



BRAAN2 Users Guide for Principal Investigators and Research Teams

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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.

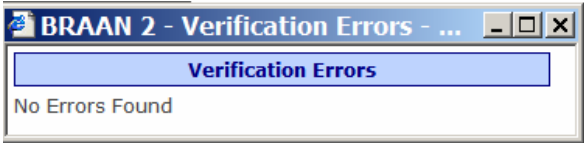
1.4 Verifying

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:



Page Name	Field Name	Error Message
Document	Multiple	SUBJECTS: Since you have indicated that you are not requesting a general certification, and this research is not eligible for NCI Central IRB review, you are required to complete the Subjects section.
Document	Multiple	SAMPLE SIZE: Since you have indicated that you are not requesting a general certification, and this research is not eligible for NCI Central IRB review, and you have selected at least one of the following design categories: Clinical Study, Survey/Questionnaire/Interview, Sample Collection Identifiable, and/or Case Reports/Series; you are required to complete the Sample Size / Data Analysis section.

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:

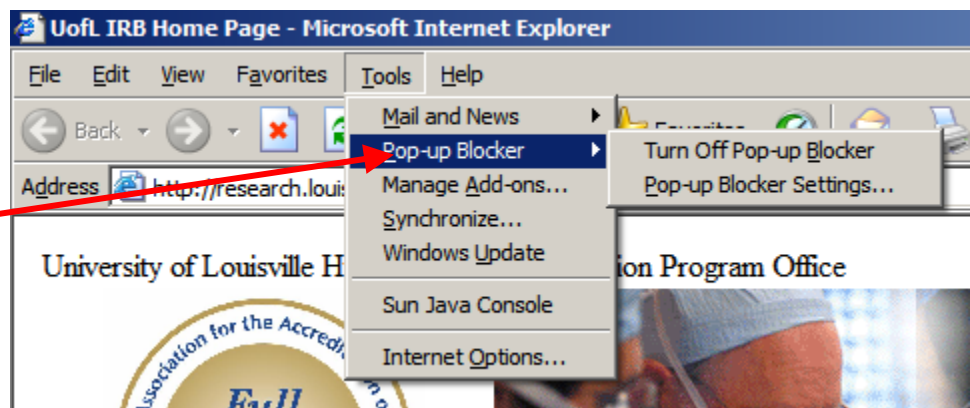
1. Click on this Icon on your desktop to open Internet Explorer.



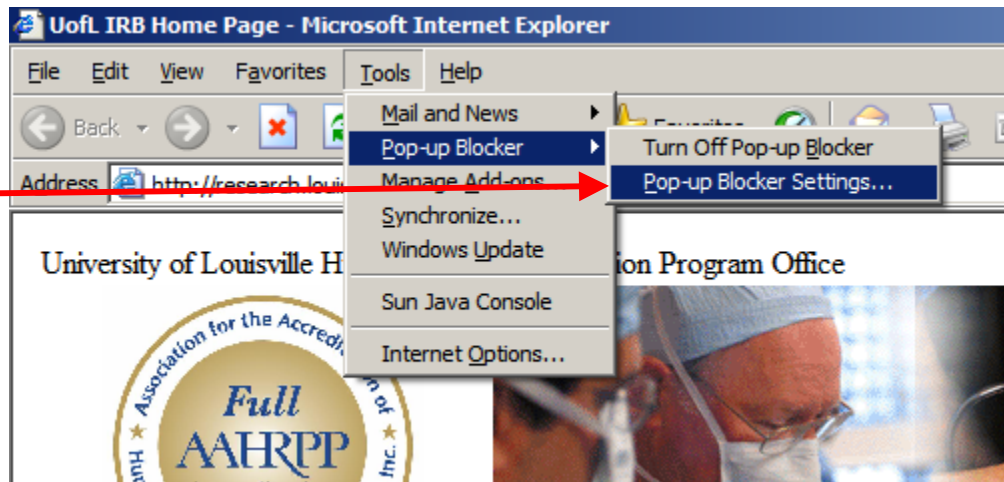
2. Click on Tools.



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



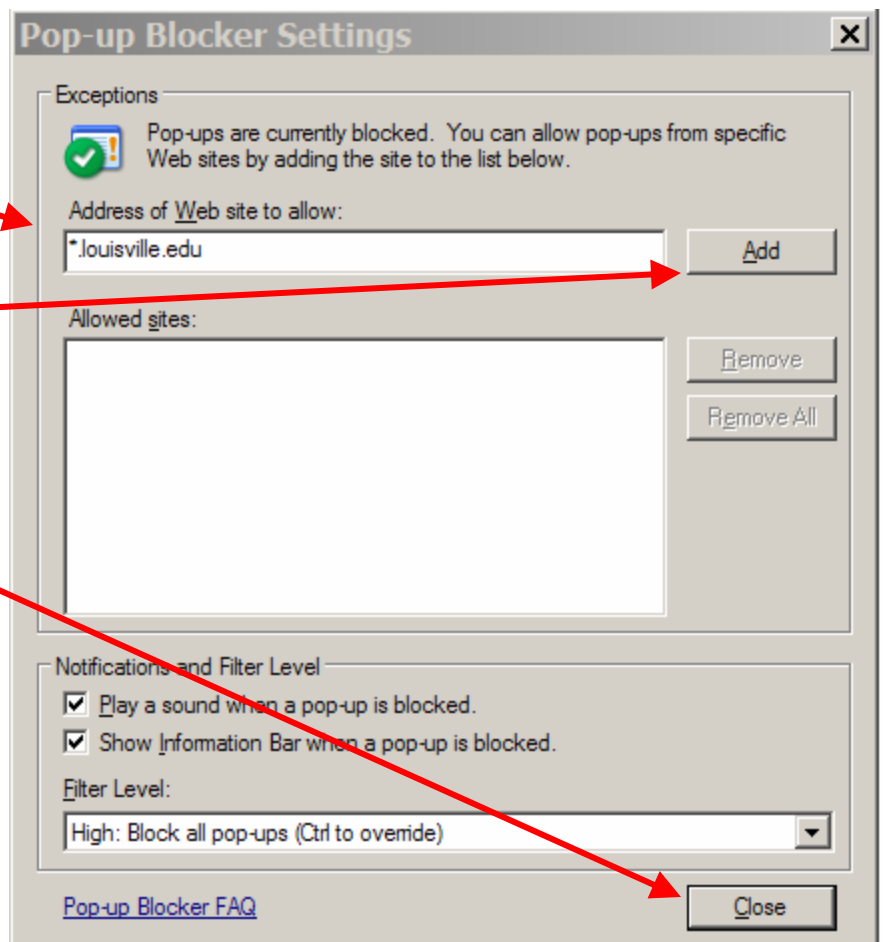
4. Click on
Pop-up Blocker Settings:



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 it 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:

