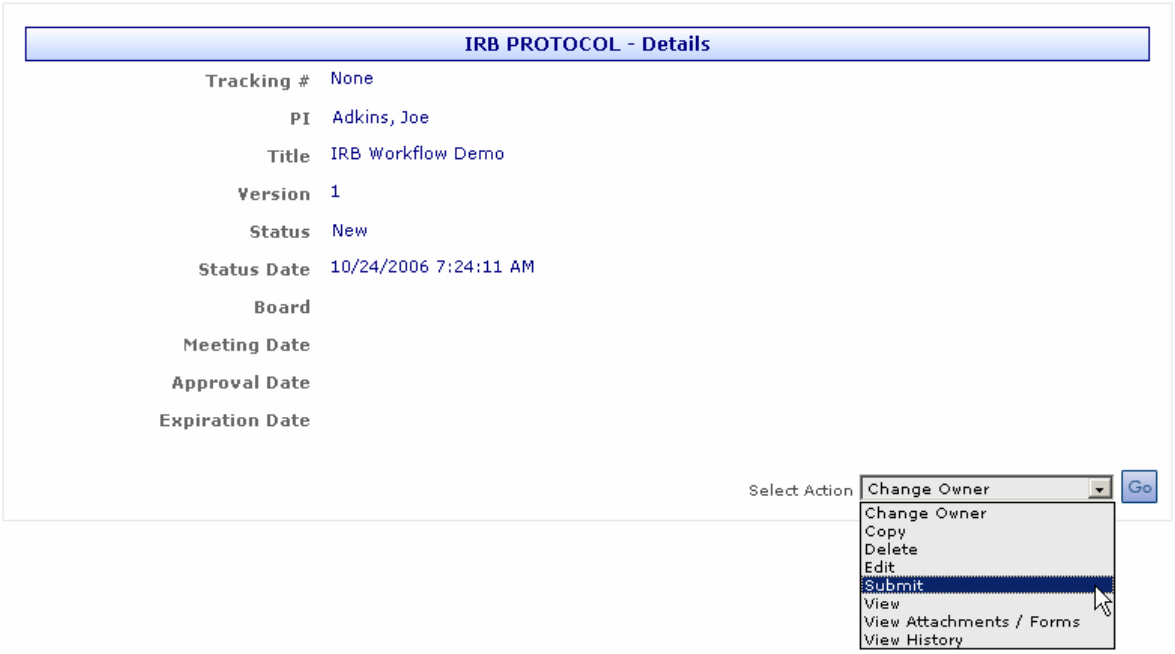
Select all of the options for documents and status and then press Apply Filter.



:

NOTE: Once a filter is applied it will remain applied until revised. Filters **ARE NOT** reset at logout.

4.6 *Select an Action*



Use the options in the Action Menu to:

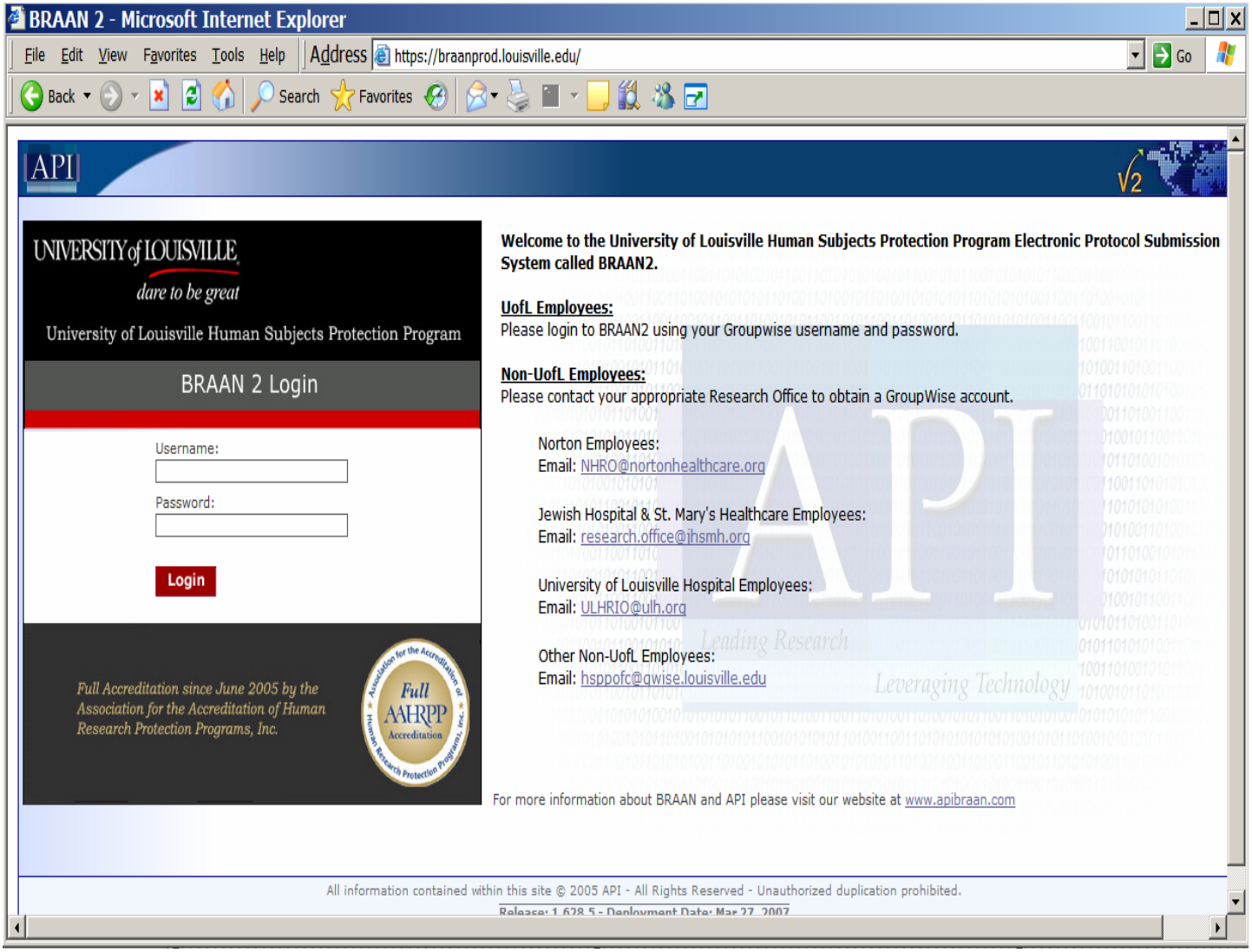
- **Copy**: Users with the Principle Investigator or Research Team role can copy protocols in which they are named and have access. Copied protocols can be used as a basis for submitted similar protocols without having to re-enter all of the information.
- **Delete**: Deletes the protocol from the system; this option can only be exercised before a protocol has been submitted
- **Edit**: Return to the protocol to continue entering data and information or to make other changes.
- **Submit** (PI only): Submit the protocol or other work for review.
- **View**, **View Attachments / Forms**, **View History:** View the protocol or protocol history.

- **Change Owner**: **DO NOT USE THE CHANGE OWNER OPTION**.

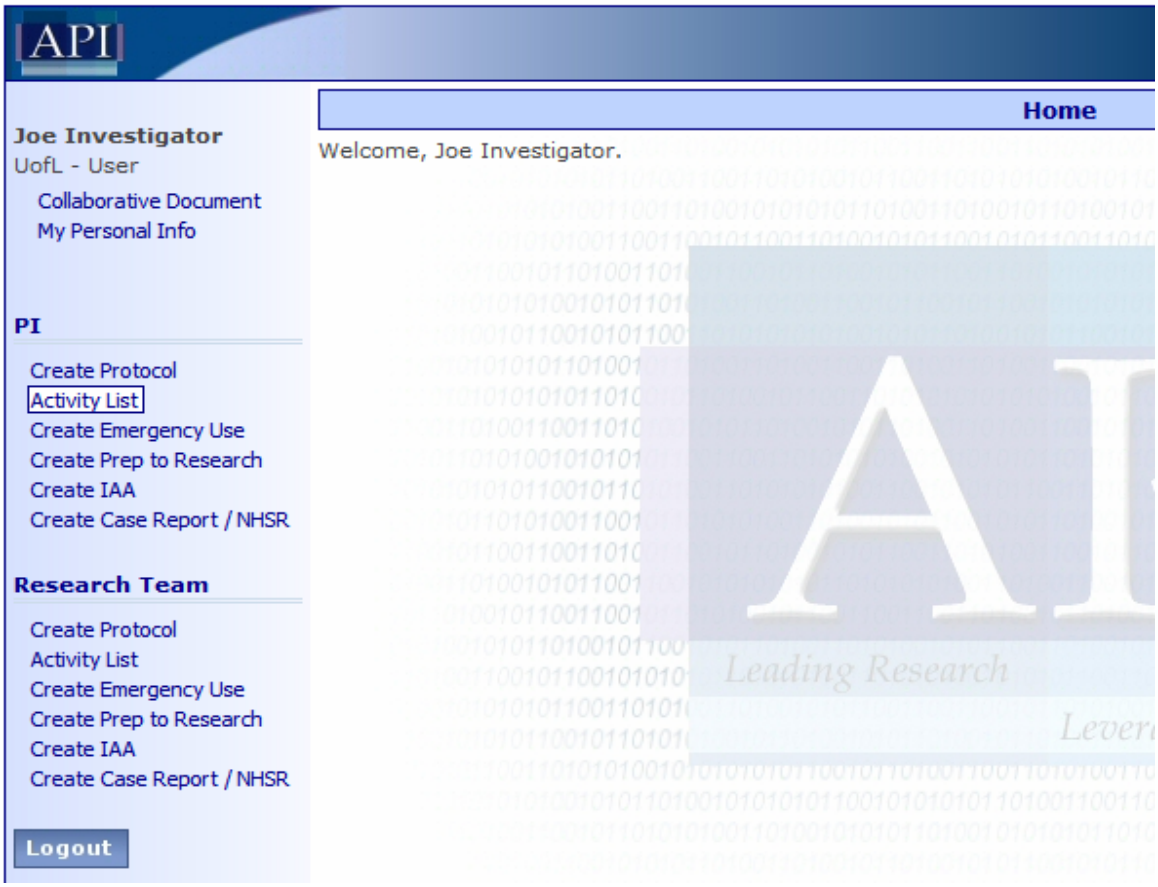
CHAPTER 5. SUBMISSION OF PROTOCOL

Go to the BRAAN2 website: https://braanprod.louisville.edu

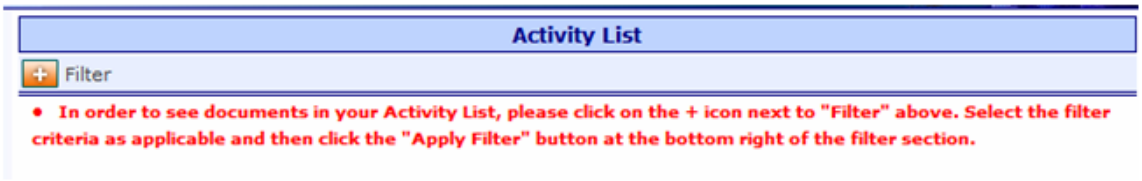
Login to BRAAN2:
As explained above, your username is your GroupWise address before the @ sign. Example: if your email is elhigg01@louisville.edu, your username is elhigg01. Your Password is your GroupWise password. The welcome screen will look like this:



Once you have logged in, you will see on the left-hand side of the screen the list of links. You will see two groups of links, PI and Research Team.



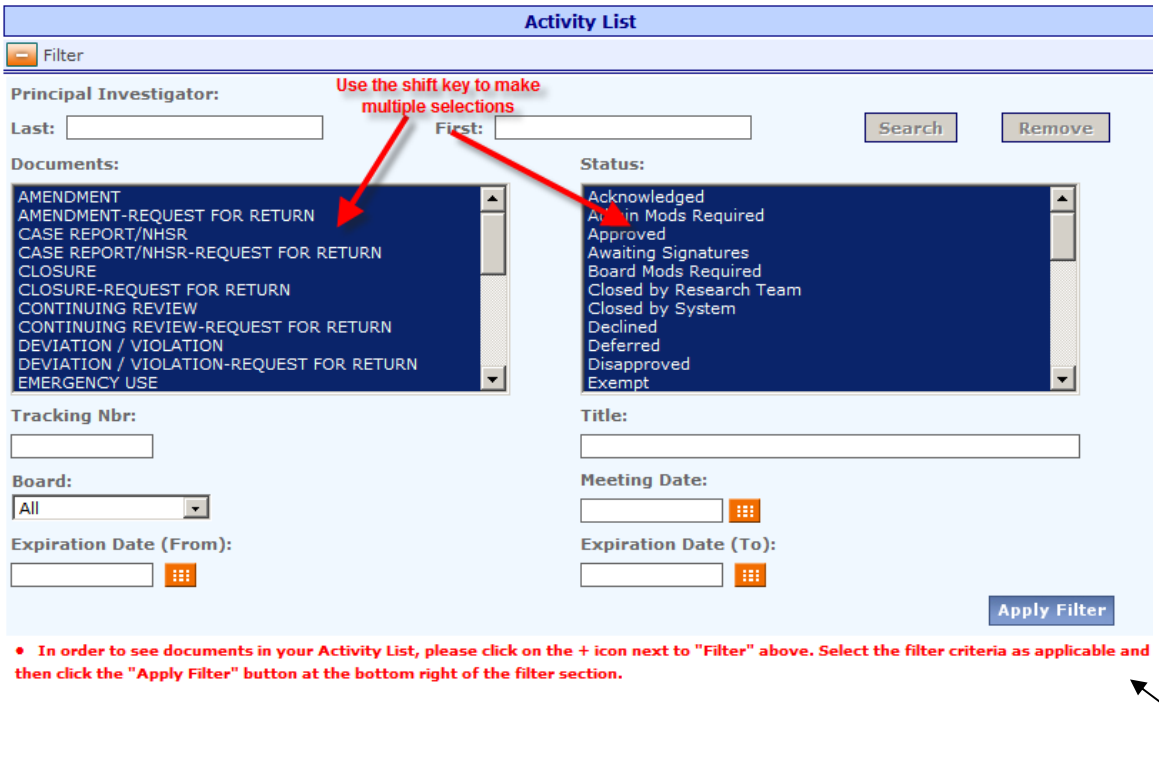
If this is your first time using BRAAN2, you will see the following message. To filter your activity list, please click on the ⊞ sign next to the word 'Filter'.



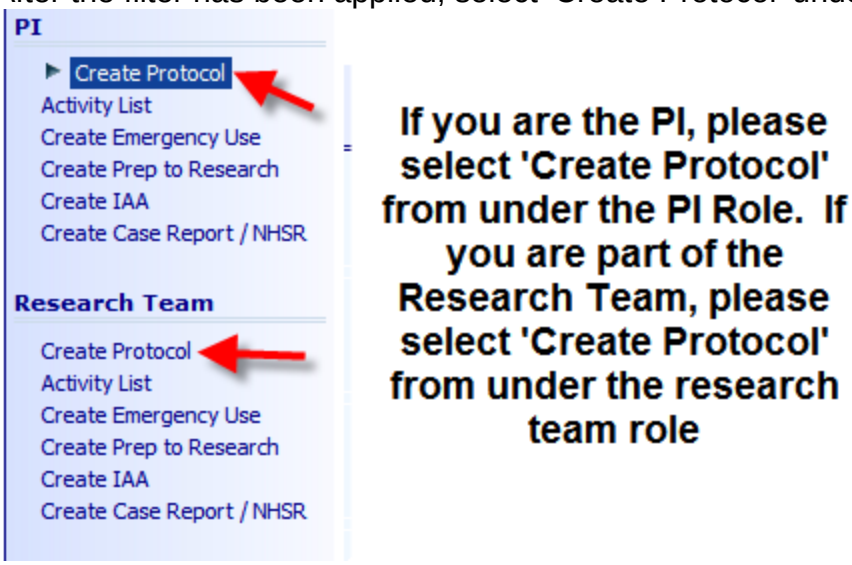
A screen will pop up showing you all the filter options available to you. There are two lists in the middle of the screen: Documents and Status (as explained in chapter four, in the '*Filter*" section).

Select all of the options for both documents and status and click Apply Filter.

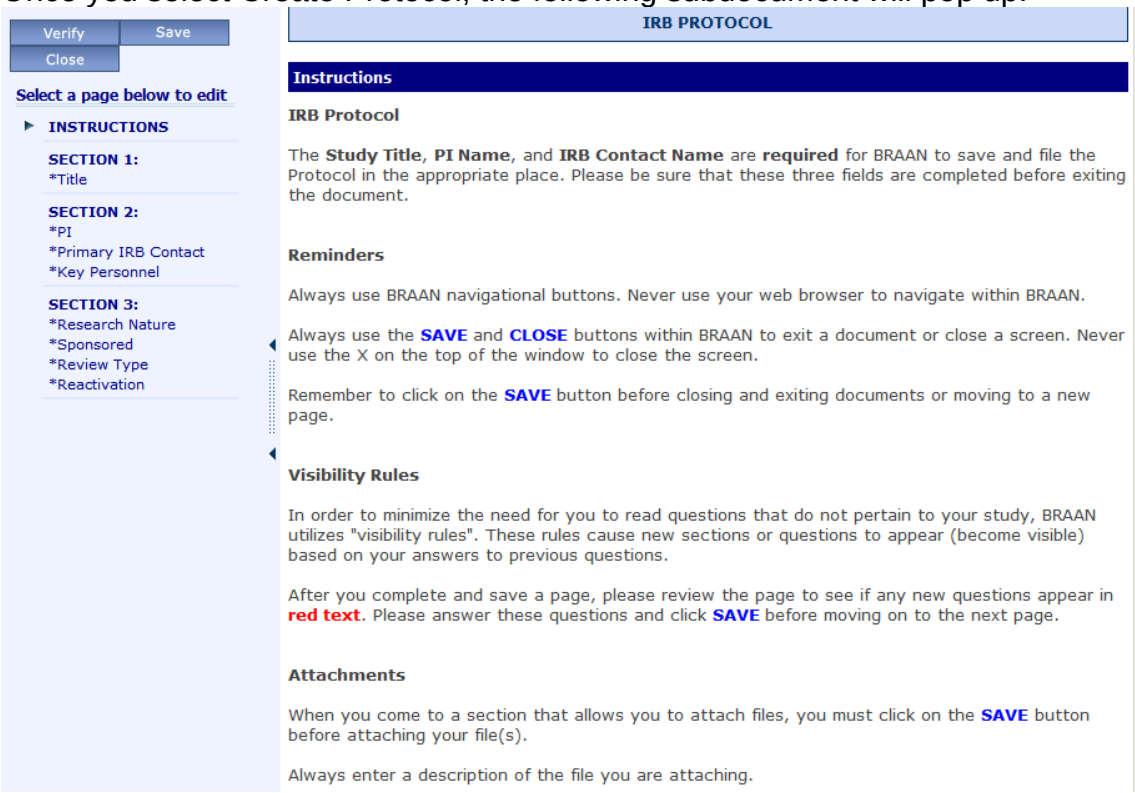
A



After the filter has been applied, select 'Create Protocol' under your role.

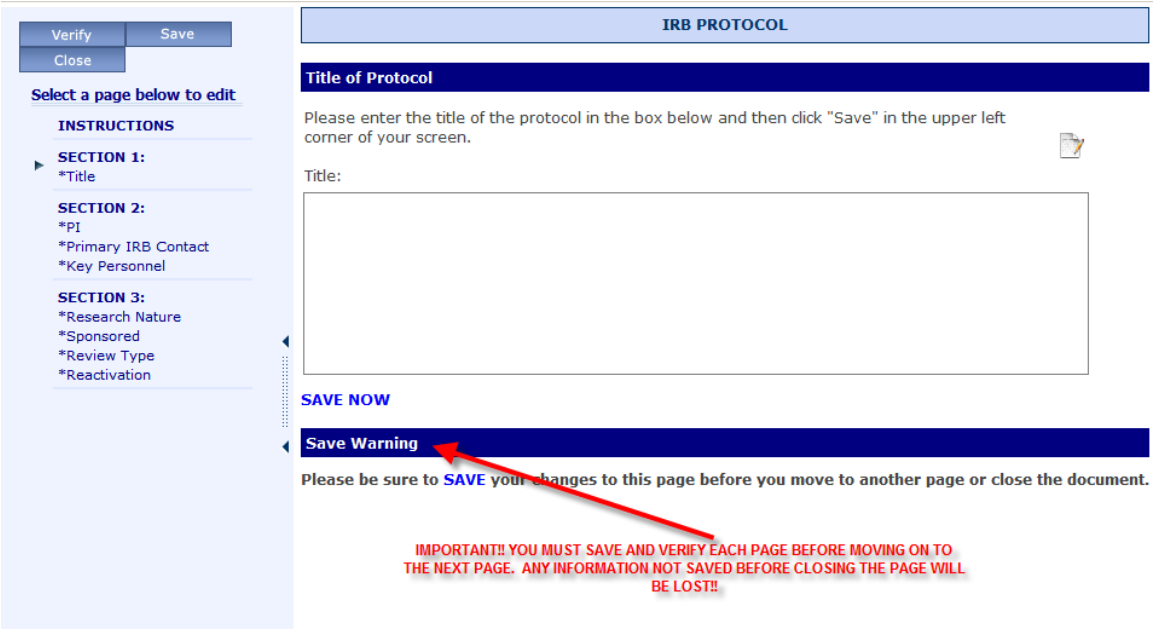


Once you select Create Protocol, the following subdocument will pop up:



Read the instructions carefully. Then, click on Section 1.