The screenshot shows the BRAAN2 main screen. On the left is a navigation menu for user Erin Perkins (UofL - User). The menu includes links for 'Collaborative Document', 'My Personal Info', and 'Navigation Menu'. Under 'IRB Coordinator', there are links for 'Activity List', 'Reviewer Feedback Report', 'Final Decision Notification Log', and 'Meeting Managers'. Under 'PI', there are links for 'Create Protocol', 'Activity List', 'Create Emergency Use', 'Create Prep to Research', 'Create IAA', and 'Create Case Report / NHR'. Under 'Research Team', there are links for 'Create Protocol', 'Activity List', 'Create Emergency Use', 'Create Prep to Research', 'Create IAA', and 'Create Case Report / NHR'. A 'Logout' button is at the bottom left. The main content area has a header 'Activity List' with a 'Filter' button. Below this is a table of amendments. A red box highlights the 'AMENDMENT' section, and a red arrow points to the 'Task Details' link. Another red arrow points to the 'Filter' button. A third red arrow points to the 'Task List' link. Below the amendments table is a table of IRB protocols. A red box highlights the 'IRB PROTOCOL' section.

Activity List

AMENDMENT

Tracking #	Principal Investigator	Title	Status	Status Date	Board	Meeting Date
AMEND-23 (07.0162)	Perkins, E	Perkins Protocol 1	Tabled	4/10/2007	Biomedical	
AMEND-25 (07.0163)	Perkins, E	Perkins Protocol 2	Tabled	4/10/2007	Biomedical	

Expiration Date: Possibly Exempt?: No

Task Details Created By: E. Perkins Created On: 4/10/2007 2:11:16 PM

IRB PROTOCOL

Tracking #	PI	Title	Status	Status Date	Board	Meeting Date
07.0159	Perkins, E	Zelem - Biomedical Meeting Pro...	In Full Board Review	4/9/2007	Biomedical	4/10/2007
07.0160	Perkins, E	Perkins - Biomedical Meeting P...	In Full Board Review	4/3/2007	Biomedical	4/10/2007
07.0161	Perkins, E	Perkins - Behavioral	Submitted	4/4/2007	Social/Behavioral/Educational	4/5/2007

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

4.2 Navigation Menu

API

Erin Perkins
University of Louisville
Collaborative Document
My Personal Info

Welcome, Erin Perkins.

IRB Coordinator
Activity List
Reviewer Feedback Report
Final Decision Notification Log
Meeting Managers

PI ← **Role**
Create Protocol ← **Action**
Activity List
Create Emergency Use
Create Prep to Research
Create IAA
Create Case Report / NHSR

Research Team
Create Protocol
Activity List
Create Emergency Use
Create Prep to Research
Create IAA

Actions which can be performed by each **role** are displayed in the Navigation Menu on the left hand side of the BRAAN2 screen.

The actions available in the Navigation Menu depend on the role(s) assigned to the user.

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 and other work and the status of each.

Activity List

Filter

AMENDMENT-REQUEST FOR RETURN

Tracking #	PI	Title	Status	Status Date	Board	Meeting Date
RR-349 (AMEND-570 (H-2752))	Leonard, Michelle	ExemptChecklist 7 19 06 to	In Review	7/19/2006		


CLOSURE

Tracking #	PI	Title	Status	Status Date	Board	Meeting Date
CLOS-123 (H-2324)	Leonard, Michelle	closure 10	Submitted	6/3/2006	Board Blue	
CLOS-125 (H-2324)	Leonard, Michelle	closure 10	Submitted	6/3/2006	Board Blue	

Items requiring a user's attention are flagged in the Activity List on his/her screen.

4.4 Task List

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


Task List							
	Tracking #	PI	Title	Status	Status Date	Board	Meeting Date
	07.0155	Noe, C	Noe - Expedited Biomedical Pro...	Approved	4/3/2007	Biomedical	
Expiration Date: Possibly Exempt?: No							
Task Created By Created On							
Details M. Soefer 4/3/2007 2:32:55 PM							

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.

Activity List

 Filter


- In order to see documents in your Activity List, please click on the + icon next to "Filter" above. Select the filter criteria as applicable and then click the "Apply Filter" button at the bottom right of the filter section.



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 .


Activity List

 Filter

Principal Investigator:
Last: First:  

 Documents:

AMENDMENT
AMENDMENT-REQUEST FOR RETURN
CASE REPORT/NHSR
CASE REPORT/NHSR-REQUEST FOR RETURN
CLOSURE
CLOSURE-REQUEST FOR RETURN
CONTINUING REVIEW
CONTINUING REVIEW-REQUEST FOR RETURN
DEVIATION / VIOLATION
DEVIATION / VIOLATION-REQUEST FOR RETURN
EMERGENCY USE


 Status:

Acknowledged
Admin Mods Required
Approved
Awaiting Signatures
Board Mods Required
Closed by Research Team
Closed by System
Declined
Deferred
Disapproved
Exempt


Tracking Nbr:


Board:


All

Expiration Date (From):
 

Title:

Meeting Date:
 

Expiration Date (To):
 



- In order to see documents in your Activity List, please click on the + icon next to "Filter" above. Select the filter criteria as applicable and then click the "Apply Filter" button at the bottom right of the filter section.

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

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4.6 Select an Action

The screenshot shows a web interface titled "IRB PROTOCOL - Details". It contains a list of protocol attributes: Tracking # (None), PI (Adkins, Joe), Title (IRB Workflow Demo), Version (1), Status (New), Status Date (10/24/2006 7:24:11 AM), Board, Meeting Date, Approval Date, and Expiration Date. At the bottom right, there is a "Select Action" dropdown menu with a "Go" button. The dropdown menu is open, showing options: Change Owner, Copy, Delete, Edit, Submit (highlighted), View, View Attachments / Forms, and View History.

IRB PROTOCOL - Details	
Tracking #	None
PI	Adkins, Joe
Title	IRB Workflow Demo
Version	1
Status	New
Status Date	10/24/2006 7:24:11 AM
Board	
Meeting Date	
Approval Date	
Expiration Date	

Select Action: Change Owner Go

- Change Owner
- Copy
- Delete
- Edit
- Submit**
- View
- View Attachments / Forms
- View History

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:

BRAAN 2 - Microsoft Internet Explorer

File Edit View Favorites Tools Help Address <https://braanprod.louisville.edu/> Go

Back Forward Stop Reload Home Search Favorites

API *v2*

UNIVERSITY of LOUISVILLE
dare to be great
University of Louisville Human Subjects Protection Program

BRAAN 2 Login

Username:

Password:

Login

Full Accreditation since June 2005 by the Association for the Accreditation of Human Research Protection Programs, Inc.

API
Leading Research
Leveraging Technology

Welcome to the University of Louisville Human Subjects Protection Program Electronic Protocol Submission System called BRAAN2.

UofL Employees:
Please login to BRAAN2 using your Groupwise username and password.