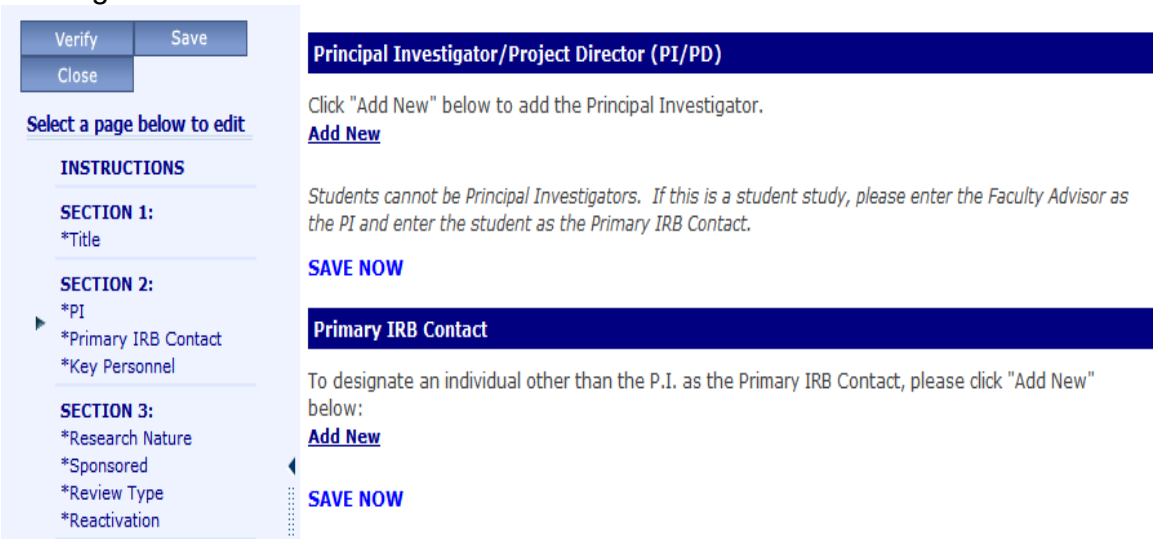
5.1 *Section 1 - Title*



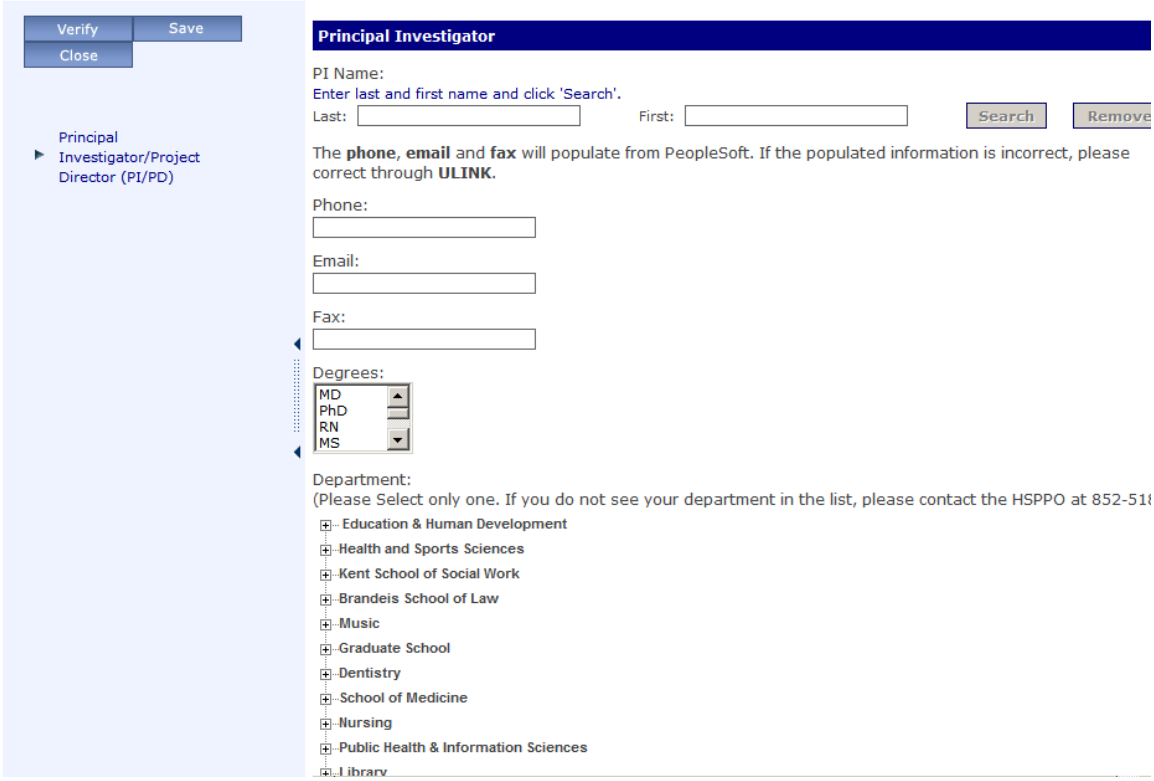
Fill in the study title and proceed to Section 2.

5.2 *Section 2 - PI, Primary IRB Contact and Key Personnel*

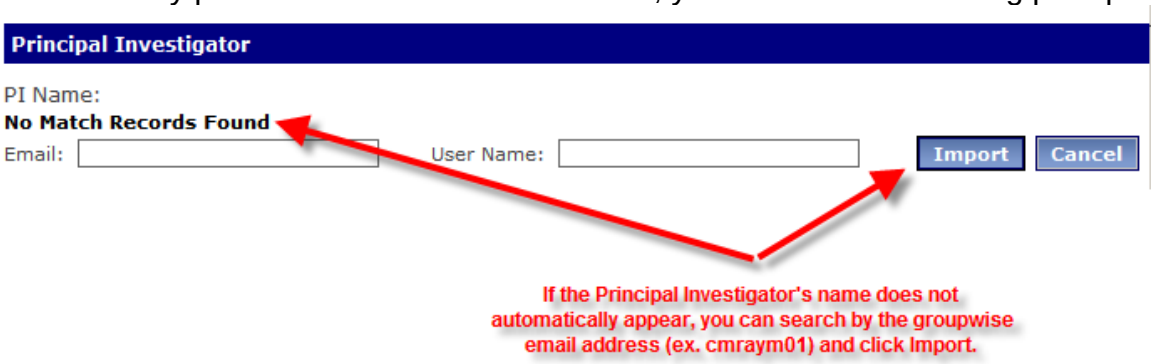
To add the principal investigator, you will need to click **Add New** in the principal investigator field.



After selecting **Add New** , the following subdocument will appear:



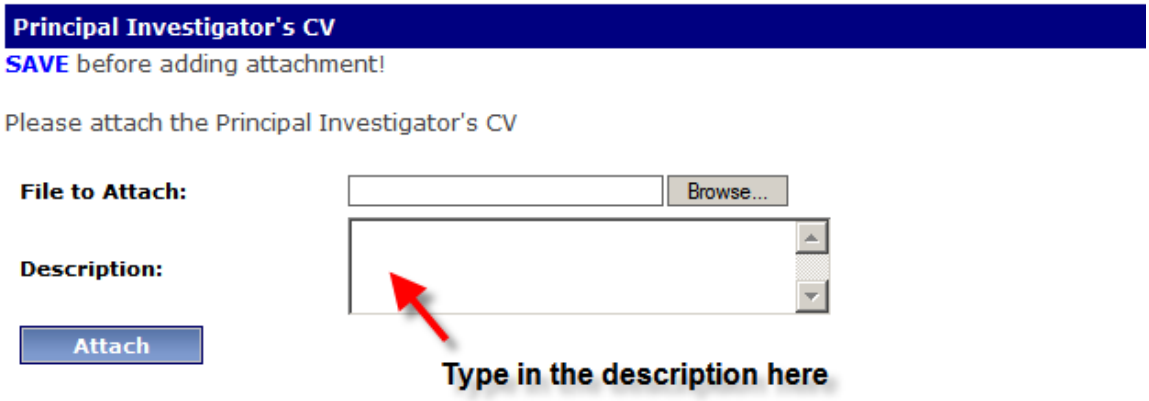
Enter the principal investigator's last name and click Search. In most cases, the principal investigator's information will pull from PeopleSoft and the sections for name, phone number, and email address will automatically fill in. If sections such as fax number do not automatically pull from PeopleSoft, please fill in that information. In some cases, such as hyphenated names, the system may not automatically pull the information. In this case, you will see the following prompt:

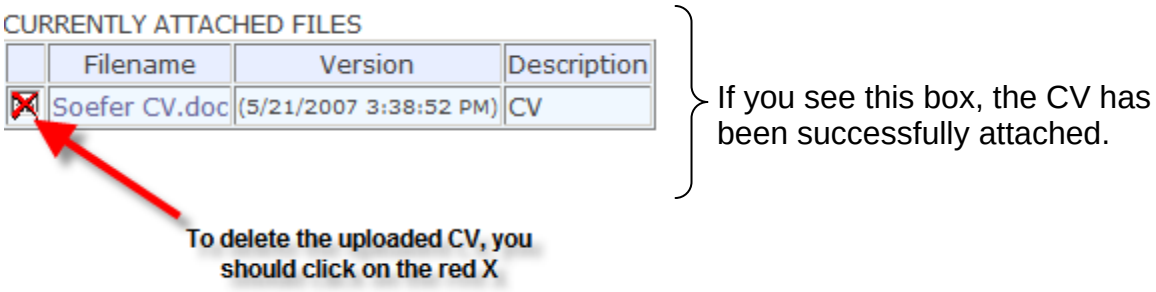


Enter the principal investigator's GroupWise Username (ex. cmraym01) and click Import.

Information such as name and phone number will then pull from PeopleSoft. Any information that does not automatically pull you will need to enter manually. Then select the appropriate department (Surgery, Health and Sport Sciences, etc).

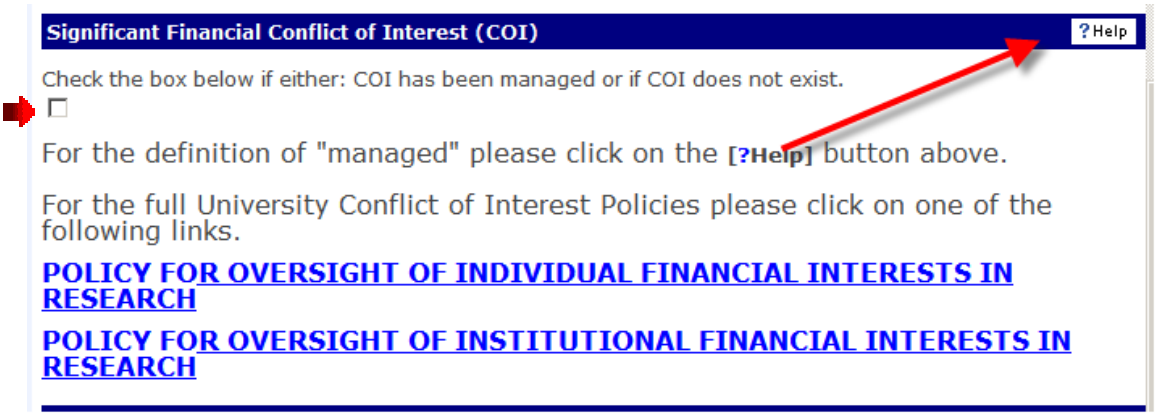
You will need to enter your mailing address in the text box provided. The next field will ask you to attach the principal investigator's CV. Click Save before attaching the CV. Make sure to add a description in the Description field.





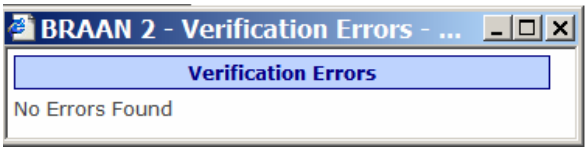
After the CV has been attached, the next two fields are checkboxes. The first check box for Faculty Advisor only needs to be checked if this study is a student study and the principal investigator is serving as the faculty advisor.

The last check box is for management of conflict of interest (COI). The principal investigator must check off this box to verify that either there is not a conflict of interest or that the conflict of interest has been managed.



Every person on the study will also need to personally log into the system and check off their conflict of interest. For instruction for how to do this, please see Chapter 6. The principal investigator is responsible for making sure that all key personnel have checked off their COI. You cannot submit your protocol until all personnel have done so.

After the principal investigator information has been input, please click the Save button. After you click save, please verify the document by clicking the Verify button. The verify button will need to be clicked after the completion of every subdocument. If you have not completed every field, the verify box will identify what is missing. If all of the information was input correctly, the verification errors report will appear:

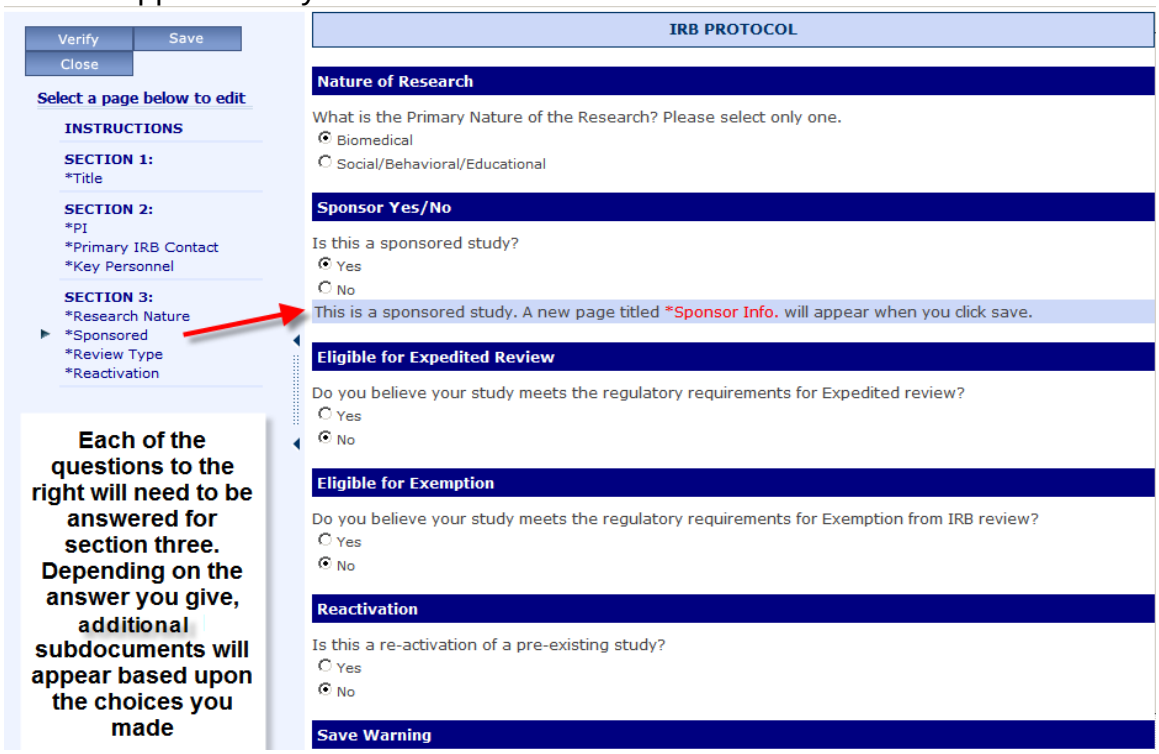


Click Save and Close.

Please follow the same steps to input all co-investigators and key personnel.

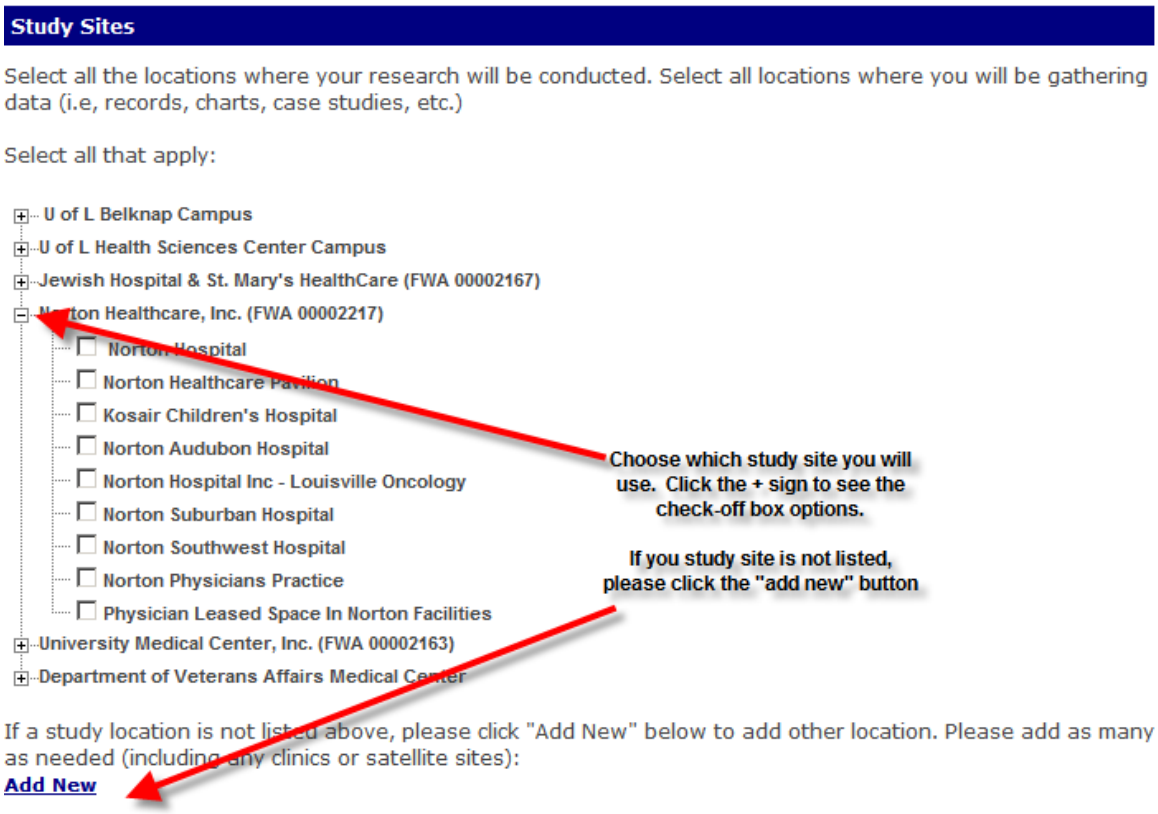
5.3 *Section 3 – Research Nature, Sponsored, Review Type and Reactivation*

In section 3, you will be asked sets of questions. Other sections and subdocuments will appear based on the answers you provided. For example, if you choose “Yes” under ‘Is this a sponsored study?’, a new page titled Sponsor Info will appear after you click save.



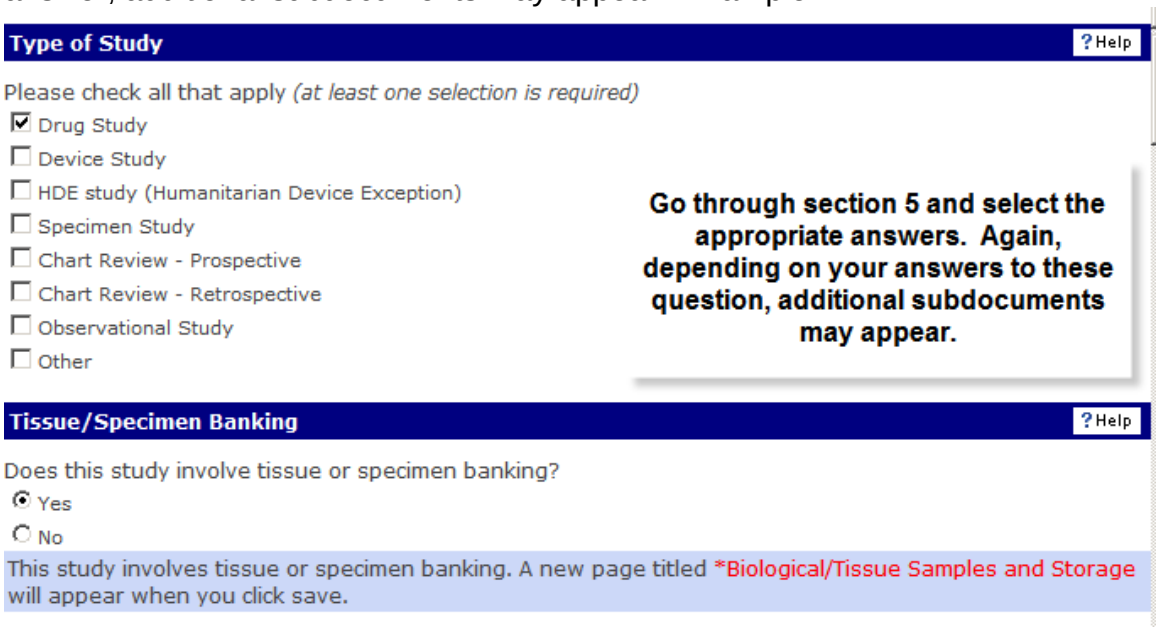
5.4 *Section 4 – Study Location(s)*

In section 4, you will need to choose the study location(s). Example:

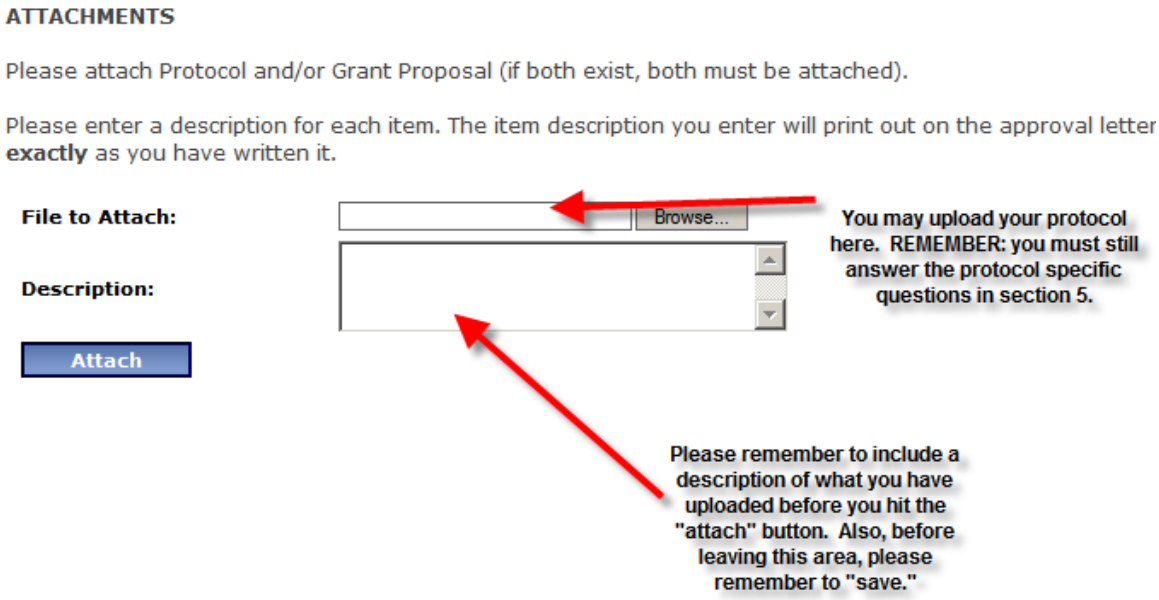


5.5 *Section 5 – Study Information*

In section 5, you will need to answer each question and depending on your answer, additional subdocuments may appear. Example:



In section 5, you will also be asked to attach the protocol or grant. Remember to save before adding any attachments.



Most questions in the BRAAN2 system are self explanatory, but if you need assistance, you may contact our office at 502-852-5188.

5.6 *Section 6 – Subject Profile*

Please go through section 6 and enter the appropriate information regarding the subject profile for your study. Be sure to answer all questions and remember to save before closing out of the subdocument.

5.7 *Section 7 – Subject Recruitment*

Please go through section 7 and enter the appropriate information regarding subject recruitment for your study. Be sure to answer all questions and remember to save before closing out of the subdocument. As previously explained, additional subdocuments may appear depending on the answers you provide.

5.8 *Section 8 – Subject Safety*

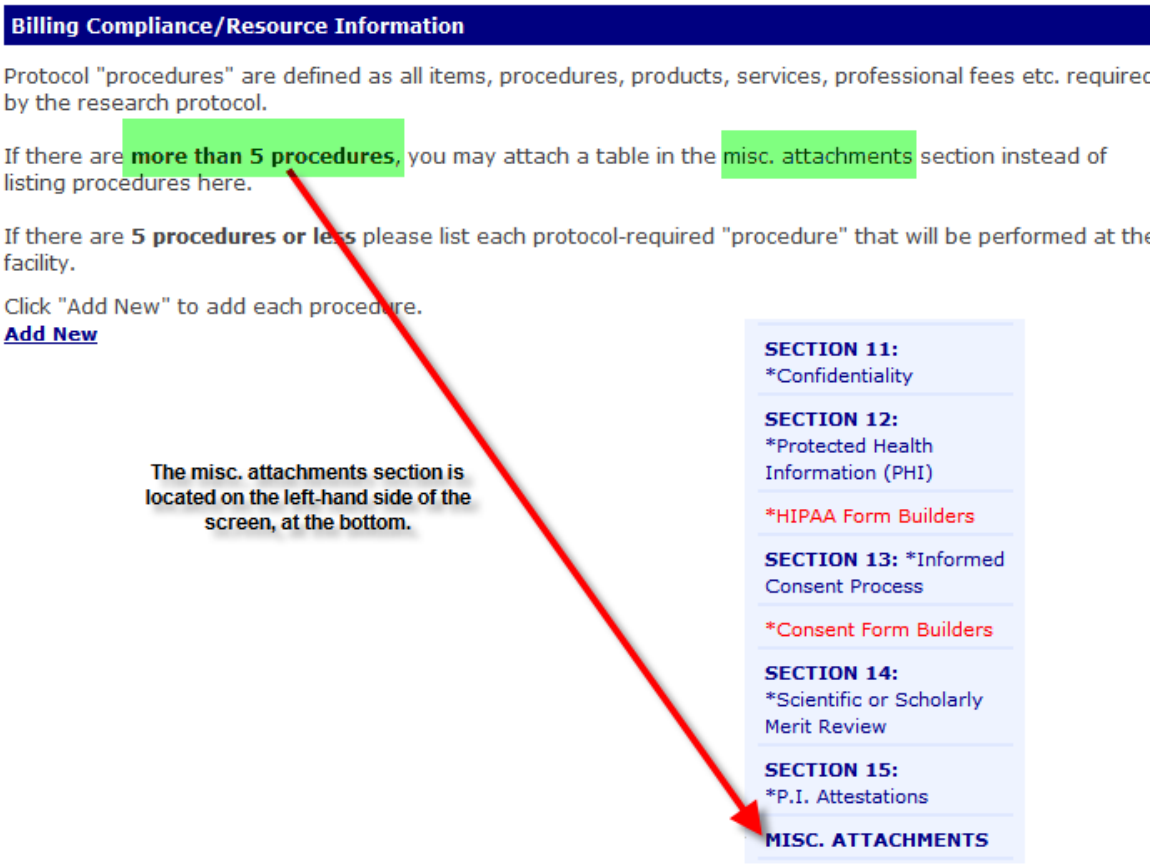
Please go through section 8 and enter the appropriate information regarding subject safety for your study. Be sure to answer all questions and remember to save before closing out of the subdocument.

5.9 *Section 9 – Compliance*

This section will address other compliance institutional and peer review committee approvals that may be required for the research. Attachments may also be added in this section.

5.10 *Section 10 – Billing Compliance*

Section 10 is basically what used to be the Multi Institutional Review Application (MIRA). In this section, you will need to add every procedure just as you would have in the Billing Compliance Table of the MIRA. If there are **more than 5 procedures**, you may attach a table in the MISC attachments section (which is after Section 15 on the left hand side of your screen).

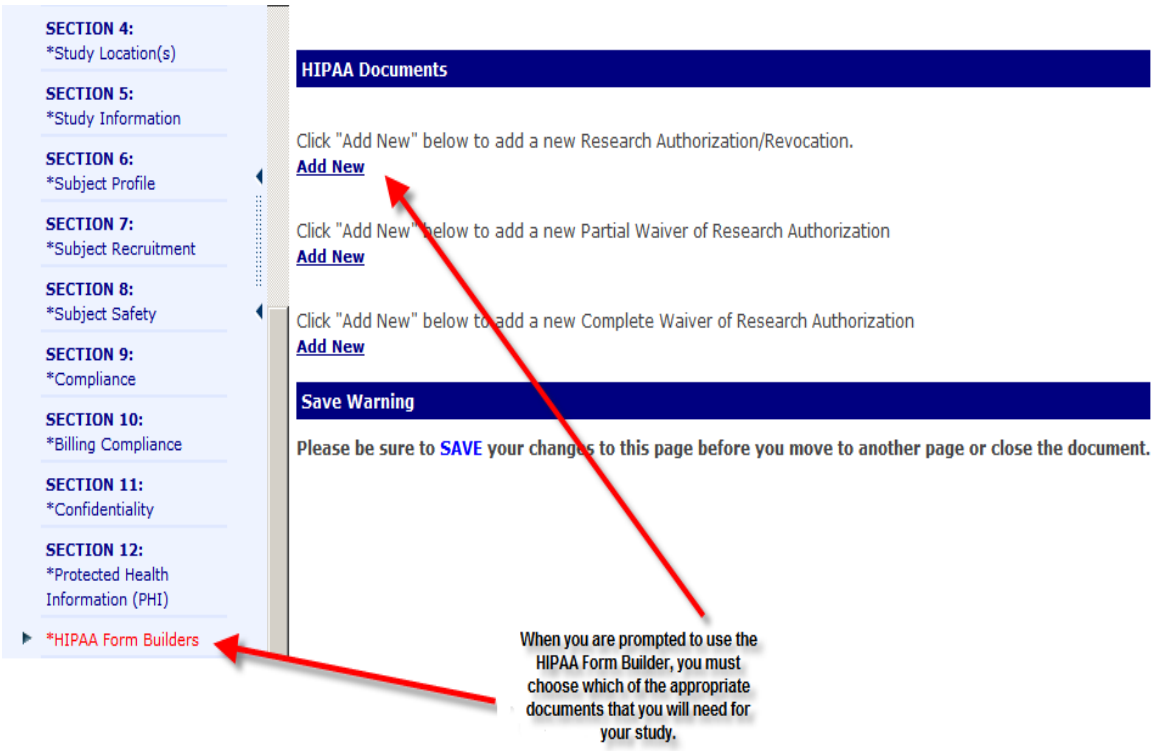


5.11 *Section 11 – Confidentiality*

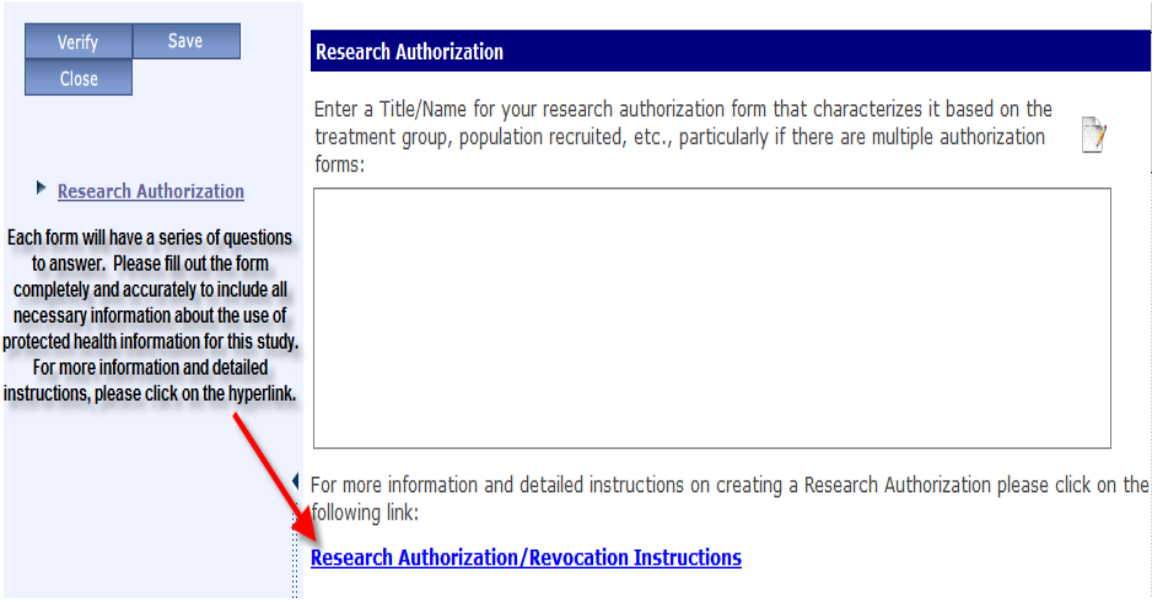
Please go through section 11 and enter the appropriate information regarding confidentiality for your study. Be sure to answer all questions and remember to save before closing out of the subdocument. As previously explained, additional subdocuments may appear depending on the answers you provide. You will need to attach copies of your data collection forms.

5.12 *Section 12 – Protected Health Information (PHI)*

In this section you will answer questions on the use of PHI for this study. If your study utilizes PHI the HIPAA Form Builder will appear on the left hand side of the screen in your navigation menu. The HIPAA Form Builder will actually create your HIPAA documents for you, however, you will need to enter study specific language.



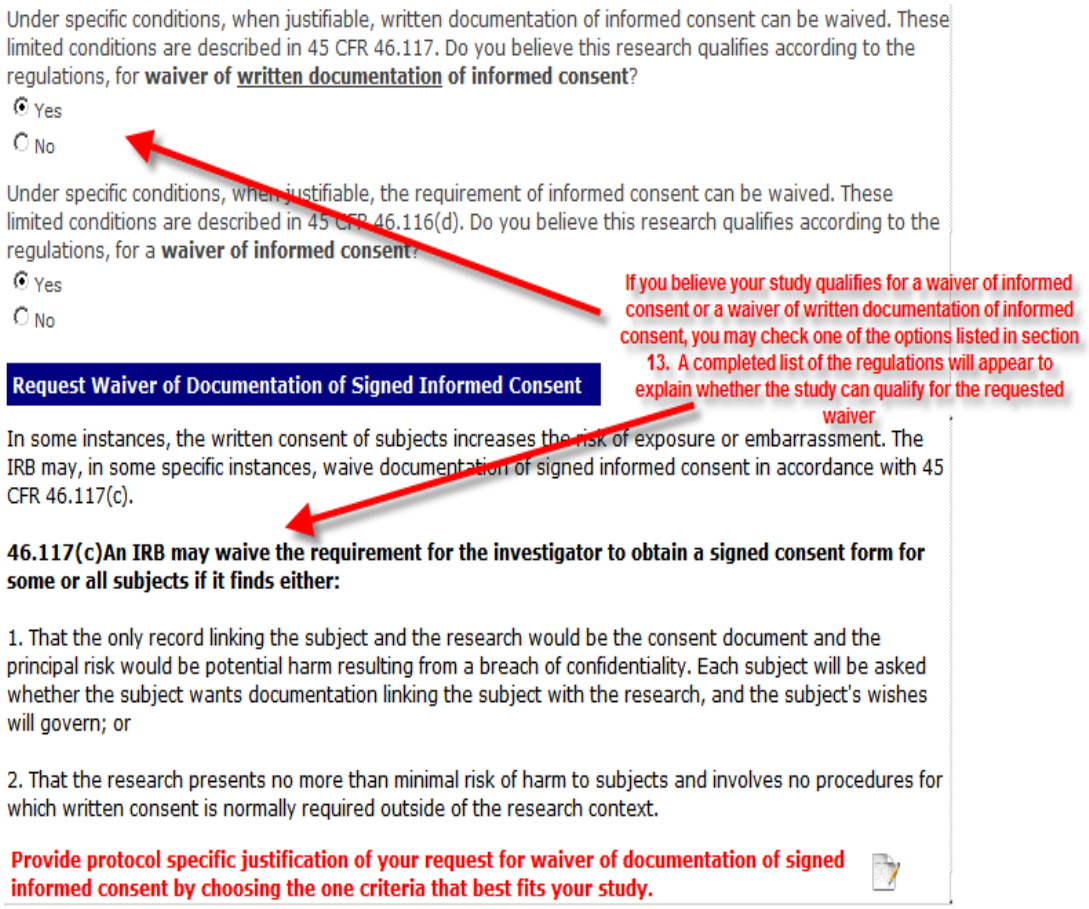
The template language is already built into the HIPAA forms. You will only need to enter information that is unique to the study. Enter a title for each document such as “Research Authorization for Main Study” or “Research Authorization for Genetic Sub-Study”.



After you have created your HIPAA document using the HIPAA Form Builder, you may preview the document you created. Click the button for View after the document has been created. If you wish to delete it, simply click delete.

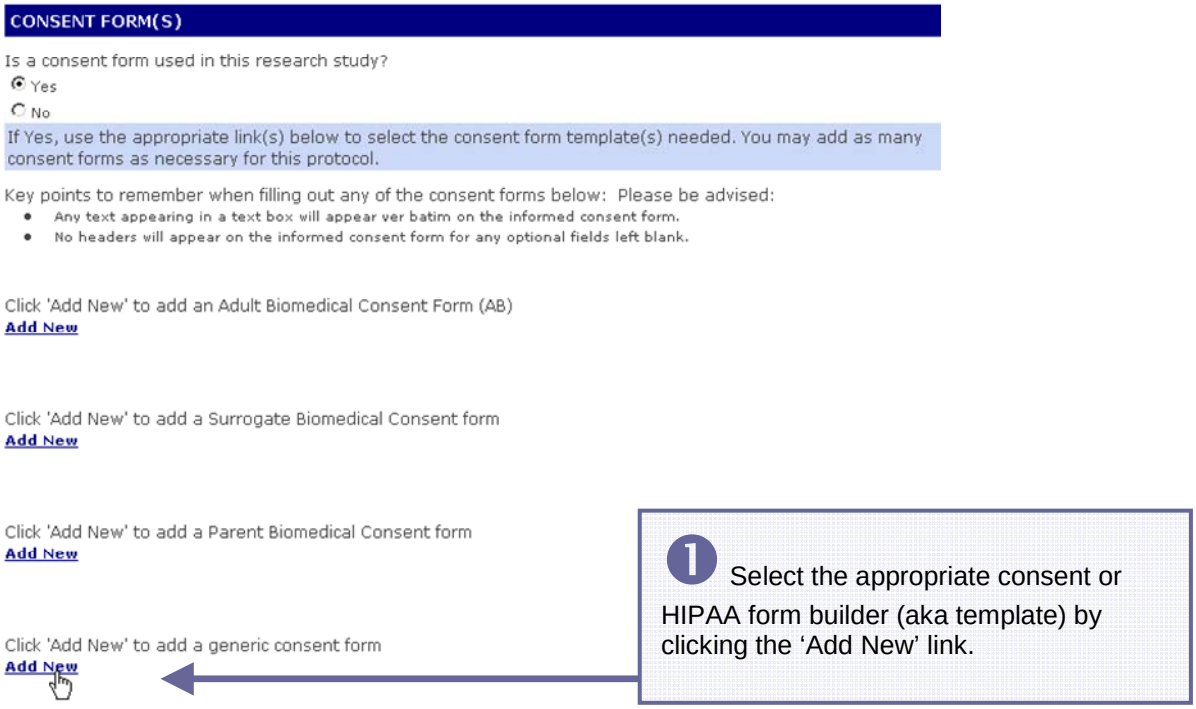
5.13 *Section 13 – Informed Consent Process*

In section 13, you will need to answer the specific questions regarding your study. If you believe your study meets the requirement to waive informed consent or signed informed consent, this is the appropriate section to state this. See the example below:

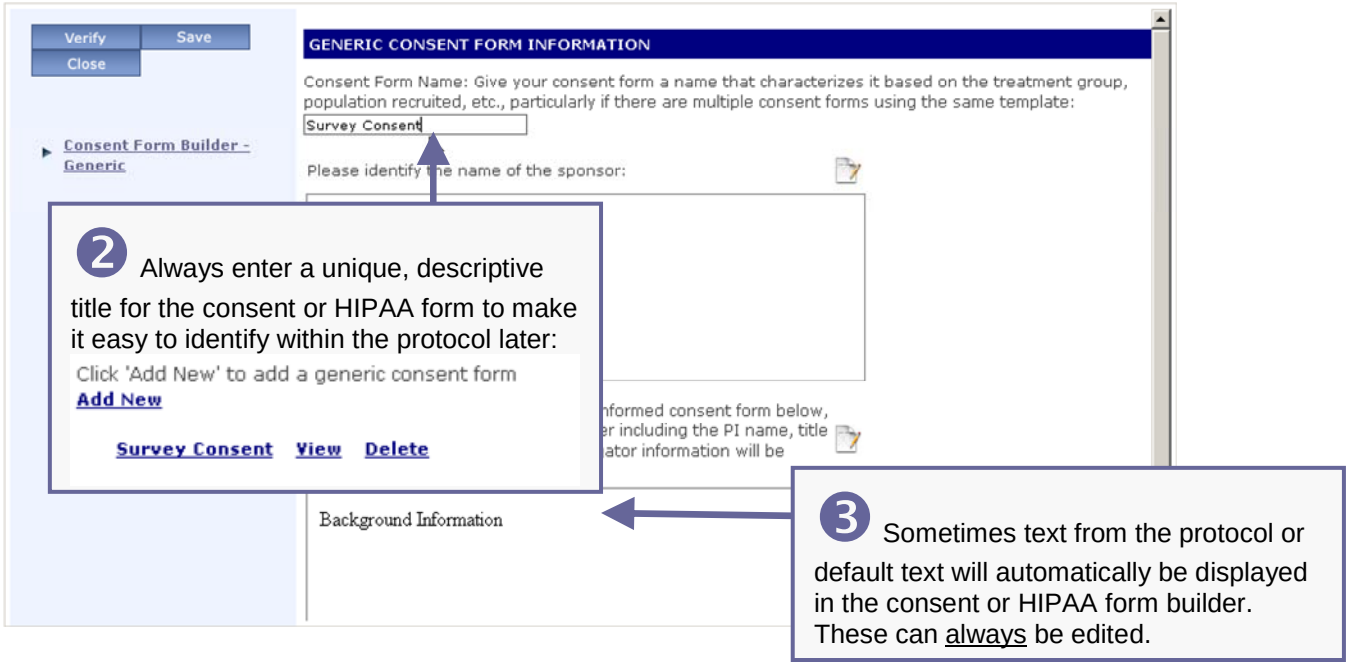


The Consent and HIPAA form builders in BRAAN2 function in the same way as the protocol forms. They are SubDocReport fields within the protocol form. Users with the **Principle Investigator (PI)** or **Research Team** role can access these SubDocReport fields on the appropriate pages within the protocol form.

NOTE: The Consent and HIPAA form builders are similar in function. For the purpose of this manual, only examples of the Consent form builder are shown.)