Non-UofL Employees:
Please contact your appropriate Research Office to obtain a GroupWise account.

Norton Employees:
Email: NHRO@nortonhealthcare.org

Jewish Hospital & St. Mary's Healthcare Employees:
Email: research.office@jhsmdh.org

University of Louisville Hospital Employees:
Email: ULHRO@ulh.org


Other Non-UofL Employees:
Email: hspofc@qwise.louisville.edu

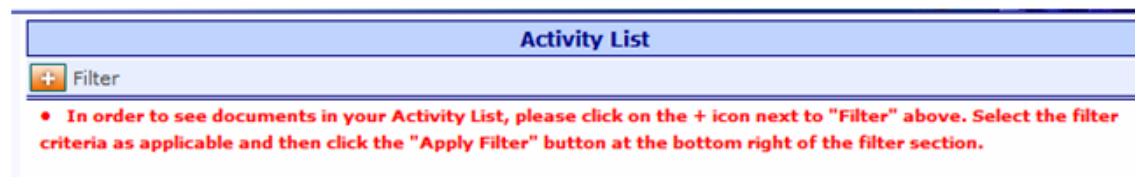
For more information about BRAAN and API please visit our website at www.apibraan.com

All information contained within this site © 2005 API - All Rights Reserved - Unauthorized duplication prohibited.
Release: 1 628 5 - Danlunment Date: Mar 27 2007

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

Activity List

Filter

Principal Investigator:

Last: First:

Documents:

- AMENDMENT
- AMENDMENT-REQUEST FOR RETURN
- CASE REPORT/NHSR
- CASE REPORT/NHSR-REQUEST FOR RETURN
- CLOSURE
- CLOSURE-REQUEST FOR RETURN
- CONTINUING REVIEW
- CONTINUING REVIEW-REQUEST FOR RETURN
- DEVIATION / VIOLATION
- DEVIATION / VIOLATION-REQUEST FOR RETURN
- EMERGENCY USE

Status:

- Acknowledged
- Awaiting Mods Required
- Approved
- Awaiting Signatures
- Board Mods Required
- Closed by Research Team
- Closed by System
- Declined
- Deferred
- Disapproved
- Exempt

Tracking Nbr:

Board:

Expiration Date (From):

Title:

Meeting Date:

Expiration Date (To):

• In order to see documents in your Activity List, please click on the + icon next to "Filter" above. Select the filter criteria as applicable and then click the "Apply Filter" button at the bottom right of the filter section.

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

PI

- Create Protocol
- Activity List
- Create Emergency Use
- Create Prep to Research
- Create IAA
- Create Case Report / NHSR

Research Team

- Create Protocol
- Activity List
- Create Emergency Use
- Create Prep to Research
- Create IAA
- Create Case Report / NHSR

If you are the PI, please select 'Create Protocol' from under the PI Role. If you are part of the Research Team, please select 'Create Protocol' from under the research team role

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

Verify Save
Close

Select a page below to edit

► INSTRUCTIONS

SECTION 1:
*Title

SECTION 2:
*PI
*Primary IRB Contact
*Key Personnel

SECTION 3:
*Research Nature
*Sponsored
*Review Type
*Reactivation

IRB PROTOCOL

Instructions

IRB Protocol

The **Study Title**, **PI Name**, and **IRB Contact Name** are **required** for BRAAN to save and file the Protocol in the appropriate place. Please be sure that these three fields are completed before exiting the document.

Reminders

Always use BRAAN navigational buttons. Never use your web browser to navigate within BRAAN.

Always use the **SAVE** and **CLOSE** buttons within BRAAN to exit a document or close a screen. Never use the X on the top of the window to close the screen.

Remember to click on the **SAVE** button before closing and exiting documents or moving to a new page.

Visibility Rules

In order to minimize the need for you to read questions that do not pertain to your study, BRAAN utilizes "visibility rules". These rules cause new sections or questions to appear (become visible) based on your answers to previous questions.

After you complete and save a page, please review the page to see if any new questions appear in **red text**. Please answer these questions and click **SAVE** before moving on to the next page.

Attachments

When you come to a section that allows you to attach files, you must click on the **SAVE** button before attaching your file(s).

Always enter a description of the file you are attaching.

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

5.1 Section 1 - Title

Verify Save
Close

Select a page below to edit

INSTRUCTIONS

► SECTION 1:
*Title

SECTION 2:
*PI
*Primary IRB Contact
*Key Personnel

SECTION 3:
*Research Nature
*Sponsored
*Review Type
*Reactivation

IRB PROTOCOL

Title of Protocol

Please enter the title of the protocol in the box below and then click "Save" in the upper left corner of your screen.

Title:

SAVE NOW

Save Warning

Please be sure to **SAVE** your changes to this page before you move to another page or close the document.

IMPORTANT!! YOU MUST SAVE AND VERIFY EACH PAGE BEFORE MOVING ON TO THE NEXT PAGE. ANY INFORMATION NOT SAVED BEFORE CLOSING THE PAGE WILL BE LOST!!

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.

Verify Save
Close

Select a page below to edit

INSTRUCTIONS

SECTION 1:
*Title

SECTION 2:
*PI
*Primary IRB Contact
*Key Personnel

SECTION 3:
*Research Nature
*Sponsored
*Review Type
*Reactivation

Principal Investigator/Project Director (PI/PD)

Click "Add New" below to add the Principal Investigator.
[Add New](#)

Students cannot be Principal Investigators. If this is a student study, please enter the Faculty Advisor as the PI and enter the student as the Primary IRB Contact.

SAVE NOW

Primary IRB Contact

To designate an individual other than the P.I. as the Primary IRB Contact, please click "Add New" below:
[Add New](#)

SAVE NOW

After selecting [Add New](#) , the following subdocument will appear:

Verify Save
Close

Principal Investigator/Project Director (PI/PD)

Principal Investigator

PI Name:
Enter last and first name and click 'Search'.
Last: First:

The phone, email and fax will populate from PeopleSoft. If the populated information is incorrect, please correct through **ULINK**.

Phone:

Email:

Fax:

Degrees:
MD
PhD
RN
MS

Department:
(Please Select only one. If you do not see your department in the list, please contact the HSPPO at 852-511)

- Education & Human Development
- Health and Sports Sciences
- Kent School of Social Work
- Brandeis School of Law
- Music
- Graduate School
- Dentistry
- School of Medicine
- Nursing
- Public Health & Information Sciences
- Library

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:

Principal Investigator

PI Name:
No Match Records Found

Email: User Name: **Import** **Cancel**

If the Principal Investigator's name does not automatically appear, you can search by the groupwise email address (ex. cmraym01) and click Import.

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.

Principal Investigator's CV

SAVE before adding attachment!