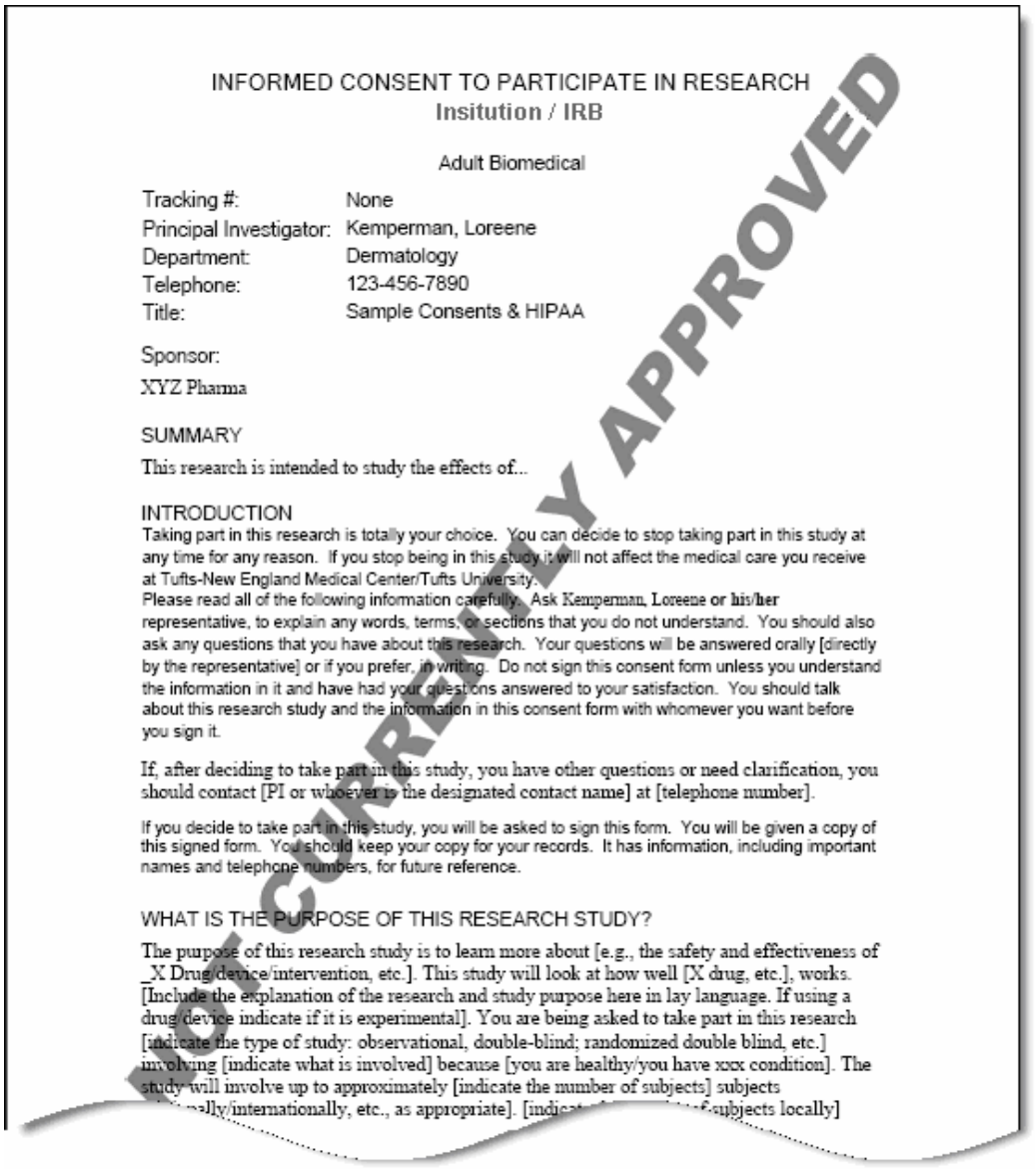


Each Consent and HIPAA form builder is a compilation of various field types & input methods described previously in this User Manual.



Remember to Save and Verify your work before you Close the window.

- Consent forms



INFORMED CONSENT TO PARTICIPATE IN RESEARCH
Insitution / IRB

Adult Biomedical

Tracking #:	None
Principal Investigator:	Kemperman, Loreene
Department:	Dermatology
Telephone:	123-456-7890
Title:	Sample Consents & HIPAA

Sponsor:

XYZ Pharma

SUMMARY

This research is intended to study the effects of...

INTRODUCTION

Taking part in this research is totally your choice. You can decide to stop taking part in this study at any time for any reason. If you stop being in this study it will not affect the medical care you receive at Tufts-New England Medical Center/Tufts University.
Please read all of the following information carefully. Ask Kemperman, Loreene or his/her representative, to explain any words, terms, or sections that you do not understand. You should also ask any questions that you have about this research. Your questions will be answered orally [directly by the representative] or if you prefer, in writing. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction. You should talk about this research study and the information in this consent form with whomever you want before you sign it.

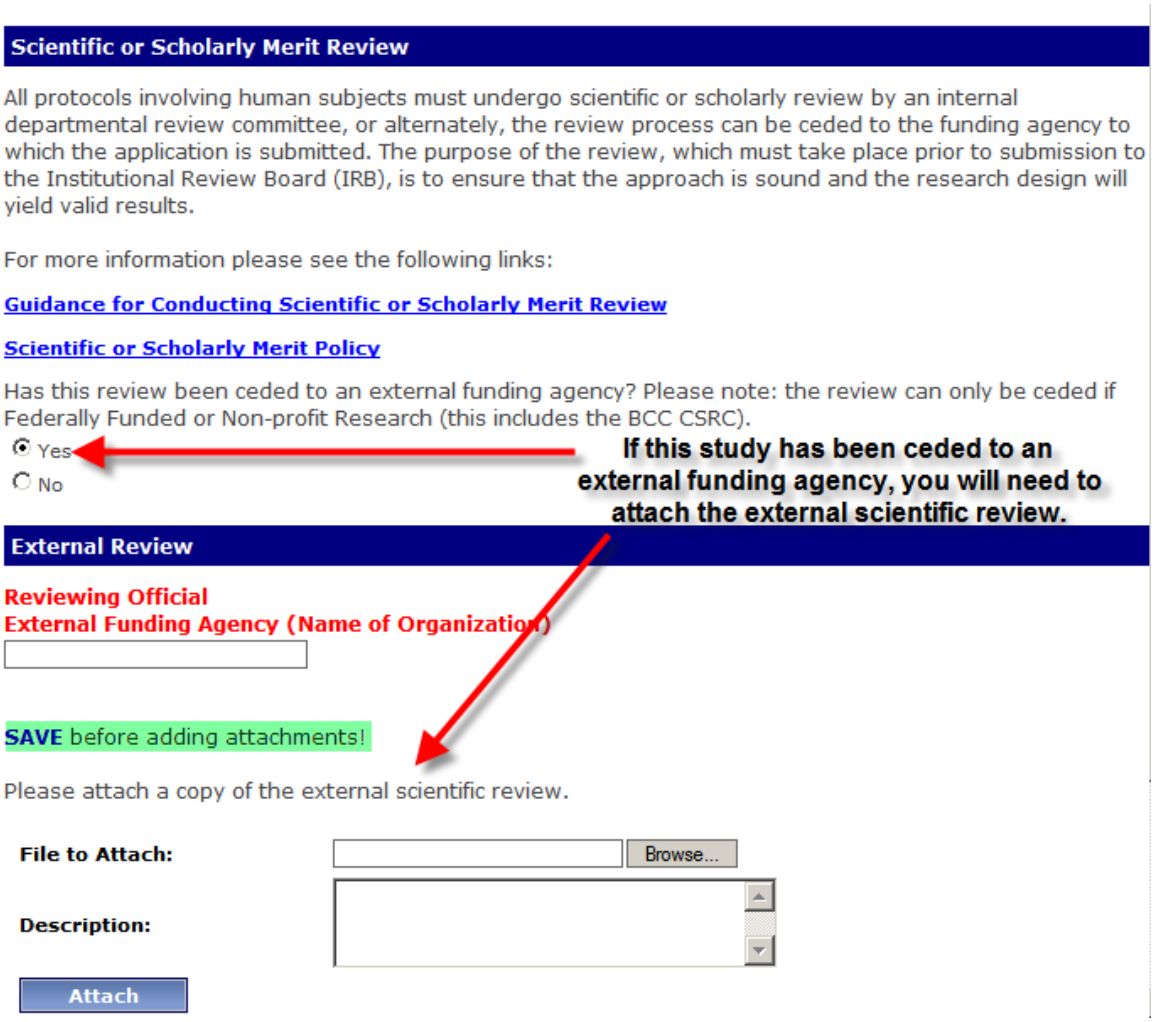
If, after deciding to take part in this study, you have other questions or need clarification, you should contact [PI or whoever is the designated contact name] at [telephone number].

If you decide to take part in this study, you will be asked to sign this form. You will be given a copy of this signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to learn more about [e.g., the safety and effectiveness of _X Drug/device/intervention, etc.]. This study will look at how well [X drug, etc.], works. [Include the explanation of the research and study purpose here in lay language. If using a drug/device indicate if it is experimental]. You are being asked to take part in this research [indicate the type of study: observational, double-blind; randomized double blind, etc.] involving [indicate what is involved] because [you are healthy/you have xxx condition]. The study will involve up to approximately [indicate the number of subjects] subjects [nationally/internationally, etc., as appropriate]. [indicate # of subjects locally]

5.14 *Section 14 – Scientific or Scholarly Merit Review*



5.15 *Section 15 – PI Attestations*

In this section, you will be asked to attest to several statements. If any statement is not checked, you will not be able to submit your study. Please see the example of the attestations below:

PI Attestations

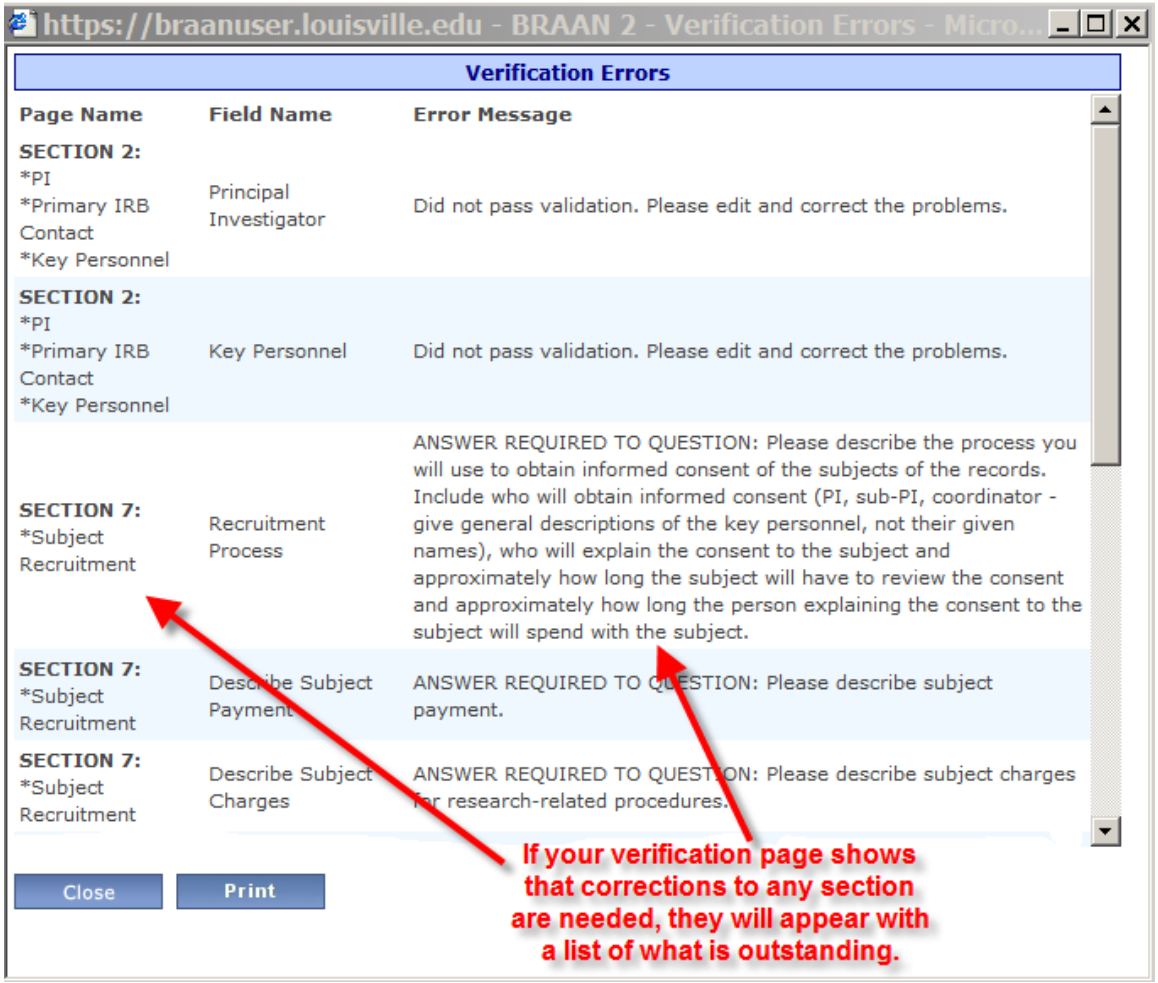
As Principal Investigator of this study, I assure that the following statements are true:

- ☑ The information provided in this application is correct.
- ☑ I will seek and obtain prior written or electronic approval from the IRB for any modifications in the proposal, including any changes inprocedures, any changes in study personnel, an changes in informed consent language, funding agencies, etc.
- ☑ I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.
- ☑ I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation.
- ☑ I will not begin my research until I have received written or electronic notification of final IRB approval.
- ☑ I will not begin my research until I have received any other written or electronic notification of additional compliance approvals I may need (e.g., administrative approvals from sites or facilities, Industry Contracts, Institutional Biosafety Committee, Radiation Safety Committee, Jefferson County Public Schools, etc.)
- ☑ I will comply with all IRB requests to report on the status of the study. This includes filing Progress Reports 8 weeks in advance of the study approval expiration.
- ☑ I will maintain records of this research according to IRB and Federal guidelines.
- ☑ The grant that I have submitted to my funding agency, if applicable, which is submitted with this IRB submission accurately and completely reflects what is contained in this application.
- ☑ If these conditions are not met, I understand that approval of this research could be placed on hold, suspended or terminated.

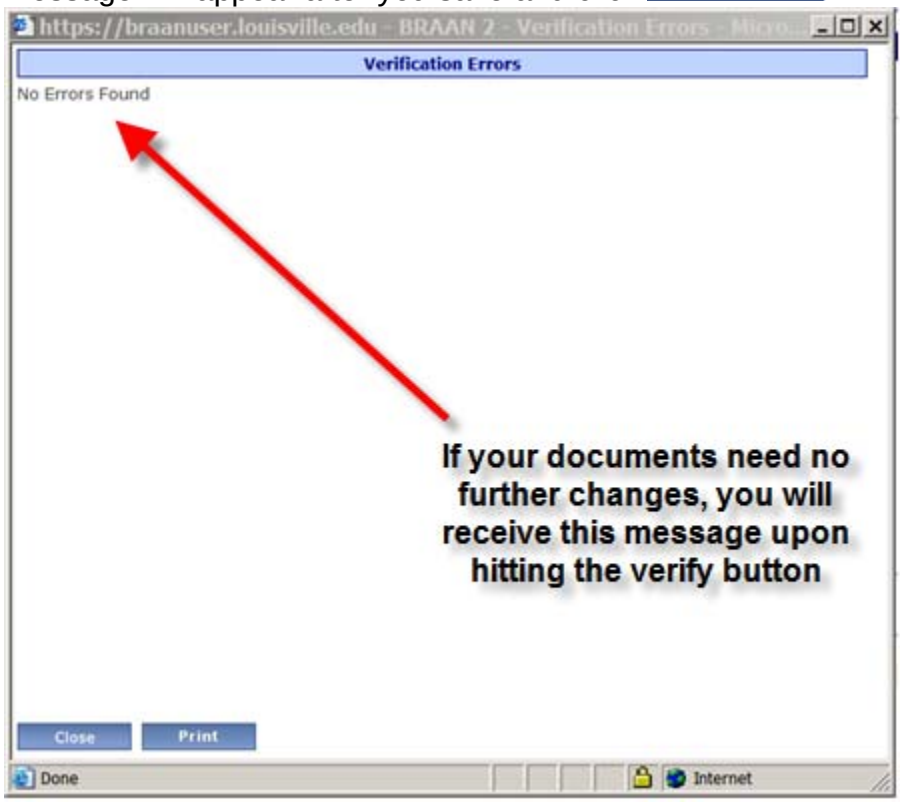
5.16 *Verification*

This is the final step in creating your protocol. After you have attested to the above statements, you will need to click Save and then click Verify.

The verification page will look like this if you still need to complete sections of your submission:

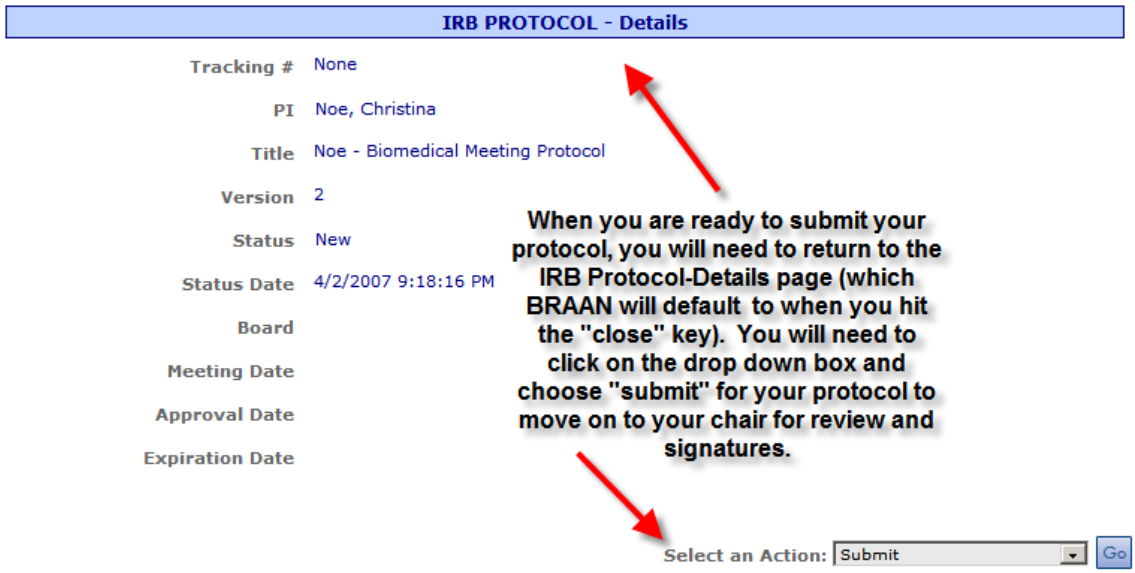


If you have completed all of the required sections, the following verification message will appear after you save and click Verify:



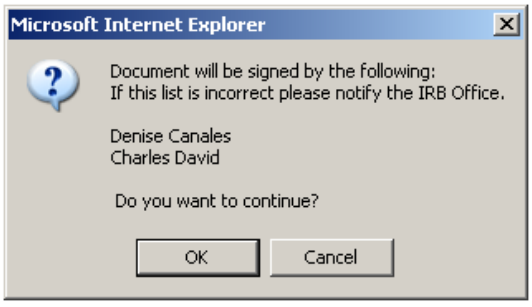
5.17 *Final Submission*

After all sections of the initial submission have been completed, saved and verified and all key personnel have checked off their conflict of interests, you are ready to submit. Close out of the create protocol window (after saving and verifying, of course) and go back to your Activity List. Select the protocol that you wish to submit and click 'Details'. In the 'Select an Action' drop down box select "Submit". See example below:



Once you have selected submit, the protocol will electronically be routed to the appropriate persons for signatures.

A pop-up window will alert the PI of the signatures that are required on the protocol based on the information contained in the protocol:



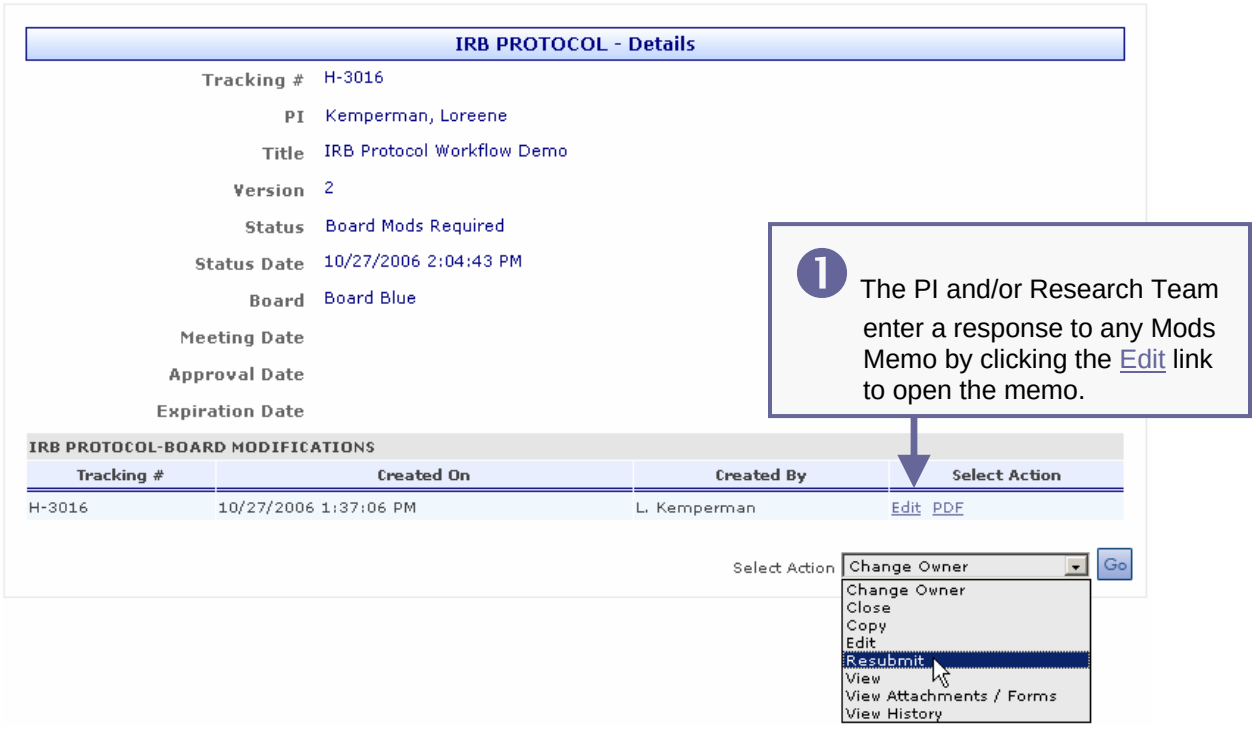
Other documents (like Emergency Use) are directly submitted to the IRB Office. If this is the case, you will see this pop-up:

5.18 *Board Modifications*

When a document is returned to the Principle Investigator (PI) and/or Research Team by sending a

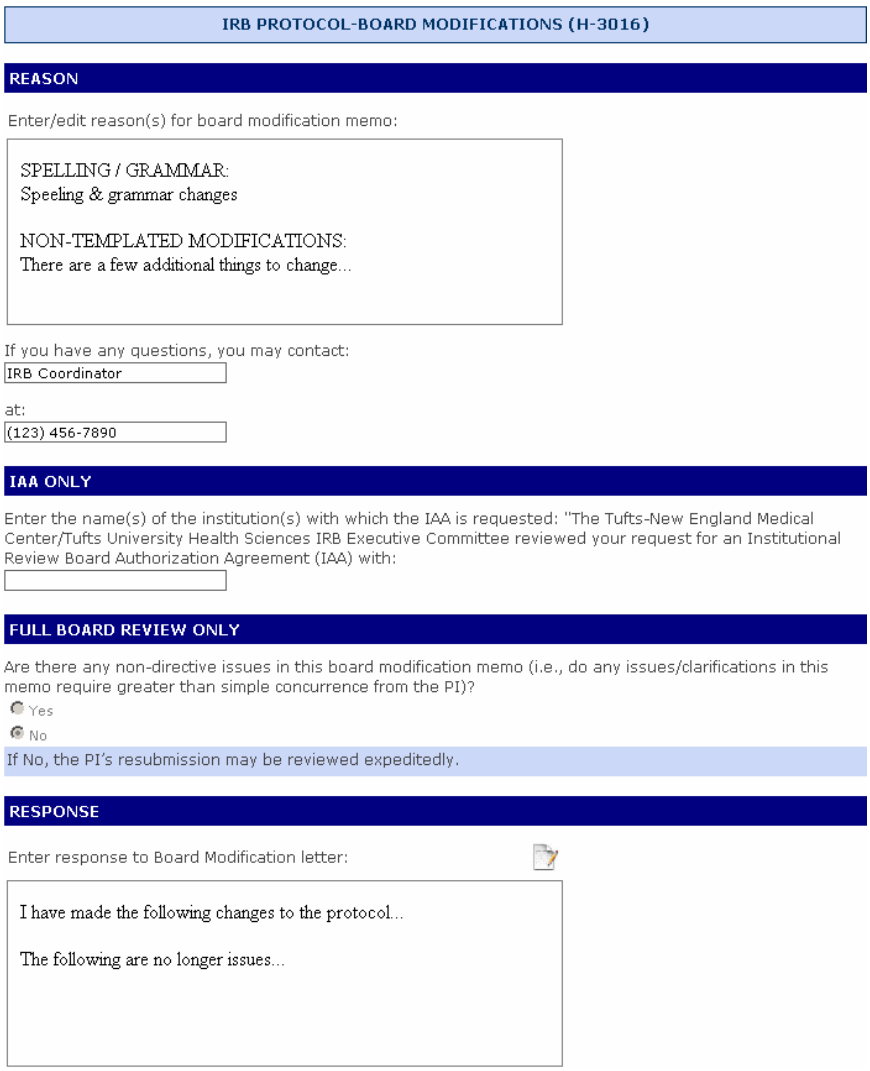
- Signature Mods Memo (IRB Protocol only)
- Admin Mods memo
- Board Mods Memo
- or Deferred Memo

The PI and/or Research Team should respond to the memo and must resubmit the protocol for it to continue in the review process.



Fields of data entered in the creation of the memo are locked and cannot be edited by the PI or Research Team.

Only the Response can be edited by the PI or Research Team. After the entire response has been entered, Save, Verify, and Close the window.



2 Select **Edit** from the Action Menu and make the necessary modifications to the protocol. The PI and/or Research Team can edit the protocol.

3 Select **Resubmit** from the Action Menu to resubmit the protocol with the response to the Mods Memo.

NOTE: Only users with the **PI** role can submit (or resubmit) protocols in BRAAN2.

Protocols resubmitted for Signature Mods will re-route to the Signature role use who issued the memo; all other protocols and other work return to Administrative review.

Users have a limited time to respond to modification memos and deferred memos before the protocol or other work will be moved to a status of Closed by System due to inactivity.

CHAPTER 6. CONFLICT OF INTEREST CHECK OFF

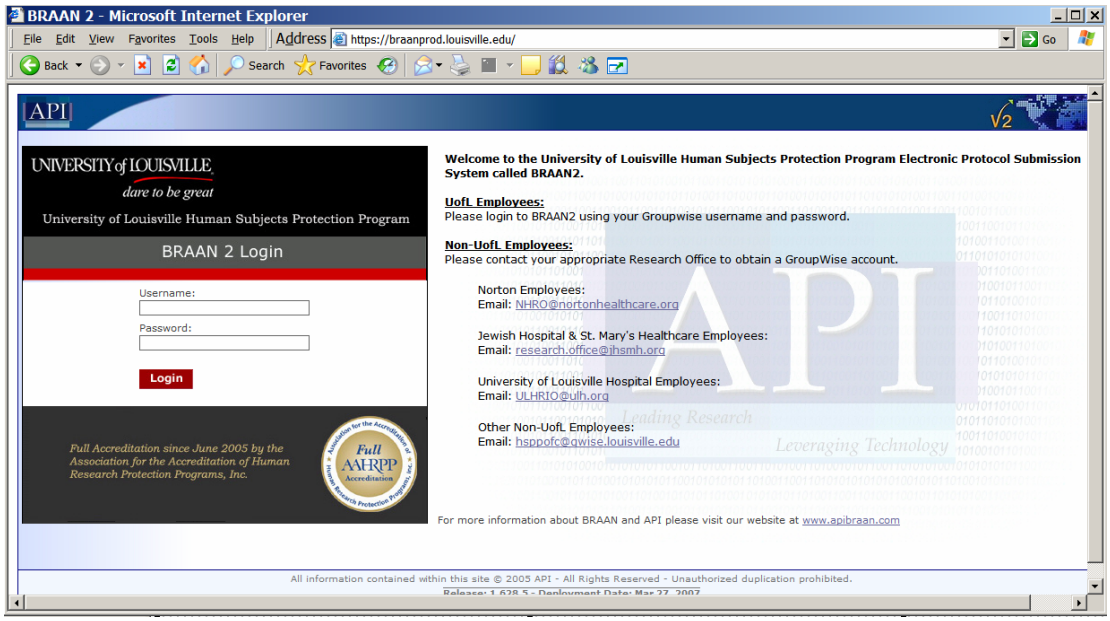
1. Go to the following website https://braanprod.louisville.edu

2. Login to BRAAN2:

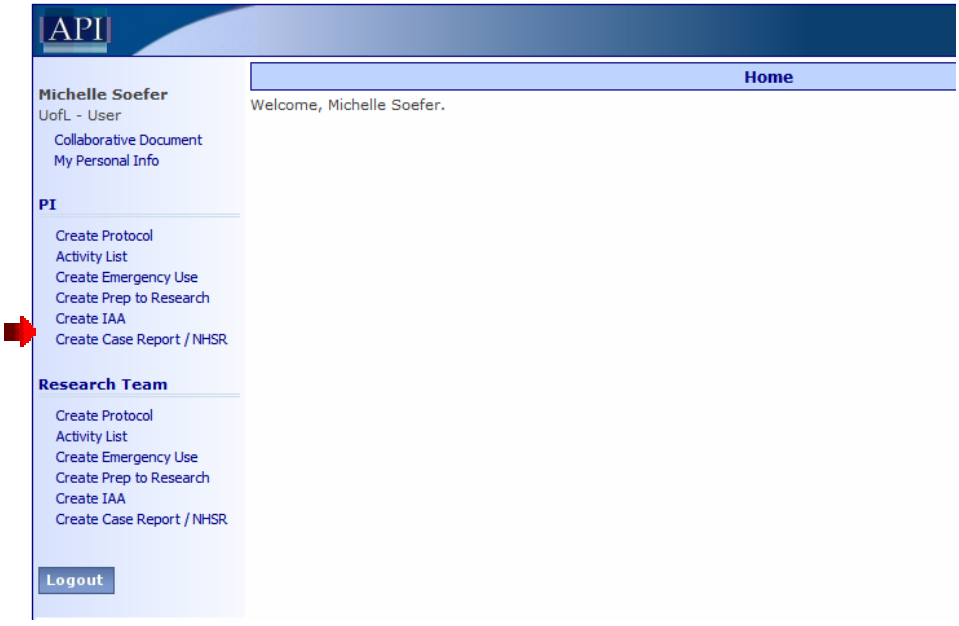
Your username is your GroupWise address before the @ sign.

Example:
If your email is mhsoef01@louisville.edu, your username is mhsoef01

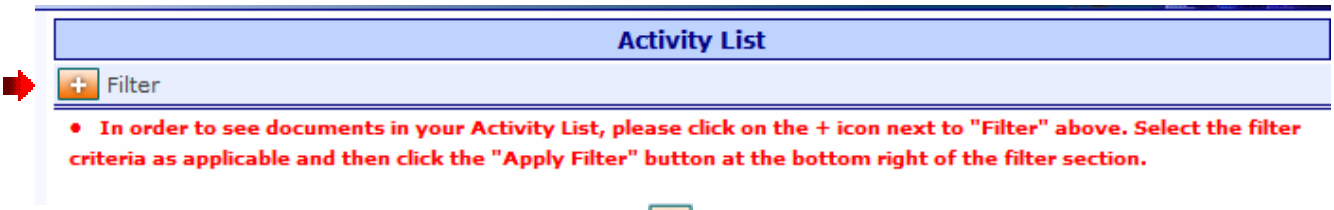
Your Password is your GroupWise password.



3. BRAAN2 will show you a welcome screen. On the left-hand side of the screen is a list of links. You will see two groups of links, PI and Research Team. Please click on the **Activity List** in the **Research Team** group.



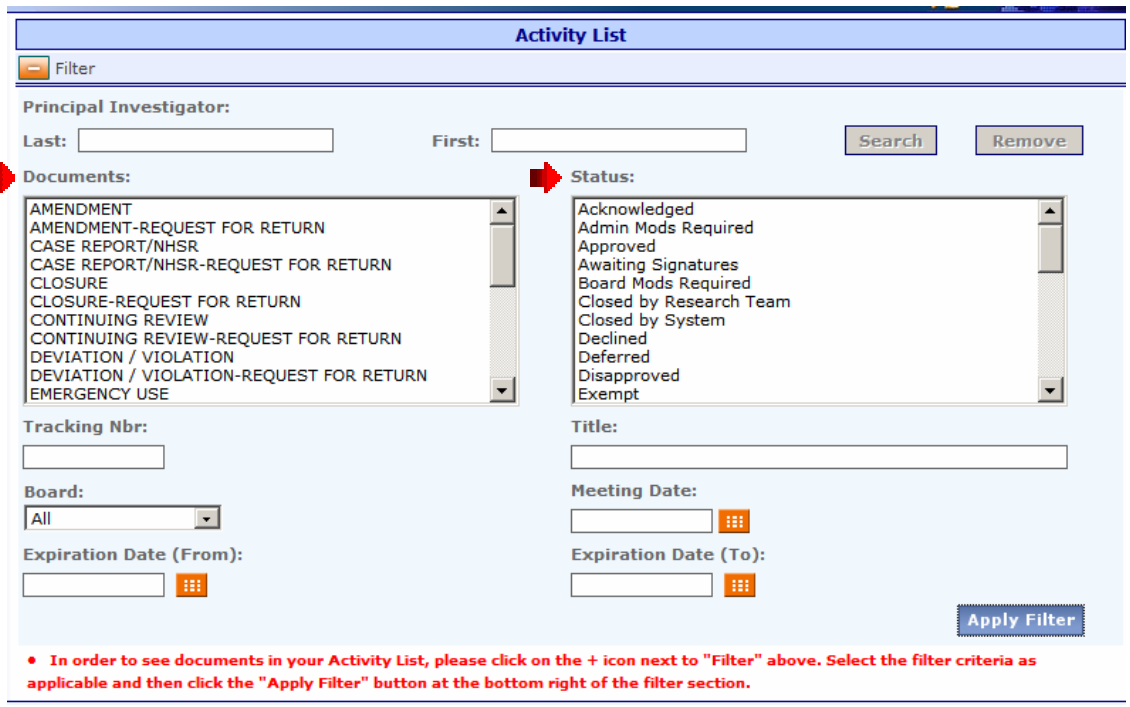
4. If this is your first time using BRAAN2, you will see the following message.



To filter your activity list please click on the + sign next to the word filter.

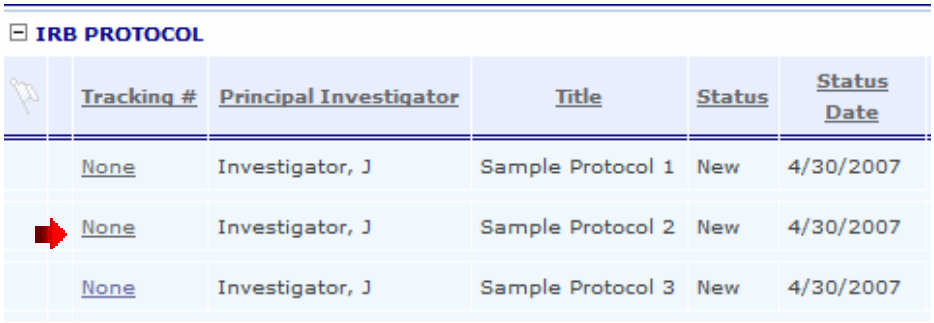
5. A screen will pop up showing you all the filter options available to you. There are two lists in the middle of the screen: Documents and Status.

Select all of the options for documents and status and then press Apply Filter.

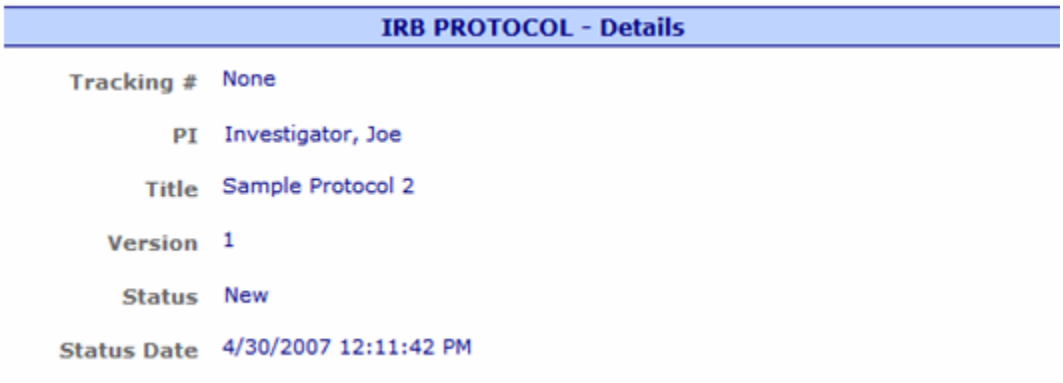


6. You will then see a list of all studies where you are listed as a Research Team Member.

Locate the study you need and click on the None link.

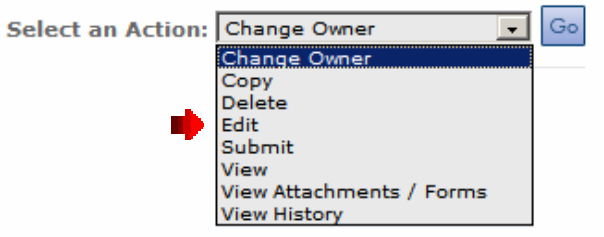


7. The Details for the protocol you selected will be displayed.

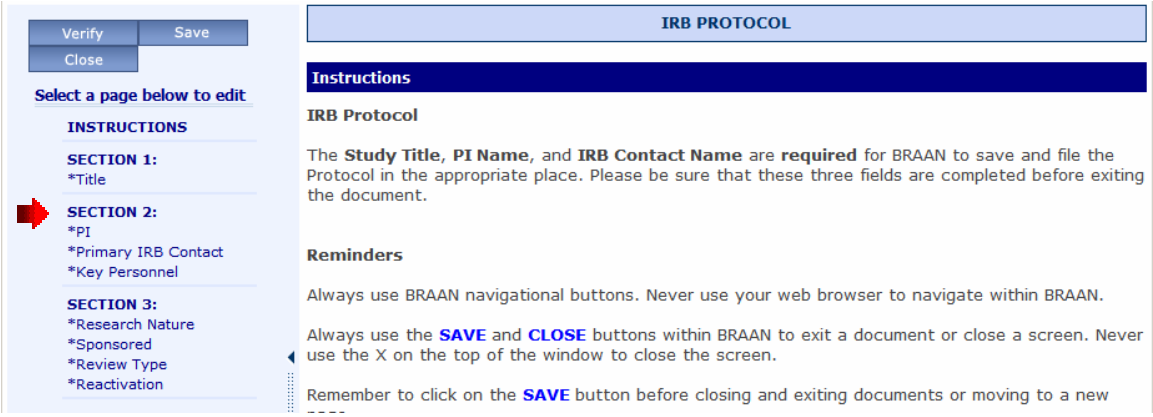


On the bottom right corner of the screen you will see a drop down box called “Select an Action”.

- Select Edit
- Press Go



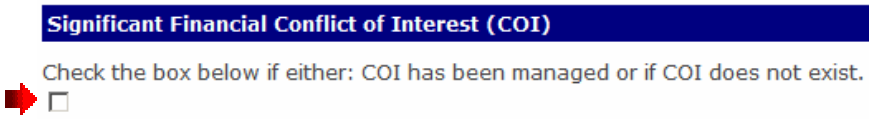
8. The Protocol will be displayed. Please click on Section 2.



9. In the section “Other Investigators and Key Personnel”, you will see your name with a red flag to the left.

Please click on your name.

10. A new page will open up. Please scroll to the **bottom** of the page where you will see the COI question.



- Check the box
- Click Save then click Close

  (These buttons are located in the upper left hand corner of the screen)

11. You should be back to the protocol and the red flag that was next to your name should be gone.

Click on the Close button to close main document.

Click on the Logout button, to log out of BRAAN.

Key personnel should NOT make any other changes at this point!

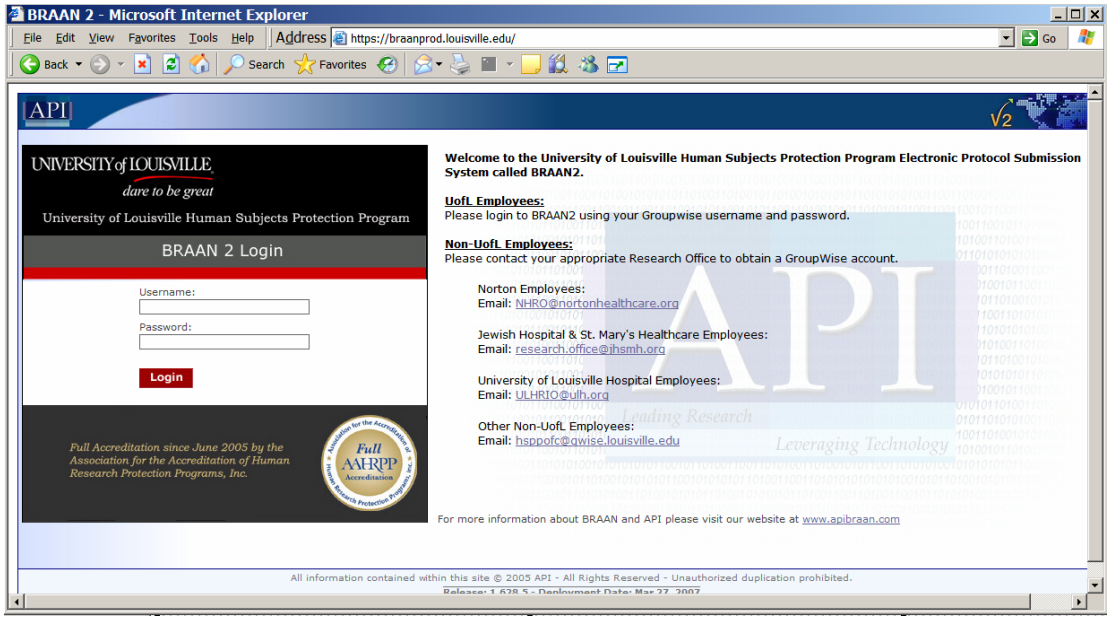
CHAPTER 7. COMPLETING THE SCIENTIFIC OR SCHOLARLY MERIT REVIEW

1. Go to the following website https://braanprod.louisville.edu

2. Login to BRAAN2:

Your username is your GroupWise address before the @ sign. Example: if your email is jdburk04@louisville.edu, your username is jdburk04

Your Password is your GroupWise password.