Please attach the Principal Investigator's CV

File to Attach: **Browse...**

Description:

Attach

Type in the description here

CURRENTLY ATTACHED FILES

	Filename	Version	Description
<input checked="" type="checkbox"/>	Soefer CV.doc	(5/21/2007 3:38:52 PM)	CV

If you see this box, the CV has been successfully attached.

To delete the uploaded CV, you should click on the red X

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.

Significant Financial Conflict of Interest (COI) ? Help

☐

Check the box below if either: COI has been managed or if COI does not exist.

For the definition of "managed" please click on the [\[?Help\]](#) button above.

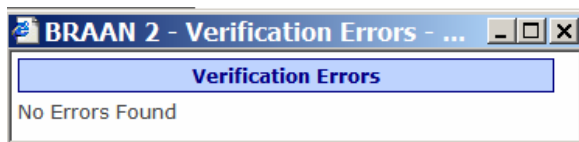
For the full University Conflict of Interest Policies please click on one of the following links.

[POLICY FOR OVERSIGHT OF INDIVIDUAL FINANCIAL INTERESTS IN RESEARCH](#)

[POLICY FOR OVERSIGHT OF INSTITUTIONAL FINANCIAL INTERESTS IN RESEARCH](#)

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.

Verify

Save

Close

Select a page below to edit

INSTRUCTIONS

SECTION 1:
*Title

SECTION 2:
*PI
*Primary IRB Contact
*Key Personnel

SECTION 3:
*Research Nature
*Sponsored
*Review Type
*Reactivation

Each of the questions to the right will need to be answered for section three. Depending on the answer you give, additional subdocuments will appear based upon the choices you made

IRB PROTOCOL

Nature of Research

What is the Primary Nature of the Research? Please select only one.
☒ Biomedical
☐ Social/Behavioral/Educational

Sponsor Yes/No

Is this a sponsored study?
☒ Yes
☐ No
This is a sponsored study. A new page titled ***Sponsor Info.** will appear when you click save.

Eligible for Expedited Review

Do you believe your study meets the regulatory requirements for Expedited review?
☐ Yes
☒ No

Eligible for Exemption

Do you believe your study meets the regulatory requirements for Exemption from IRB review?
☐ Yes
☒ No

Reactivation

Is this a re-activation of a pre-existing study?
☐ Yes
☒ No

Save Warning

5.4 Section 4 – Study Location(s)

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

Study Sites

Select all the locations where your research will be conducted. Select all locations where you will be gathering data (i.e, records, charts, case studies, etc.)

Select all that apply:

- ☒ U of L Belknap Campus
- ☒ U of L Health Sciences Center Campus
- ☒ Jewish Hospital & St. Mary's HealthCare (FWA 00002167)
- ☒ Norton Healthcare, Inc. (FWA 00002217)
 - ☐ Norton Hospital
 - ☐ Norton Healthcare Pavilion
 - ☐ Kosair Children's Hospital
 - ☐ Norton Audubon Hospital
 - ☐ Norton Hospital Inc - Louisville Oncology
 - ☐ Norton Suburban Hospital
 - ☐ Norton Southwest Hospital
 - ☐ Norton Physicians Practice
 - ☐ Physician Leased Space In Norton Facilities
- ☒ University Medical Center, Inc. (FWA 00002163)
- ☒ Department of Veterans Affairs Medical Center

Choose which study site you will use. Click the + sign to see the check-off box options.

If you study site is not listed, please click the "add new" button

If a study location is not listed above, please click "Add New" below to add other location. Please add as many as needed (including any clinics or satellite sites):

[Add New](#)

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:

The screenshot shows two sections of the BRAAN2 system. The first section, 'Type of Study', has a blue header with a '? Help' link. Below the header, it asks the user to 'Please check all that apply (at least one selection is required)'. There are seven checkboxes: 'Drug Study' (checked), 'Device Study', 'HDE study (Humanitarian Device Exception)', 'Specimen Study', 'Chart Review - Prospective', 'Chart Review - Retrospective', 'Observational Study', and 'Other'. To the right of these checkboxes is a callout box with the text: 'Go through section 5 and select the appropriate answers. Again, depending on your answers to these question, additional subdocuments may appear.' The second section, 'Tissue/Specimen Banking', also has a blue header with a '? Help' link. It asks 'Does this study involve tissue or specimen banking?' with two radio buttons: 'Yes' (selected) and 'No'. Below this, a light blue box contains the text: 'This study involves tissue or specimen banking. A new page titled *Biological/Tissue Samples and Storage will appear when you click save.'

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

ATTACHMENTS

Please attach Protocol and/or Grant Proposal (if both exist, both must be attached).

Please enter a description for each item. The item description you enter will print out on the approval letter **exactly** as you have written it.

File to Attach:

Description:

You may upload your protocol here. REMEMBER: you must still answer the protocol specific questions in section 5.

Please remember to include a description of what you have uploaded before you hit the "attach" button. Also, before leaving this area, please remember to "save."

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).

Billing Compliance/Resource Information

Protocol "procedures" are defined as all items, procedures, products, services, professional fees etc. required by the research protocol.

If there are **more than 5 procedures**, you may attach a table in the **misc. attachments** section instead of listing procedures here.

If there are **5 procedures or less** please list each protocol-required "procedure" that will be performed at the facility.

Click "Add New" to add each procedure.
[Add New](#)

The misc. attachments section is located on the left-hand side of the screen, at the bottom.

SECTION 11:
*Confidentiality

SECTION 12:
*Protected Health Information (PHI)

*HIPAA Form Builders

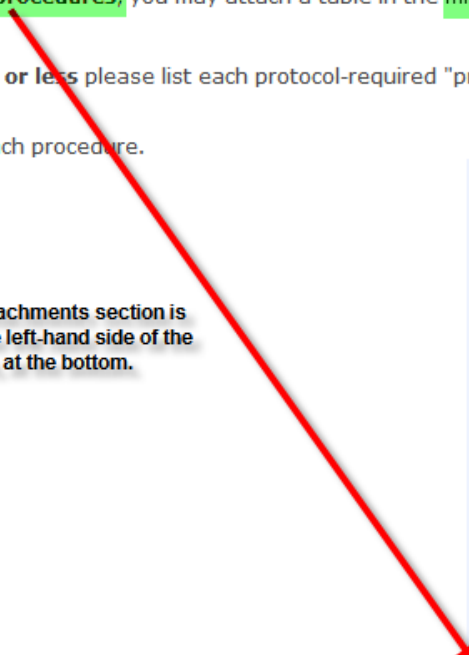
SECTION 13: *Informed Consent Process

*Consent Form Builders

SECTION 14:
*Scientific or Scholarly Merit Review

SECTION 15:
*P.I. Attestations

MISC. ATTACHMENTS



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 screenshot shows a web application interface. On the left is a vertical navigation menu with sections 4 through 12, each with a sub-item. Section 12, 'Protected Health Information (PHI)', is highlighted in red. Below it is a red arrow pointing to the 'HIPAA Form Builders' link. On the right, the main content area has a dark blue header 'HIPAA Documents'. Below this, there are three instructions, each followed by a blue 'Add New' link. A red arrow points from the 'Add New' link for the first instruction to the 'HIPAA Form Builders' link in the navigation menu. Below the instructions is another dark blue header 'Save Warning', followed by a text prompt. A red arrow points from the 'Save Warning' header to the 'HIPAA Form Builders' link in the navigation menu.