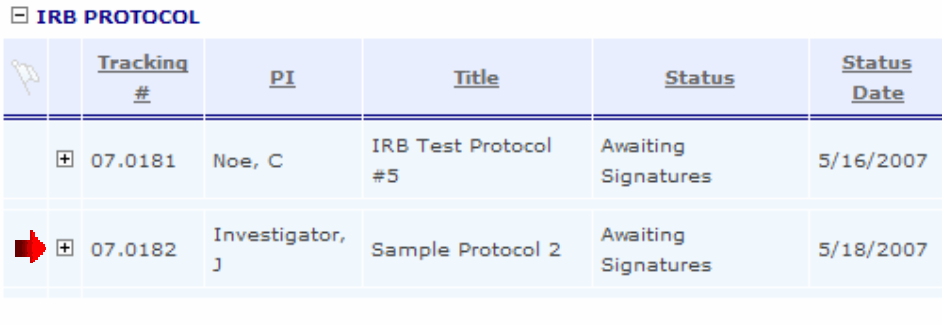
3. BRAAN2 will show you a welcome screen.

On the left-hand side of the screen is a list of links.

Please click on the **Activity List** under **Signature**.

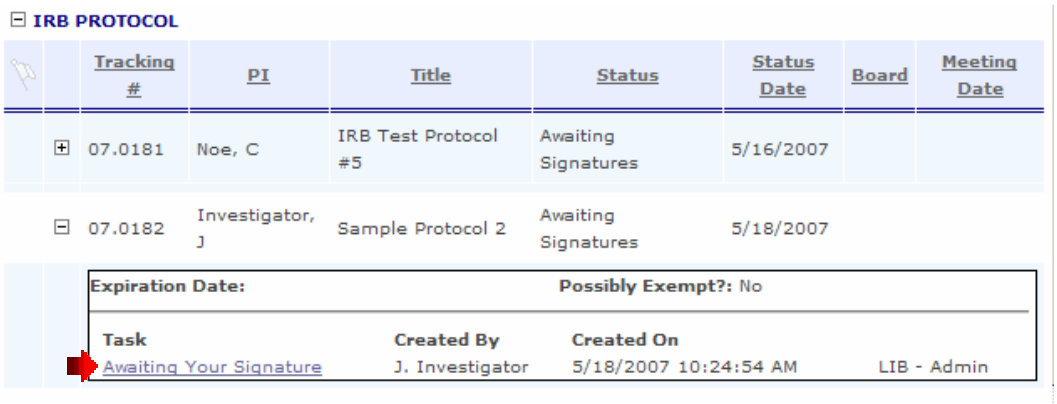
4. You will see a list of studies waiting for your signature.

Click on the plus sign next to the study you are planning to review.



5. A box will appear under the study you chose to review.

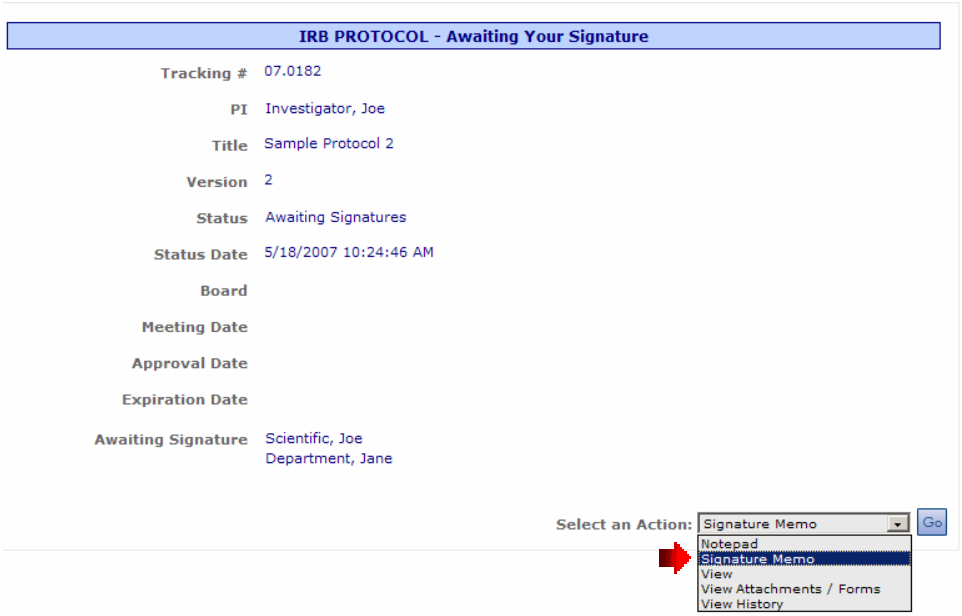
Click on the link [Awaiting your Signature.]



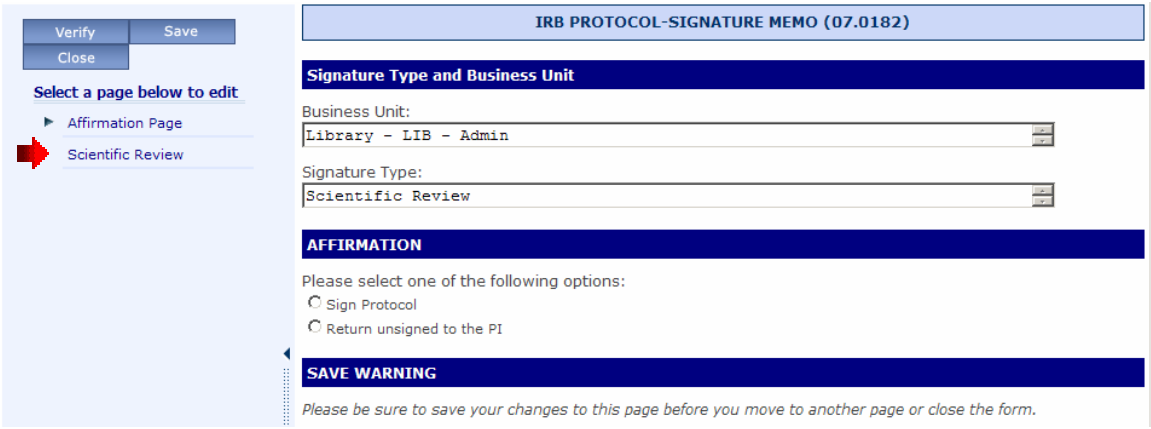
6. The study details screen will appear.

In the bottom right hand corner you will see a drop down box called: **Select an Action**

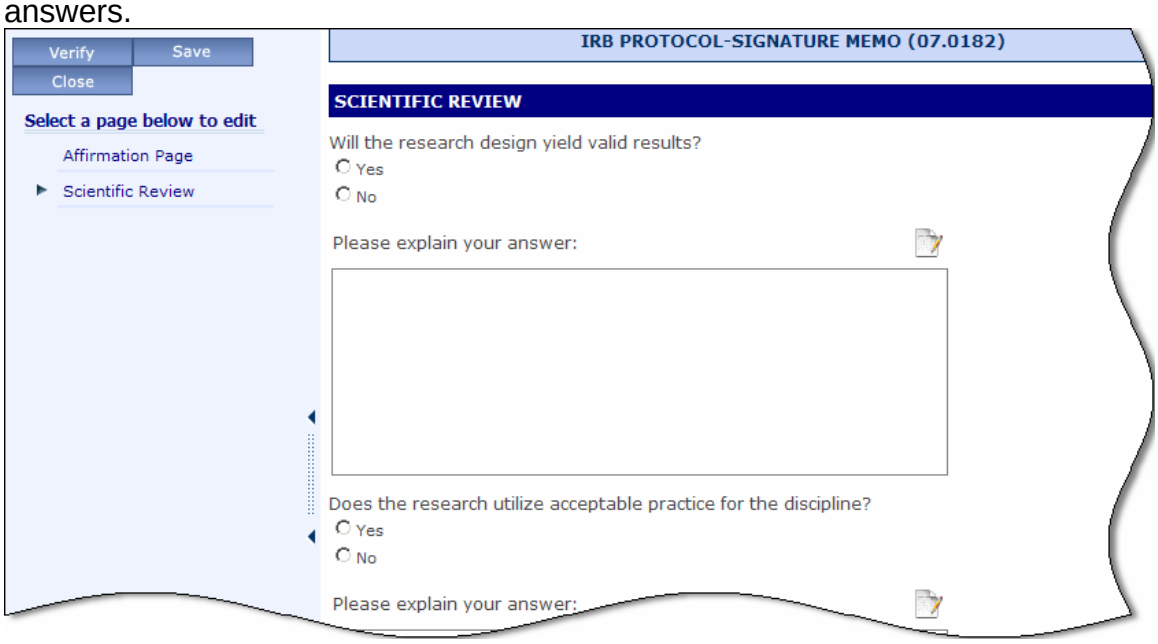
Click on the drop down box and select: **Signature Memo**



7. The signature memo will pop up. Click on the page Scientific Review.

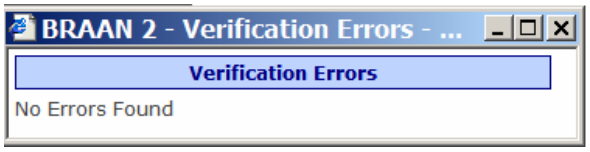


8. You will see an electronic version of the Scientific and Scholarly Merit Review Form. Please answer all three of the yes no questions and explain each of your answers.



9. When you have completed the form click on the **SAVE** button in the top left had corner of the screen and then click on the **VERIFY** button.

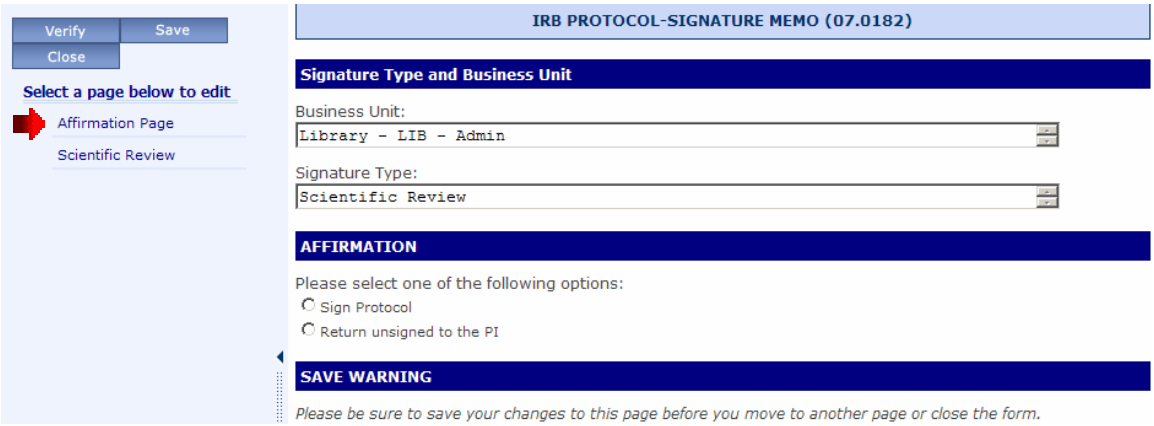
This box should pop up



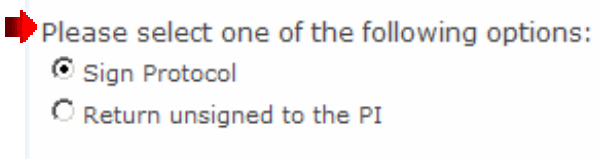
Click Save then click Close

(If the box says something other than “No Error Found”, please go back and complete the items that are listed in the box and then repeat #9)

10. Click on the Affirmation Page.



11. If you want to sign off on the protocol choose **Sign Protocol.**

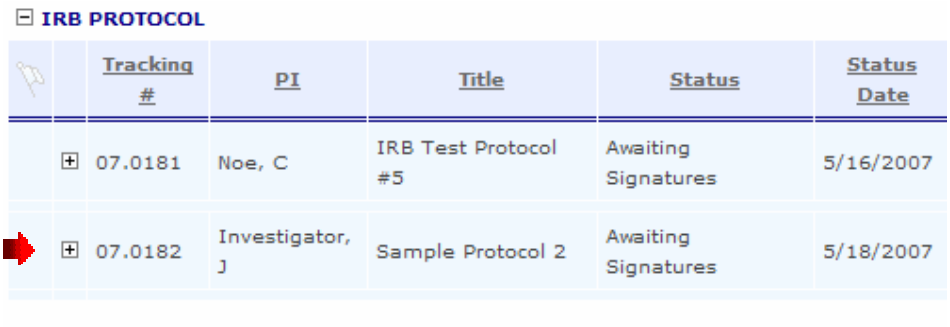


(If you want to send the protocol back to the PI choose **Return unsigned to PI)**

Click Save then click Close

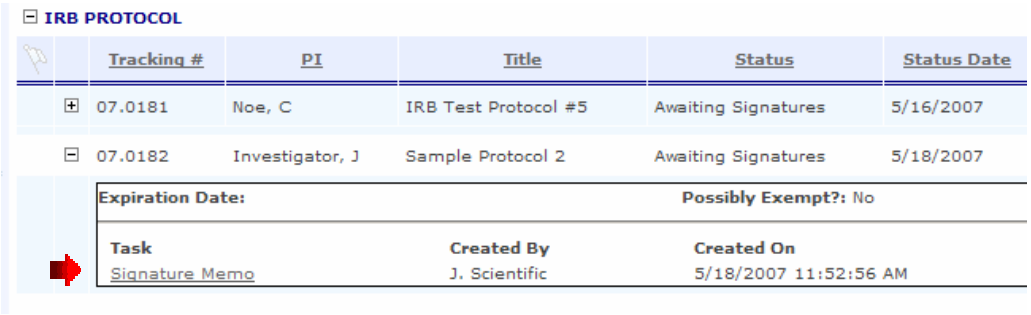
12. You will see the list of studies again.

Click on the plus sign next to the study you just reviewed.



13. A box will appear under the study you chose to review.

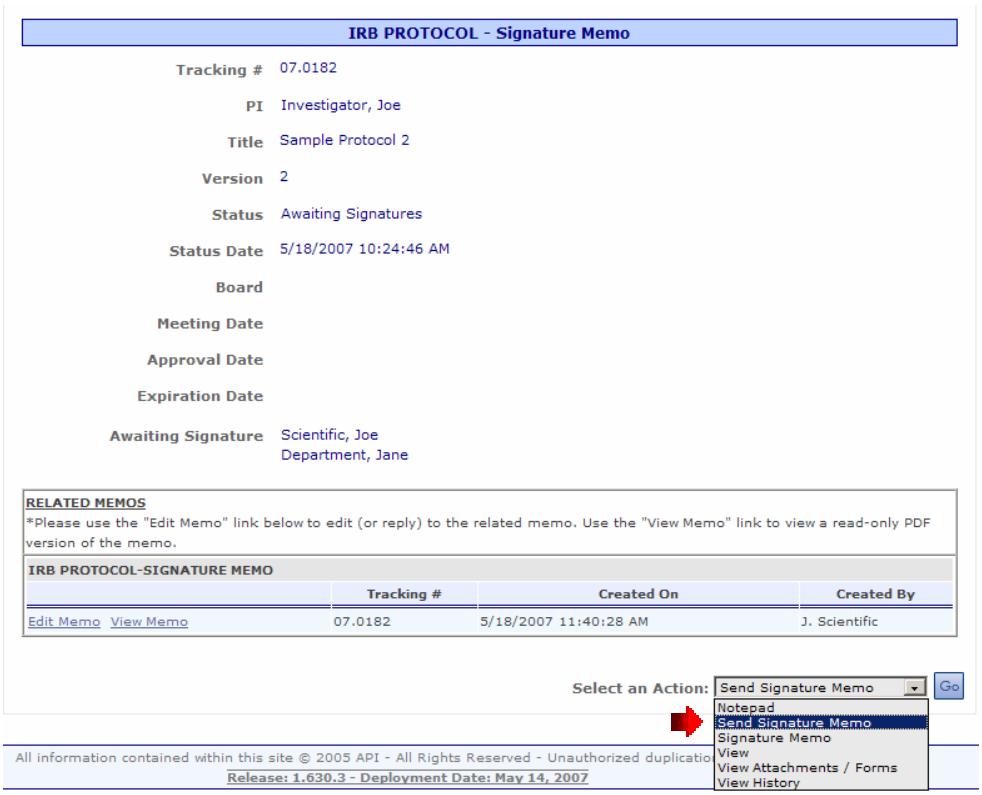
Click on the link Signature Memo.



14.. The study details screen will appear.

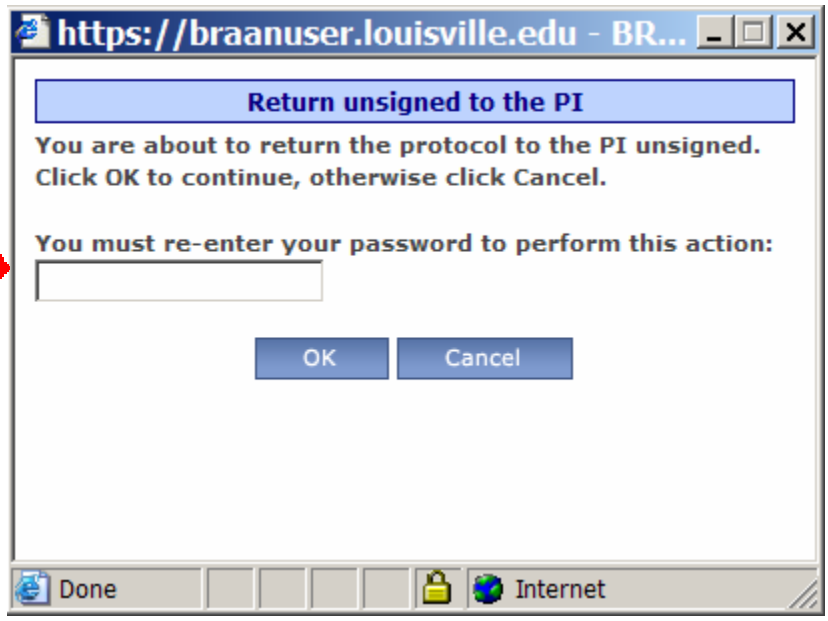
In the bottom right hand corner you will see a drop down box called: **Select an Action**

Click on the drop down box and select: **Send Signature Memo**

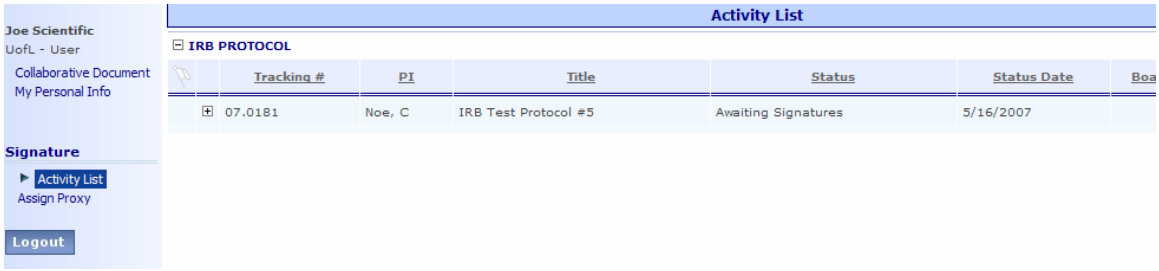


5. This box will popup.

Type in your password and click OK.



16. The protocol will now be gone from your activity list.



CHAPTER 8. DEPARTMENT SIGNATURE

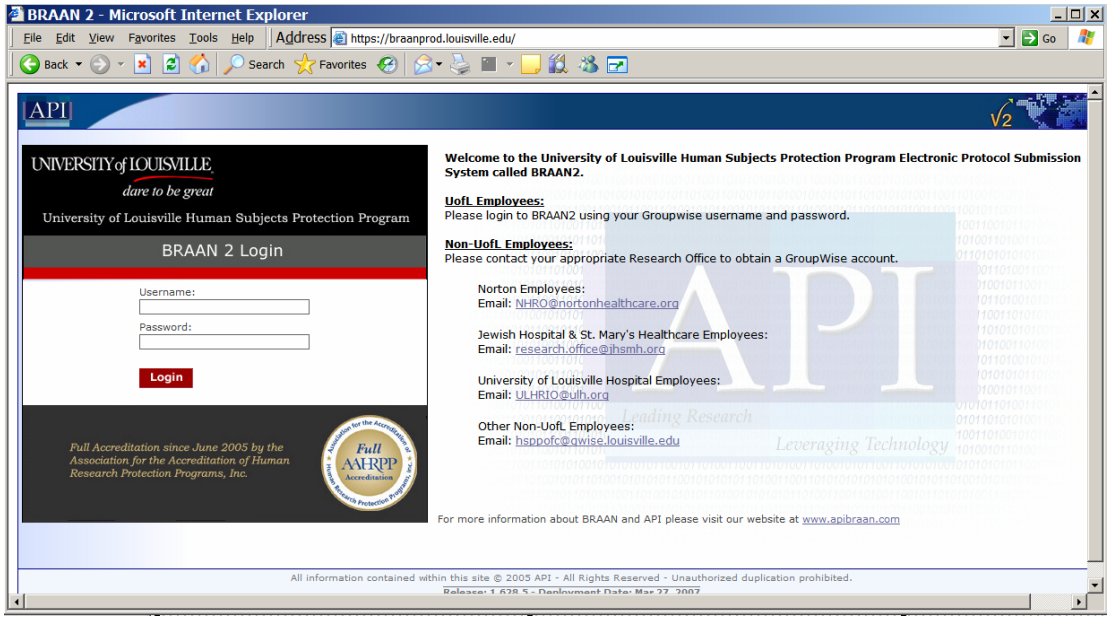
1. Go to the following website https://braanprod.louisville.edu

2. Login to BRAAN2:

Your username is your GroupWise address before the @ sign.