SECTION 4:
*Study Location(s)

SECTION 5:
*Study Information

SECTION 6:
*Subject Profile

SECTION 7:
*Subject Recruitment

SECTION 8:
*Subject Safety

SECTION 9:
*Compliance

SECTION 10:
*Billing Compliance

SECTION 11:
*Confidentiality

SECTION 12:
*Protected Health Information (PHI)

► ***HIPAA Form Builders**

HIPAA Documents

Click "Add New" below to add a new Research Authorization/Revocation.
[Add New](#)

Click "Add New" below to add a new Partial Waiver of Research Authorization
[Add New](#)

Click "Add New" below to add a new Complete Waiver of Research Authorization
[Add New](#)

Save Warning

Please be sure to **SAVE** your changes to this page before you move to another page or close the document.

When you are prompted to use the HIPAA Form Builder, you must choose which of the appropriate documents that you will need for your study.

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".

Verify Save
Close

► [Research Authorization](#)

Each form will have a series of questions to answer. Please fill out the form completely and accurately to include all necessary information about the use of protected health information for this study. For more information and detailed instructions, please click on the hyperlink.

Research Authorization

Enter a Title/Name for your research authorization form that characterizes it based on the treatment group, population recruited, etc., particularly if there are multiple authorization forms:

For more information and detailed instructions on creating a Research Authorization please click on the following link:

[Research Authorization/Revocation Instructions](#)

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.

Click "Add New" below to add a new Research Authorization/Revocation.

[Add New](#)

[Research Authorization/Revocation for Main Study](#) [View](#) [Delete](#)

Click **View** to preview your
HIPAA document, or click
Delete to delete it

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:

Under specific conditions, when justifiable, written documentation of informed consent can be waived. These limited conditions are described in 45 CFR 46.117. Do you believe this research qualifies according to the regulations, for **waiver of written documentation of informed consent**?

☒ Yes
☐ No

Under specific conditions, when justifiable, the requirement of informed consent can be waived. These limited conditions are described in 45 CFR 46.116(d). Do you believe this research qualifies according to the regulations, for a **waiver of informed consent**?

☒ Yes
☐ No

Request Waiver of Documentation of Signed Informed Consent

In some instances, the written consent of subjects increases the risk of exposure or embarrassment. The IRB may, in some specific instances, waive documentation of signed informed consent in accordance with 45 CFR 46.117(c).

46.117(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Provide protocol specific justification of your request for waiver of documentation of signed informed consent by choosing the one criteria that best fits your study.

If you believe your study qualifies for a waiver of informed consent or a waiver of written documentation of informed consent, you may check one of the options listed in section 13. A completed list of the regulations will appear to explain whether the study can qualify for the requested waiver

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.)

CONSENT FORM(S)

Is a consent form used in this research study?

- ☒ Yes
☐ No

If Yes, use the appropriate link(s) below to select the consent form template(s) needed. You may add as many consent forms as necessary for this protocol.

Key points to remember when filling out any of the consent forms below: Please be advised:

- Any text appearing in a text box will appear verbatim on the informed consent form.
- No headers will appear on the informed consent form for any optional fields left blank.

Click 'Add New' to add an Adult Biomedical Consent Form (AB)

[Add New](#)

Click 'Add New' to add a Surrogate Biomedical Consent form

[Add New](#)

Click 'Add New' to add a Parent Biomedical Consent form

[Add New](#)

Click 'Add New' to add a generic consent form

[Add New](#)

1 Select the appropriate consent or HIPAA form builder (aka template) by clicking the 'Add New' link.

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

The screenshot shows the 'GENERIC CONSENT FORM INFORMATION' form. It includes a sidebar with 'Verify', 'Save', and 'Close' buttons, and a 'Consent Form Builder - Generic' section. The main form area contains fields for 'Consent Form Name' (with a value of 'Survey Consent'), 'Please identify the name of the sponsor:', and a section for 'Background Information'. Three numbered callouts are present: 1. Points to the 'Add New' link for a generic consent form. 2. Points to the 'Survey Consent' text in the 'Consent Form Name' field. 3. Points to the 'Background Information' section.

2 Always enter a unique, descriptive title for the consent or HIPAA form to make it easy to identify within the protocol later:
Click 'Add New' to add a generic consent form
[Add New](#)
[Survey Consent](#) [View](#) [Delete](#)

3 Sometimes text from the protocol or default text will automatically be displayed in the consent or HIPAA form builder. These can always be edited.

Remember to [Save](#) and [Verify](#) your work before you [Close](#) the window.

- Consent forms

INFORMED CONSENT TO PARTICIPATE IN RESEARCH
Institution / 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 [locally/internationally, etc., as appropriate]. [indicate the number of subjects locally]

5.14 Section 14 – Scientific or Scholarly Merit Review

Scientific or Scholarly Merit Review

All protocols involving human subjects must undergo scientific or scholarly review by an internal departmental review committee, or alternately, the review process can be ceded to the funding agency to which the application is submitted. The purpose of the review, which must take place prior to submission to the Institutional Review Board (IRB), is to ensure that the approach is sound and the research design will yield valid results.

For more information please see the following links:

[Guidance for Conducting Scientific or Scholarly Merit Review](#)

[Scientific or Scholarly Merit Policy](#)

Has this review been ceded to an external funding agency? Please note: the review can only be ceded if Federally Funded or Non-profit Research (this includes the BCC CSRC).

☒ Yes

☐ No

If this study has been ceded to an external funding agency, you will need to attach the external scientific review.

External Review

Reviewing Official
External Funding Agency (Name of Organization)

SAVE before adding attachments!

Please attach a copy of the external scientific review.

File to Attach:

 Browse...

Description:

Attach

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 in procedures, any changes in study personnel, any 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:

The screenshot shows a web browser window with the address bar displaying <https://braanuser.louisville.edu> and the page title "BRAAN 2 - Verification Errors - Micro...". The page content is titled "Verification Errors" and contains a table with three columns: "Page Name", "Field Name", and "Error Message".