Example: if your email is jdepart01@louisville.edu, your username is jdepart01

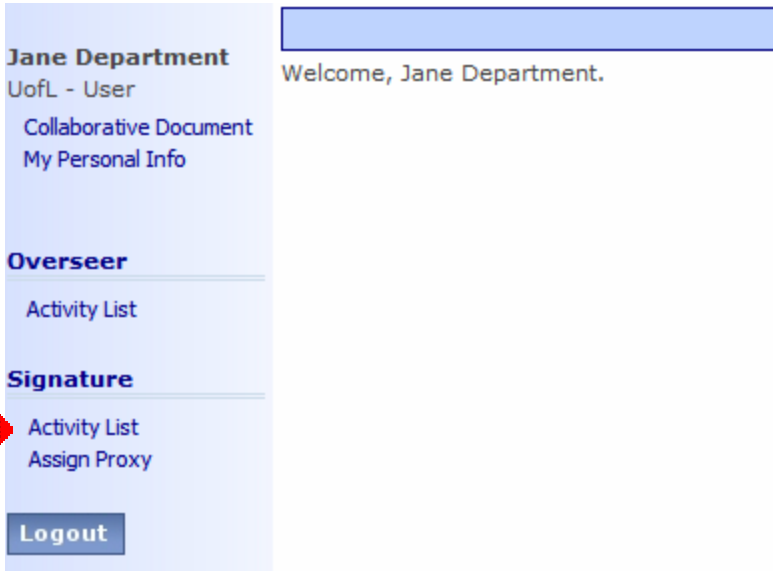
Your Password is your GroupWise password.



3. BRAAN2 will show you a welcome screen.

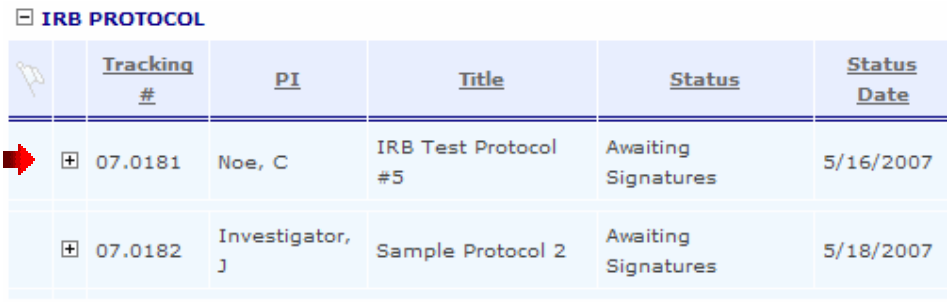
On the left-hand side of the screen is a list of links.

Please click on the **Activity List** under **Signature**.



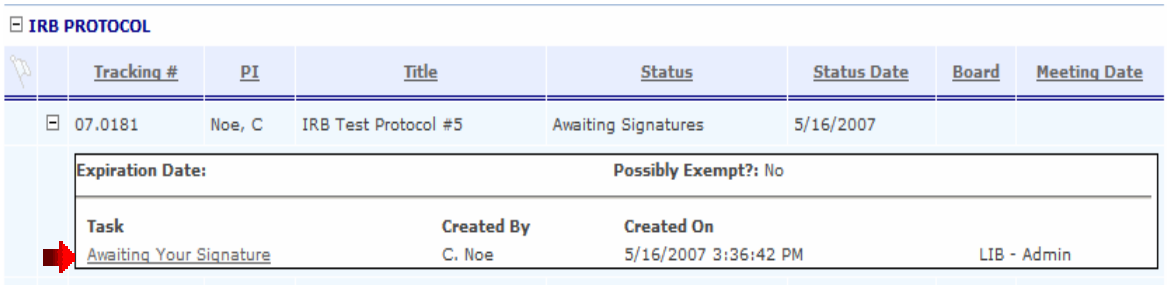
4. You will see a list of studies waiting for your signature.

Click on the plus sign next to the study you are planning to sign.



5. A box will open up under the study.

Click on the link Awaiting your Signature.

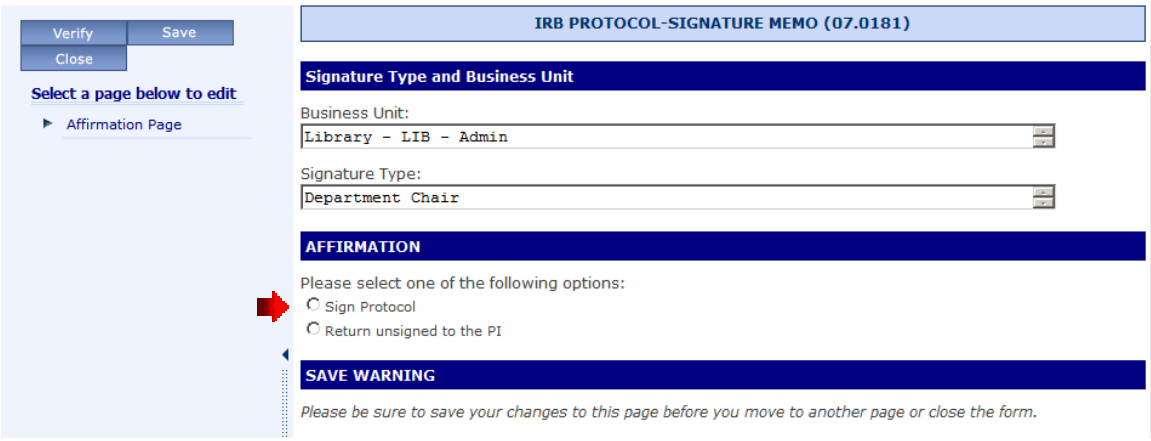


6. The study details screen will appear.

In the bottom right hand corner you will see a drop down box called: **Select an Action**

Click on the drop down box and select: **Signature Memo**

7. The signature memo will pop up and you will see the Affirmation Section.



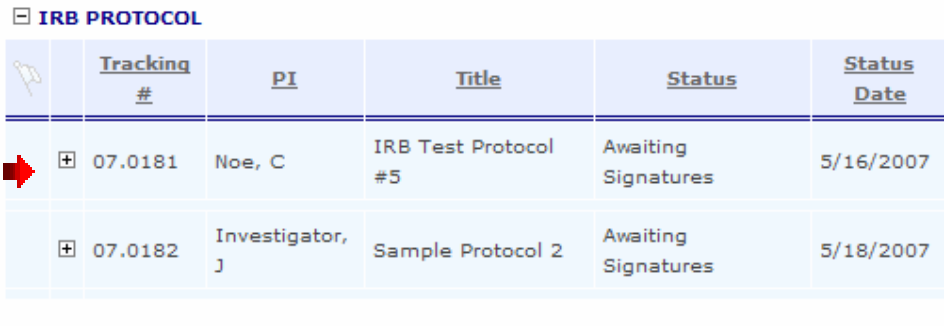
If you want to sign off on the protocol choose **Sign Protocol.**

(If you want to send the protocol back to the PI choose **Return unsigned to PI)**

Click Save then click Close

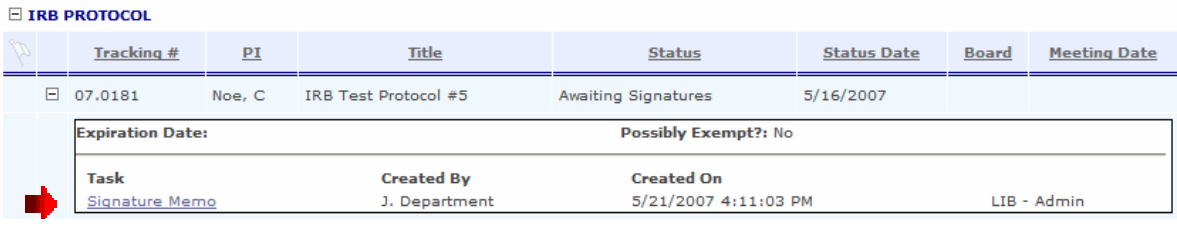
8. You will see the list of studies again.

Click on the plus sign next to the study you just signed.



9. A box will appear under the study.

Click on the link Signature Memo.



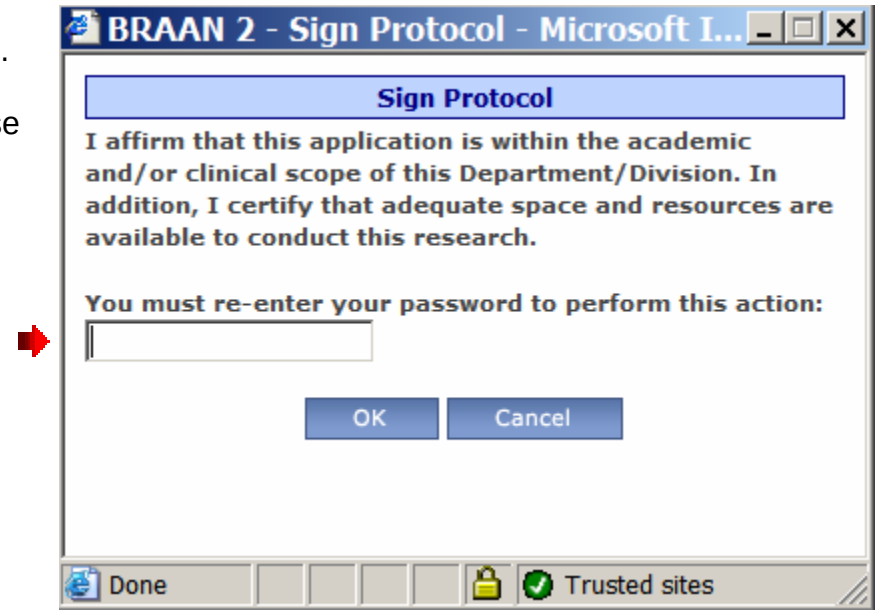
10. The study details screen will appear.

In the bottom right hand corner you will see a drop down box called: **Select an Action**

Click on the drop down box and select: **Send Signature Memo**

15. This box will popup.

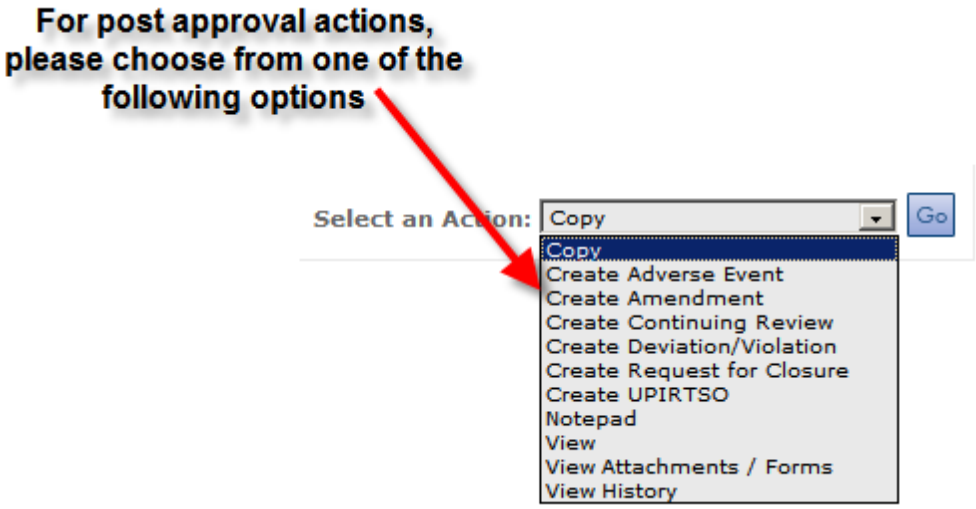
Type in your GroupWise password and click OK.



16. The protocol is signed and will be gone from your activity list.

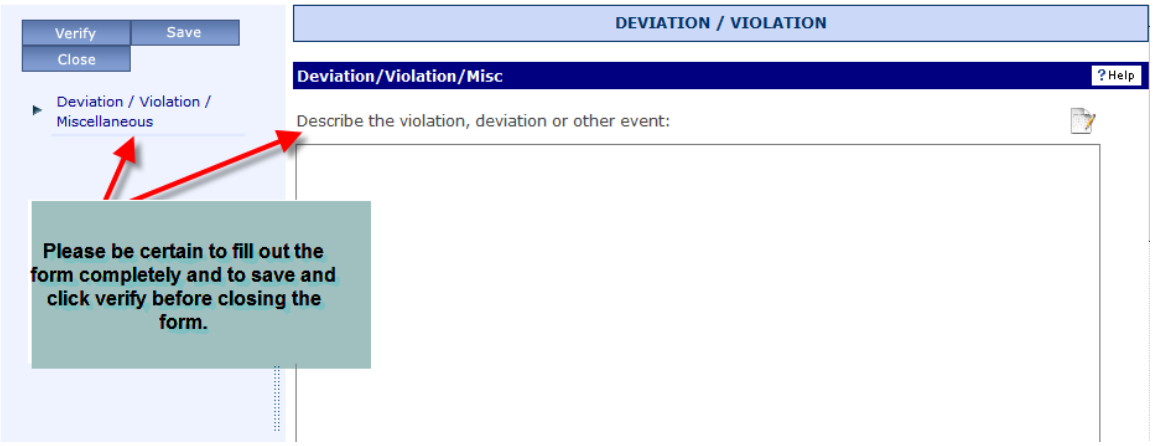
CHAPTER 9. CREATE POST APPROVAL DOCUMENTS

After a protocol has been approved there are some additional actions that can be taken by the PI or research team. See example below:



9.1 *Create Protocol Deviation/Violation*

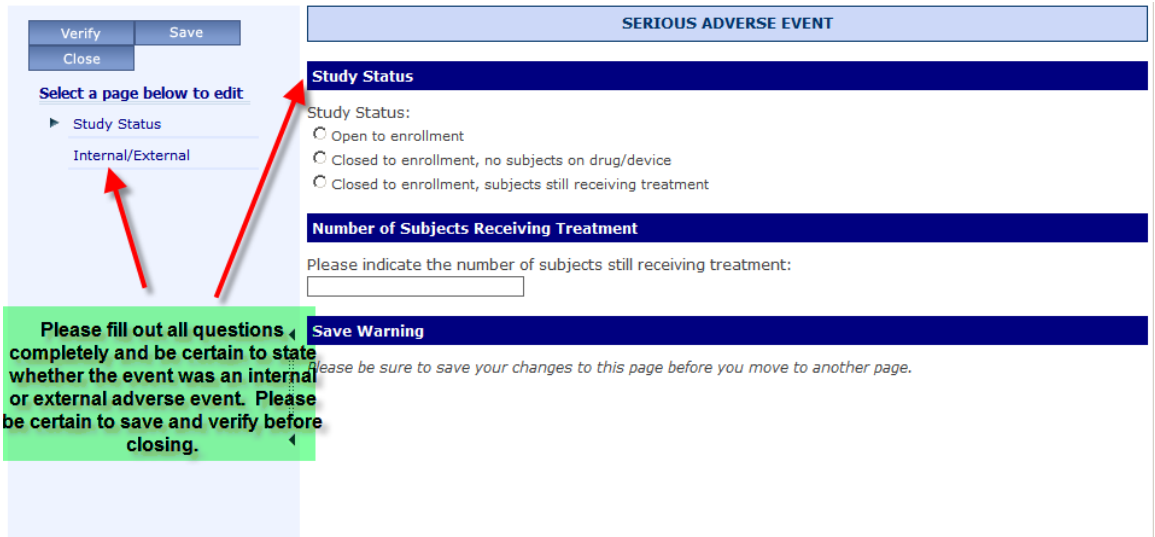
Log into BRAAN2 by using your GroupWise Username and password. In your activity list, please select the protocol for which you need to submit this report for. Click on the ⊞ sign next to the appropriate study and select "Details". Once in the details screen, please select "Create Deviation/Violation" from the drop down box and click Go. A subdocument will open up and will look like this:



Fill in the appropriate information and save the subdocument before closing. After you have saved and verified this subdocument, close this screen and return to your activity list. Click on the appropriate deviation/violation and select Details. In the details screen, select "Submit" from the Select an Action drop down box.

9.2 *Create Adverse Event Reports (SAE)*

Log into BRAAN2 by using your GroupWise Username and password. In your Activity List, please select the protocol that you wish to submit an adverse event for. Click on the ⊞ sign next to the appropriate study and select "Details". Once in the details screen, select "Create Adverse Event" from the drop down box and click Go.

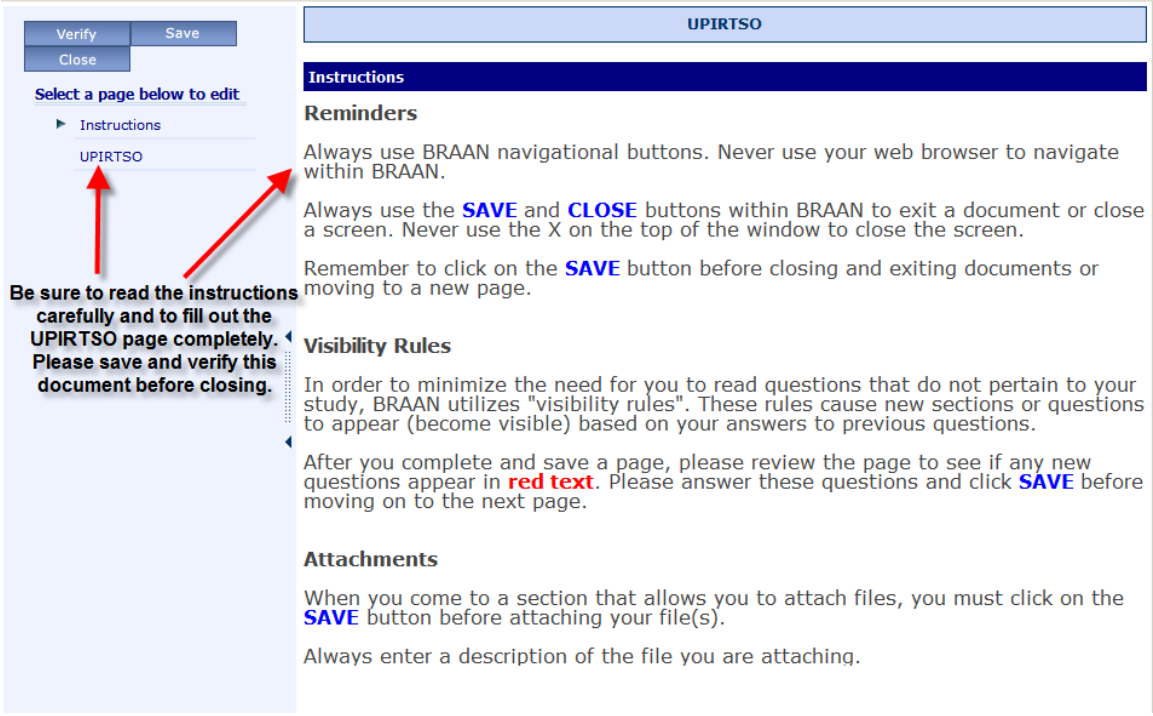


Fill out this subdocument completely and save and verify before closing. Return to your Activity List and select the Serious Adverse Event that you just created. Click on Details and select "Submit" from the Select an Action drop down box.

REMEMBER: There is no limit to the number of Adverse Events, Deviations/Violations, and/or UPIRTSOs can be submitted on any one protocol at a given time.

9.3 *Create UPIRTSO*

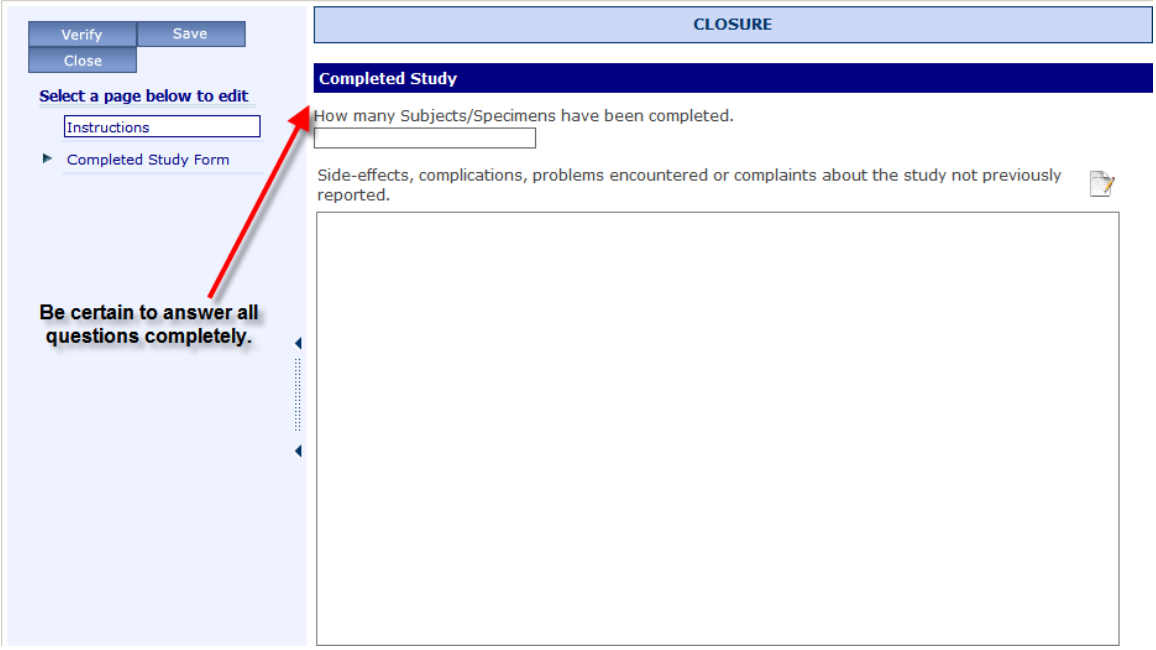
Log into BRAAN2 by using your GroupWise Username and password. In your Activity List, please select the protocol that you wish to submit an UPIRTSO for. Click on the ⊞ sign next to the appropriate study and select “Details”. Once in the details screen, select “Create UPIRTSO” from the drop down box and click Go.



Fill in the appropriate information and save the subdocument before closing. After you have saved and verified this subdocument, close this screen and return to your activity list. Click on the UPIRTSO that you just created and select Details. In the details screen, select “Submit” from the Select an Action drop down box.

9.4 *Create Request for Closure*

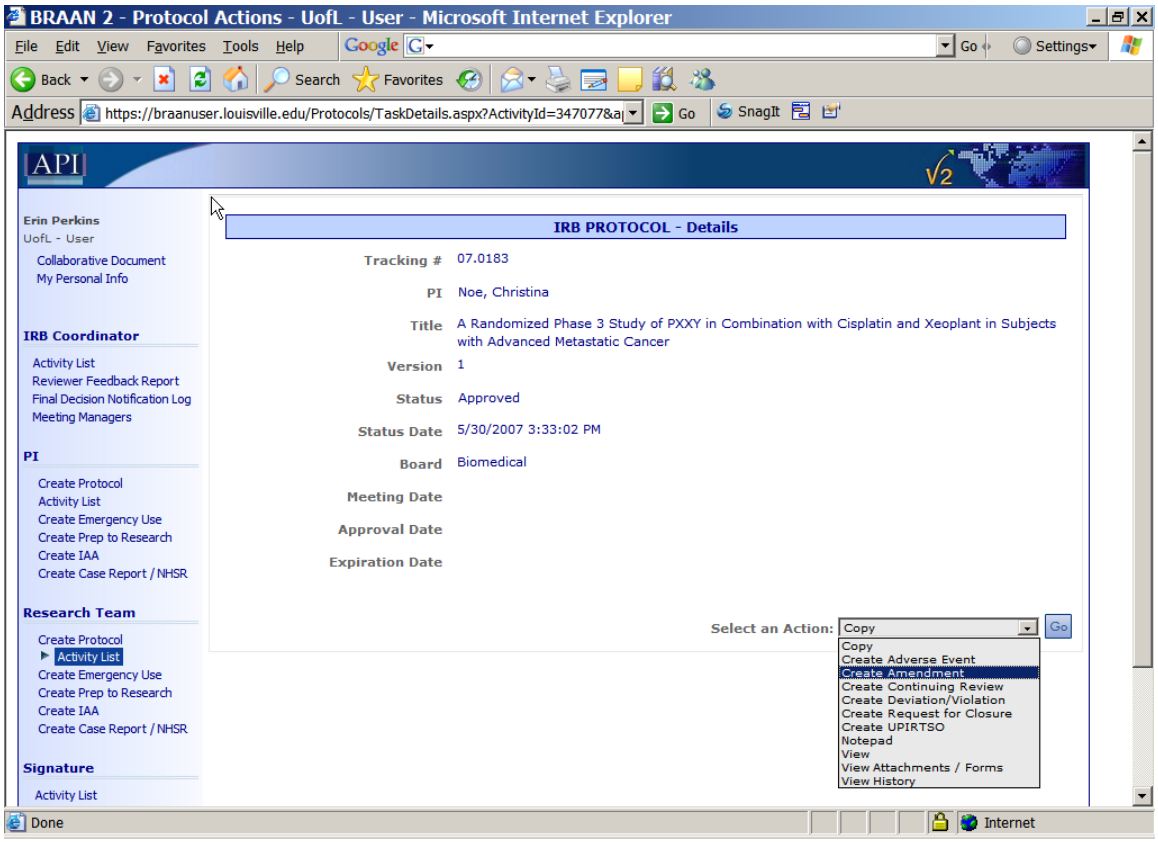
Log into BRAAN2 by using your GroupWise Username and password. In your Activity List, please select the protocol that you wish to close. Click on the ⊞ sign next to the appropriate study and select “Details”. Once in the details screen, select “Create Request for Closure” from the drop down box and click Go.



Fill in the appropriate information and save the subdocument before closing. After you have saved and verified this subdocument, close this screen and return to your activity list. Click on the Closure that you just created and select Details. In the details screen, select “Submit” from the Select an Action drop down box.

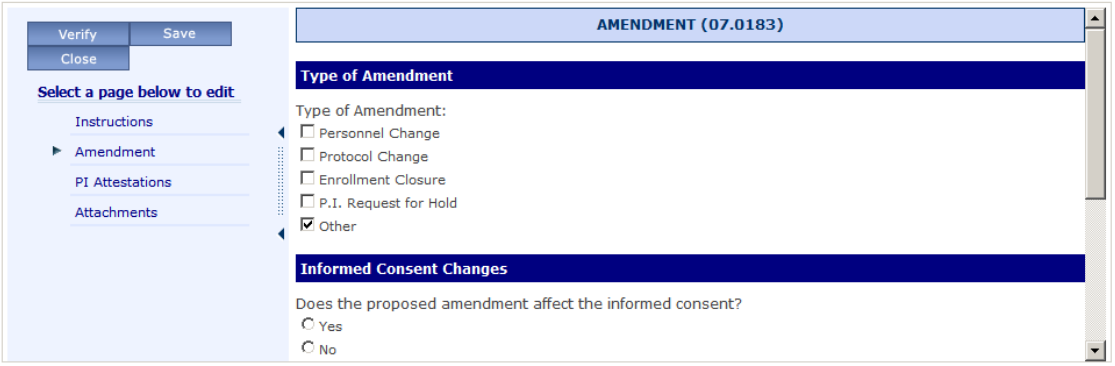
9.5 *Create Amendment*

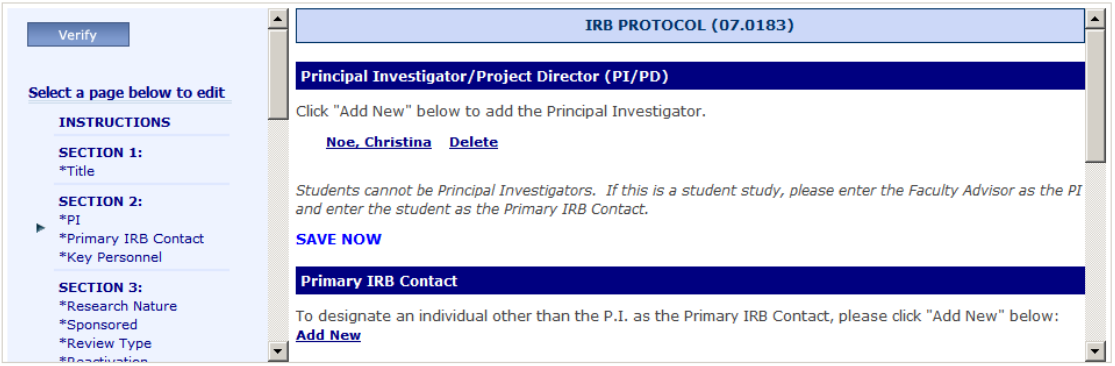
After an IRB Protocol has been approved, the PI and/or Research Team can choose to do an Amendment.



Enter the information in the applicable fields in the Amendment Form **and** make changes in the protocol. Save, Verify, and Close the window.

The amendment will appear in a split screen format for easier use. The top screen of the amendment is where you will describe your changes. The bottom screen will display your protocol, where you will make your changes. You will need to attach the amended protocol when prompted.



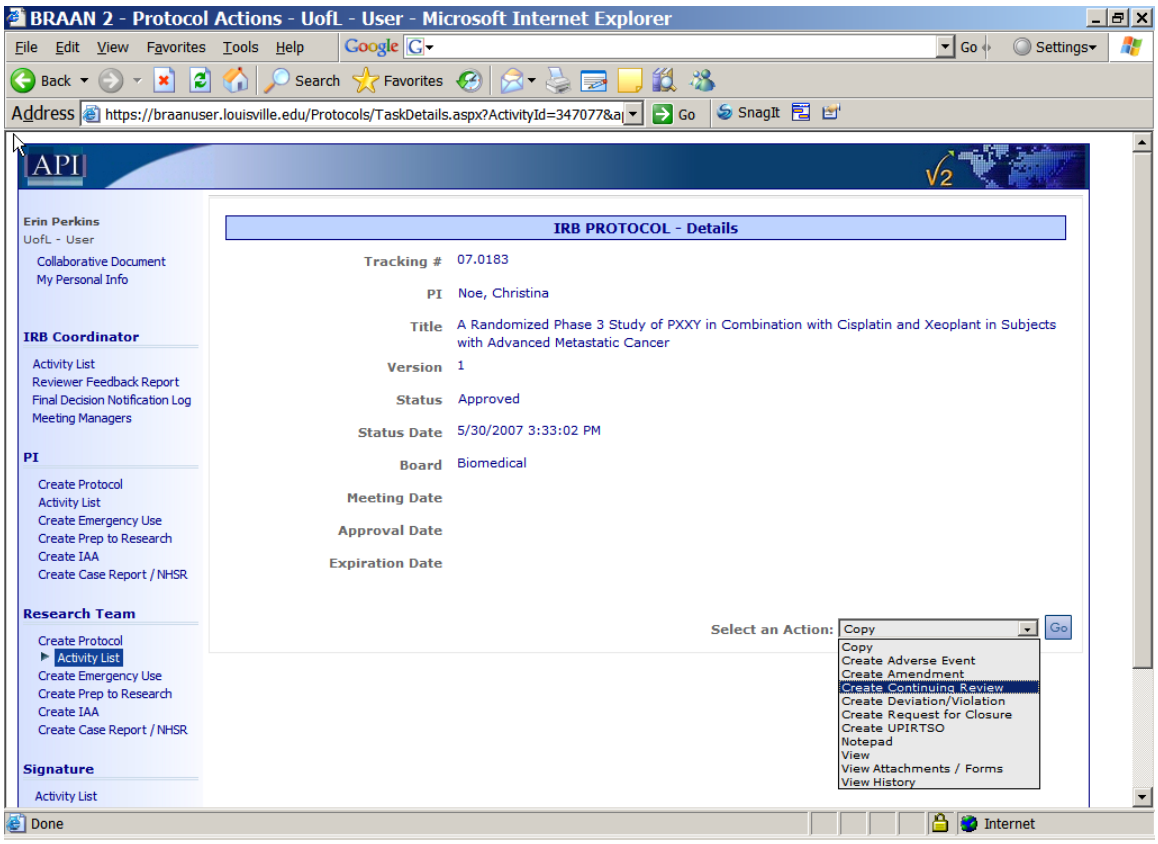


Amendments are submitted and routed for review like other documents:

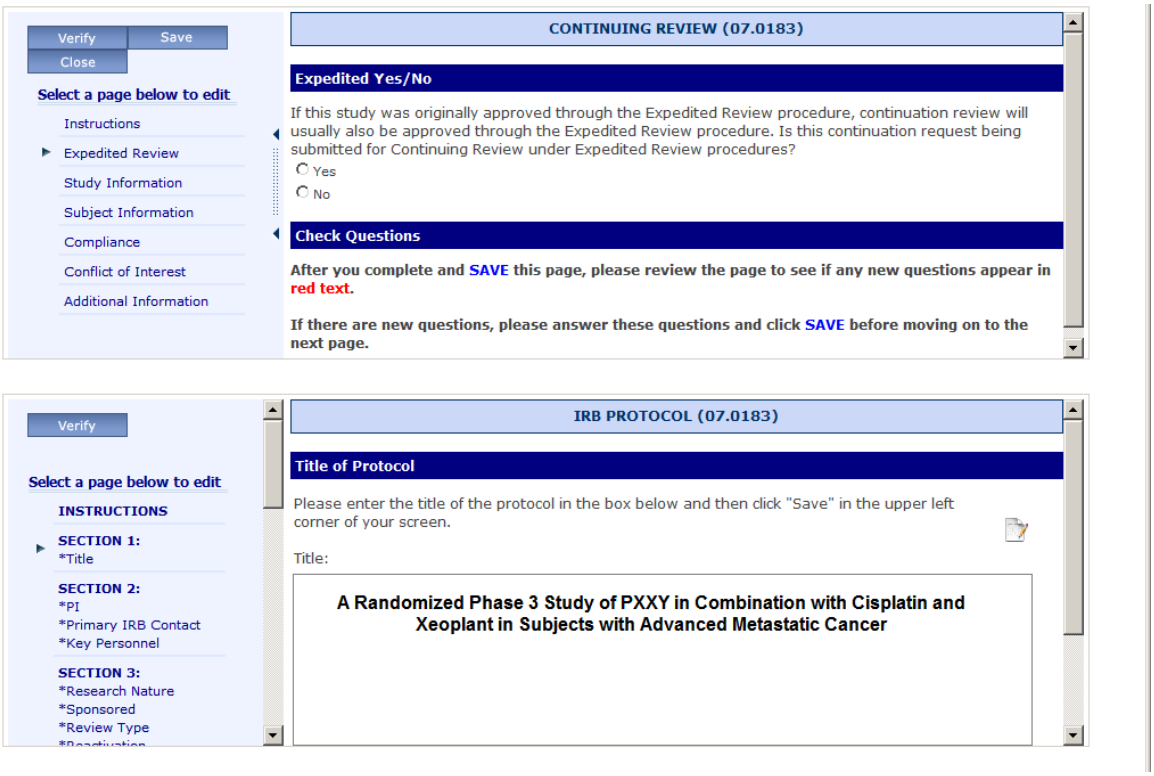
NOTE: ***Only*** users with the **PI** role can submit amendments in the BRAAN2 system.

9.6 *Create Continuing Review*

Log into BRAAN2 by using your GroupWise Username and password. Select "Create Continuing Review" from your activity list. Follow the instructions and fill in the required information. The continuation form will appear in a split screen format for easier use. Save and verify before closing.



The continuation review will appear in a split screen format for easier use. The top screen of the continuation review is the form where you will fill out your continuation information. The bottom screen will display your current protocol.



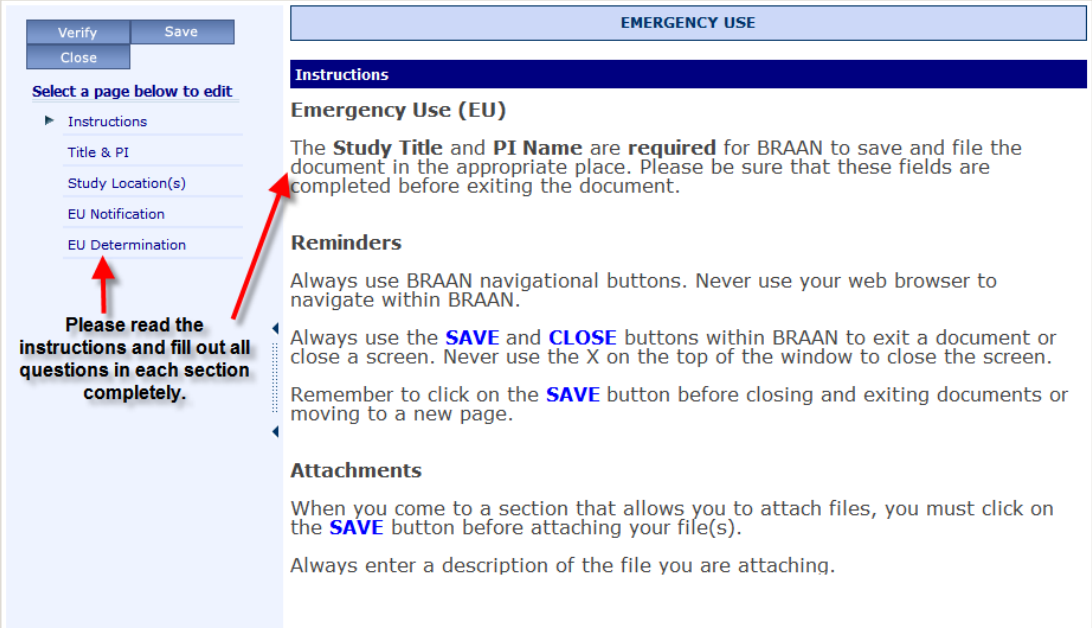
Continuation revews are submitted and routed for review like other documents. **NOTE**: ***Only*** users with the **PI** role can submit amendments in the BRAAN2 system.

APPENDIX A: CREATE EMERGENCY USE

The emergency use of an unapproved investigational drug or biologic requires an IND. If the intended subject does not meet the criteria of an existing study protocol, or if an approved study protocol does not exist, the usual procedure is to contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the company's IND.

The need for an investigational drug or biologic may arise in an emergency situation that does not allow time for submission of an IND. In such a case, FDA may authorize shipment of the test article in advance of the IND submission. Requests for such authorization may be made by telephone or other rapid communication means [21 CFR 312.36].

Log into BRAAN2 by using your GroupWise Username and password. Select "Create Emergency Use" from your activity list. Follow the instructions and fill in the required information. Save and verify before closing.

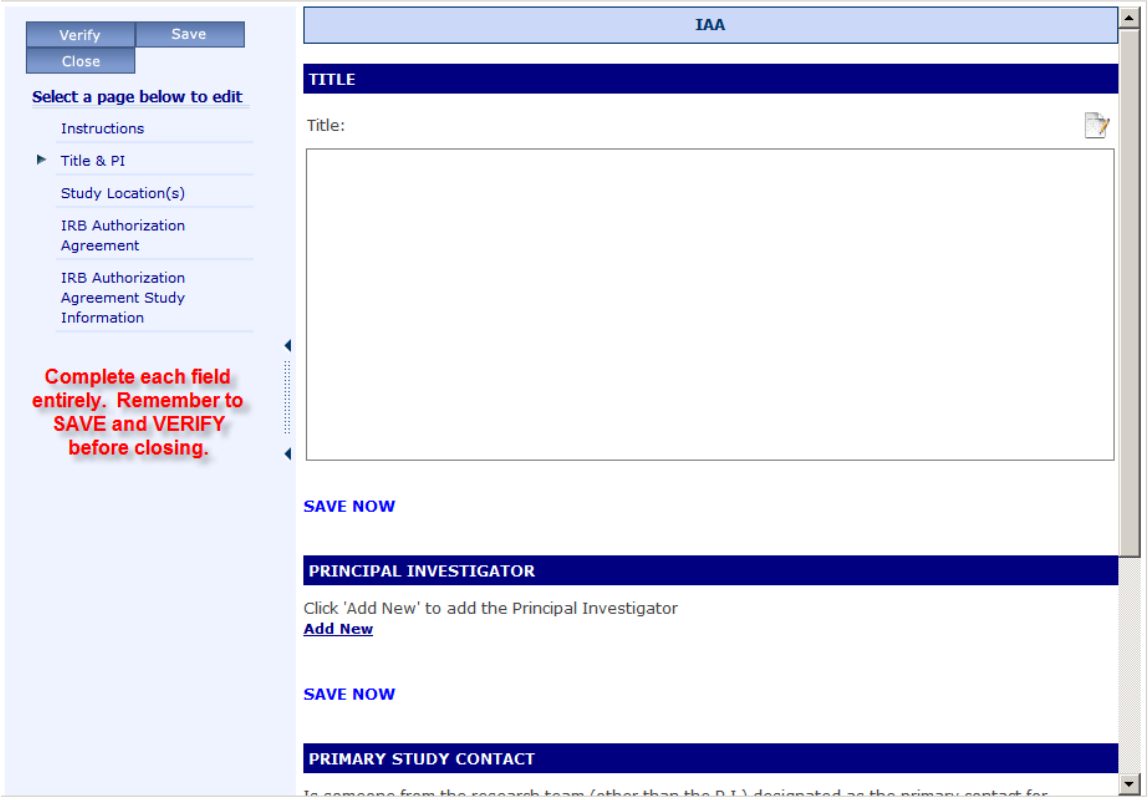


After you have saved and verified this subdocument, close this screen and return to your activity list. Click on the Emergency Use that you just created and select Details. In the details screen, select "Submit" from the Select an Action drop down box.

APPENDIX B: CREATE IRB AUTHORIZATION AGREEMENT (IAA)

Research activities conducted at performance sites that are not owned or operated by the University of Louisville, at sites that are geographically separate from UofL, or at sites that do not fall under the UofL IRB's authority are subject to special procedures for coordination of research review. Additional information is required.

Log into BRAAN2 by using your GroupWise Username and password. Select "Create IRB Authorization Agreement (IAA)" from your activity list. Follow the instructions and fill in the required information. Save and verify before closing.



APPENDIX C: CREATE CASE REPORT/NOT HUMAN SUBJECTS RESEARCH APPLICATION (NHSR)

This document contains two separate applications. One for Case Reports and one for Not Human Subjects Research applications. In the navigation menu, you will select either the case report or not human subjects research application.

Case Report
The University of Louisville Case Report Policy defines Case Reports as medical information collected and presented on three or fewer patients to highlight an interesting treatment, presentation or outcome.

Not Human Subjects Research (NHSR)
Federal regulations define research at 45 CFR 46.102(d) as follows: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The following are generally **NOT** considered human subjects research:
1. Class Projects
2. Program evaluation, quality improvement, needs assessment
3. Publicly available de-identified data sets

Log into BRAAN2 by using your GroupWise Username and password. Select "Create Case Report/NHSR" from your activity list. Follow the instructions and fill in the required information. Save and verify before closing.