Page Name	Field Name	Error Message
SECTION 2:		
*PI *Primary IRB Contact *Key Personnel	Principal Investigator	Did not pass validation. Please edit and correct the problems.
SECTION 2:		
*PI *Primary IRB Contact *Key Personnel	Key Personnel	Did not pass validation. Please edit and correct the problems.
SECTION 7: *Subject Recruitment	Recruitment Process	ANSWER REQUIRED TO QUESTION: Please describe the process you will use to obtain informed consent of the subjects of the records. Include who will obtain informed consent (PI, sub-PI, coordinator - give general descriptions of the key personnel, not their given names), who will explain the consent to the subject and approximately how long the subject will have to review the consent and approximately how long the person explaining the consent to the subject will spend with the subject.
SECTION 7: *Subject Recruitment	Describe Subject Payment	ANSWER REQUIRED TO QUESTION: Please describe subject payment.
SECTION 7: *Subject Recruitment	Describe Subject Charges	ANSWER REQUIRED TO QUESTION: Please describe subject charges for research-related procedures.

At the bottom of the table, there are two buttons: "Close" and "Print".

A red callout box with the text "If your verification page shows that corrections to any section are needed, they will appear with a list of what is outstanding." is positioned at the bottom right, with two red arrows pointing to the error messages in the table.

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:

IRB PROTOCOL - Details

Tracking # None

PI Noe, Christina

Title Noe - Biomedical Meeting Protocol

Version 2

Status New

Status Date 4/2/2007 9:18:16 PM

Board

Meeting Date

Approval Date

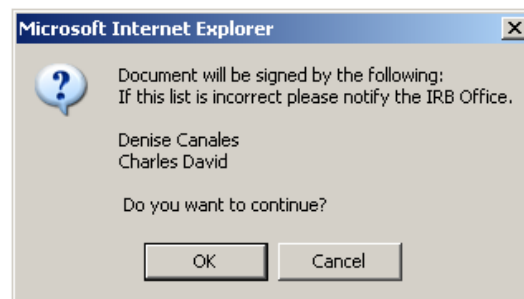
Expiration Date

Select an Action:

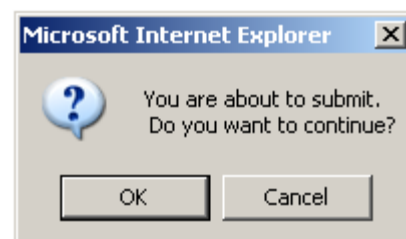
When you are ready to submit your protocol, you will need to return to the IRB Protocol-Details page (which BRAAN will default to when you hit the "close" key). You will need to click on the drop down box and choose "submit" for your protocol to move on to your chair for review and signatures.

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.

IRB PROTOCOL - Details

Tracking # H-3016
PI Kemperman, Loreene
Title IRB Protocol Workflow Demo
Version 2
Status Board Mods Required
Status Date 10/27/2006 2:04:43 PM
Board Board Blue
Meeting Date
Approval Date
Expiration Date

IRB PROTOCOL-BOARD MODIFICATIONS

Tracking #	Created On	Created By	Select Action
H-3016	10/27/2006 1:37:06 PM	L. Kemperman	Edit PDF

Select Action

- Change Owner
- Close
- Copy
- Edit
- Resubmit**
- View
- View Attachments / Forms
- View History

1 The PI and/or Research Team enter a response to any Mods Memo by clicking the [Edit](#) link to open the memo.

IRB PROTOCOL-BOARD MODIFICATIONS (H-3016)	
REASON	
Enter/edit reason(s) for board modification memo:	
<div> <div>SPELLING / GRAMMAR: Spelling & grammar changes</div> <div>NON-TEMPLATED MODIFICATIONS: There are a few additional things to change...</div> </div>	
If you have any questions, you may contact:	
<div>IRB Coordinator</div> <div>at:</div> <div>(123) 456-7890</div>	
IAA ONLY	
Enter the name(s) of the institution(s) with which the IAA is requested: "The Tufts-New England Medical Center/Tufts University Health Sciences IRB Executive Committee reviewed your request for an Institutional Review Board Authorization Agreement (IAA) with:	
FULL BOARD REVIEW ONLY	
Are there any non-directive issues in this board modification memo (i.e., do any issues/clarifications in this memo require greater than simple concurrence from the PI)?	
<input type="radio"/> Yes <input checked="" type="radio"/> No	
If No, the PI's resubmission may be reviewed expeditedly.	
RESPONSE	
Enter response to Board Modification letter:	
<div> <div>I have made the following changes to the protocol...</div> <div>The following are no longer issues...</div> </div>	

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, , , and 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 user 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>

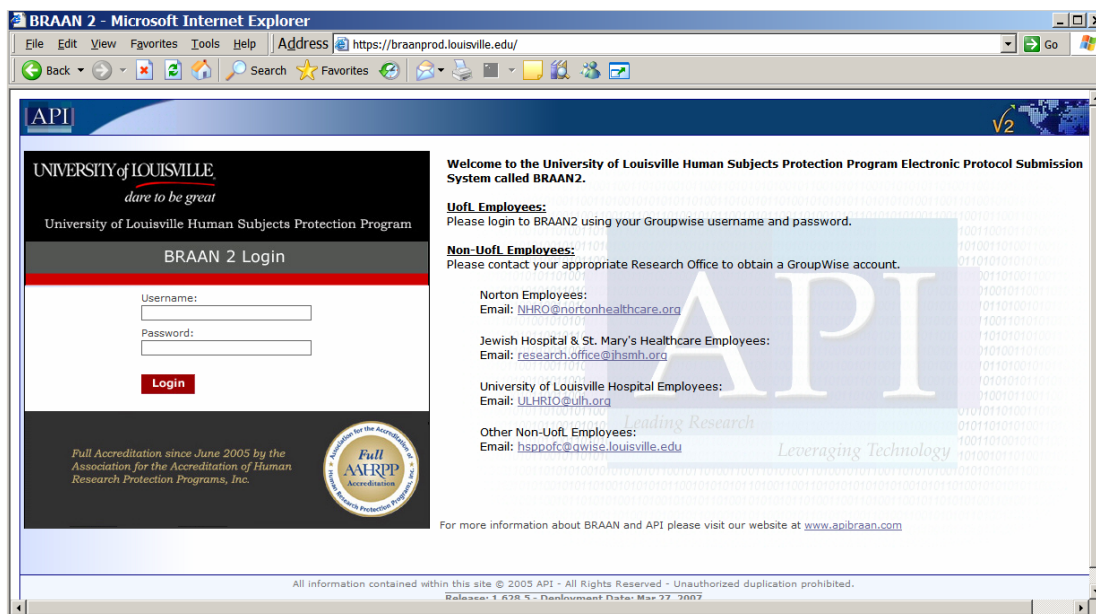
2. Login to BRAAN2:

Your username is your GroupWise address before the @ sign.

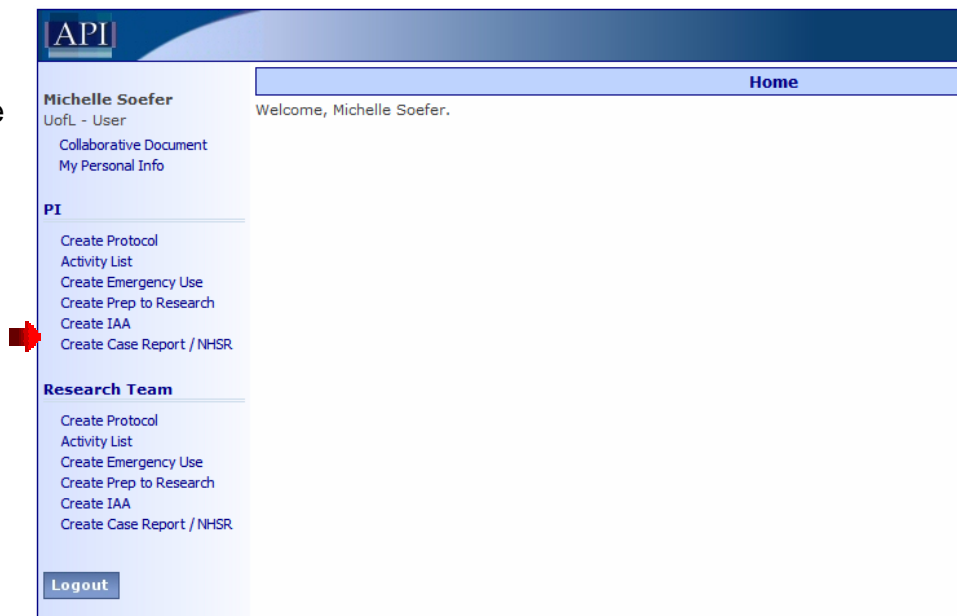
Example:

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

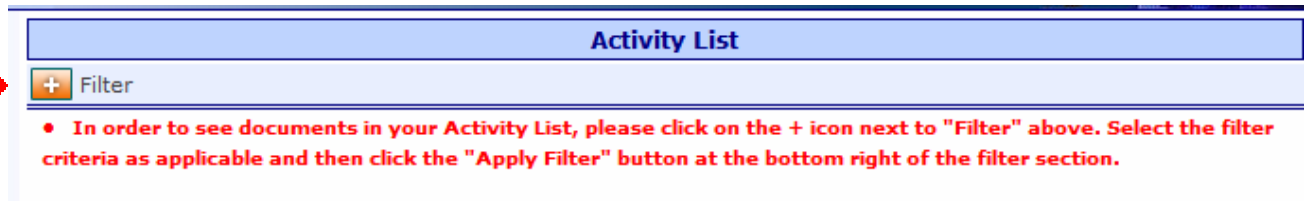
Your Password is your GroupWise password.




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.



Activity List

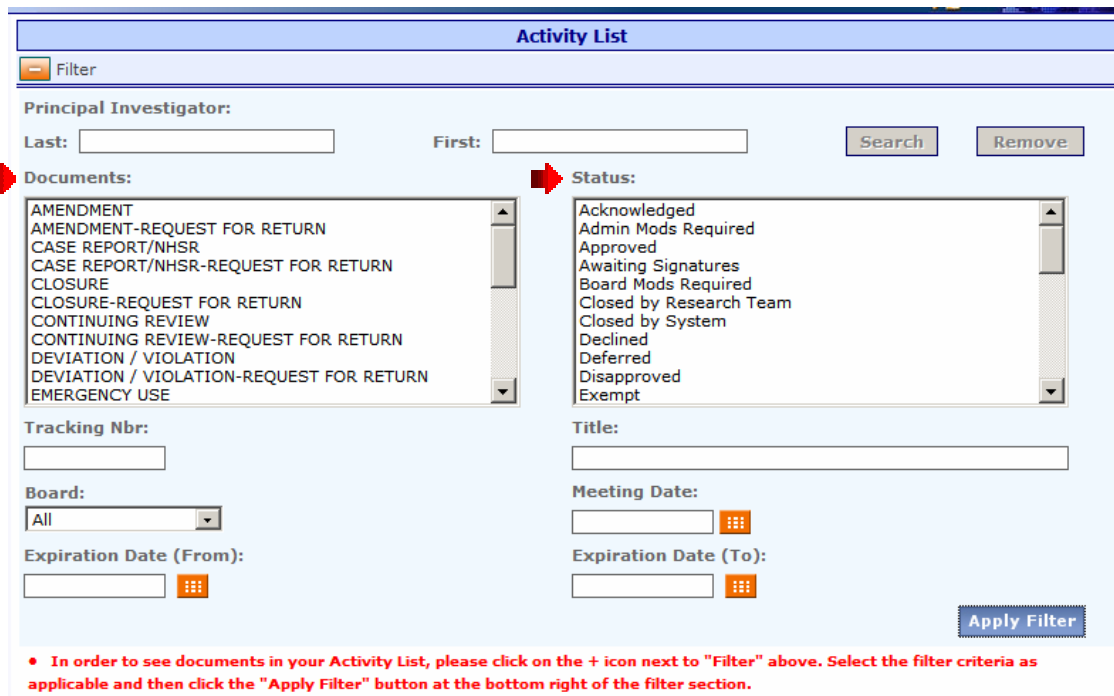
 Filter

• In order to see documents in your Activity List, please click on the + icon next to "Filter" above. Select the filter criteria as applicable and then click the "Apply Filter" button at the bottom right of the filter section.


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 .



Activity List

 Filter

Principal Investigator:
Last: First:  


 Documents:  Status:

AMENDMENT
AMENDMENT-REQUEST FOR RETURN
CASE REPORT/NHSR
CASE REPORT/NHSR-REQUEST FOR RETURN
CLOSURE
CLOSURE-REQUEST FOR RETURN
CONTINUING REVIEW
CONTINUING REVIEW-REQUEST FOR RETURN
DEVIATION / VIOLATION
DEVIATION / VIOLATION-REQUEST FOR RETURN
EMERGENCY USE


Acknowledged
Admin Mods Required
Approved
Awaiting Signatures
Board Mods Required
Closed by Research Team
Closed by System
Declined
Deferred
Disapproved
Exempt


Tracking Nbr:


Board:

Expiration Date (From): 

Title:

Meeting Date: 



Expiration Date (To): 



• In order to see documents in your Activity List, please click on the + icon next to "Filter" above. Select the filter criteria as applicable and then click the "Apply Filter" button at the bottom right of the filter section.

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.

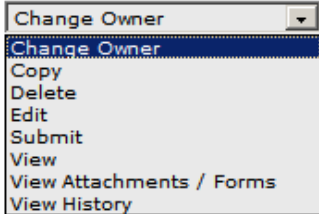

IRB PROTOCOL					
	Tracking #	Principal Investigator	Title	Status	Status Date
	None	Investigator, J	Sample Protocol 1	New	4/30/2007
	None	Investigator, J	Sample Protocol 2	New	4/30/2007
	None	Investigator, J	Sample Protocol 3	New	4/30/2007

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

IRB PROTOCOL - Details	
Tracking #	None
PI	Investigator, Joe
Title	Sample Protocol 2
Version	1
Status	New
Status Date	4/30/2007 12:11:42 PM

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

- Select Edit
- Press 

Select an Action:  

Change Owner

- Change Owner
- Copy
- Delete
- Edit
- Submit
- View
- View Attachments / Forms
- View History

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

IRB PROTOCOL	
Instructions	
IRB Protocol	
The Study Title , PI Name , and IRB Contact Name are required for BRAAN to save and file the Protocol in the appropriate place. Please be sure that these three fields are completed before exiting the document.	
Reminders	
Always use BRAAN navigational buttons. Never use your web browser to navigate within BRAAN.	
Always use the SAVE and CLOSE buttons within BRAAN to exit a document or close a screen. Never use the X on the top of the window to close the screen.	
Remember to click on the SAVE button before closing and exiting documents or moving to a new	

Verify Save

Close

Select a page below to edit

INSTRUCTIONS

SECTION 1:
*Title

 SECTION 2:
*PI
*Primary IRB Contact
*Key Personnel

SECTION 3:
*Research Nature
*Sponsored
*Review Type
*Reactivation

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.

Other Investigators and Key Personnel

List all co-investigators, sub-investigators and any subjects in this study.

***Definition of key personnel** (as included in the Inve: **Participants in a research team who contribute in development or execution of a project.**

Please use the "Add New" link to add as many k

Click "Add New" below to add key personnel.

[Add New](#)

 [Soefer, Michelle](#) [Delete](#)

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

Significant Financial Conflict of Interest (COI)

Check the box below if either: COI has been managed or if COI does not exist.



- 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.

Other Investigators and Key Personnel

List all co-investigators, sub-investigators and key per: any subjects in this study.

***Definition of key personnel** (as included in the Inve: **Participants in a research team who contribute in development or execution of a project.**

Please use the "Add New" link to add as many key pers

Click "Add New" below to add key personnel.

[Add New](#)

 [Soefer, Michelle](#) [Delete](#)

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!

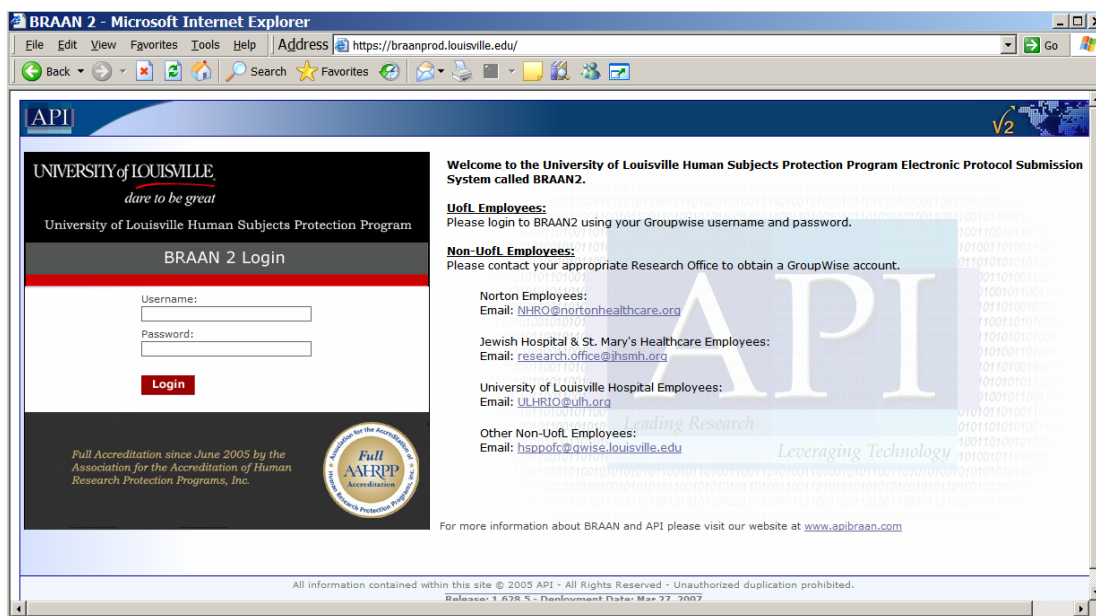
CHAPTER 7. COMPLETING THE SCIENTIFIC OR SCHOLARLY MERIT REVIEW

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

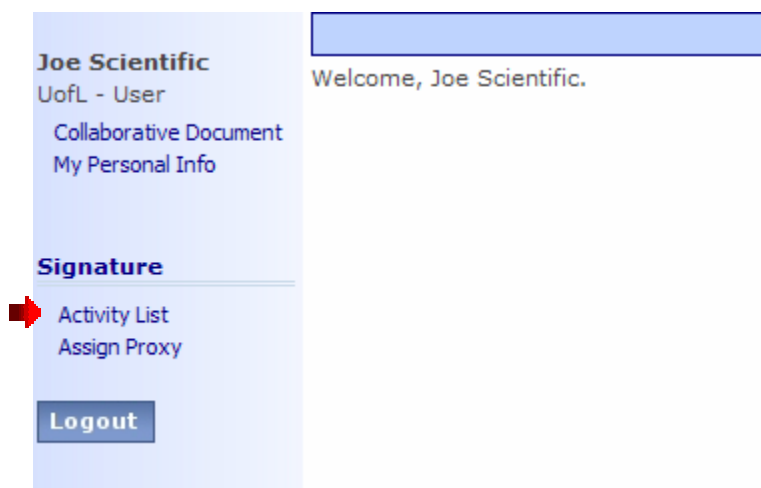
Your Password is your GroupWise password.



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.

IRB PROTOCOL

	<u>Tracking #</u>	<u>PI</u>	<u>Title</u>	<u>Status</u>	<u>Status Date</u>
	07.0181	Noe, C	IRB Test Protocol #5	Awaiting Signatures	5/16/2007
	07.0182	Investigator, J	Sample Protocol 2	Awaiting Signatures	5/18/2007

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

Click on the link [Awaiting your Signature.](#)

IRB PROTOCOL

	<u>Tracking #</u>	<u>PI</u>	<u>Title</u>	<u>Status</u>	<u>Status Date</u>	<u>Board</u>	<u>Meeting Date</u>
	07.0181	Noe, C	IRB Test Protocol #5	Awaiting Signatures	5/16/2007		
	07.0182	Investigator, J	Sample Protocol 2	Awaiting Signatures	5/18/2007		

Expiration Date:

Possibly Exempt?: No

Task	Created By	Created On
Awaiting Your Signature	J. Investigator	5/18/2007 10:24:54 AM

LTB - Admin

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**

IRB PROTOCOL - Awaiting Your Signature

Tracking #

07.0182

PI

Investigator, Joe

Title

Sample Protocol 2

Version

2

Status

Awaiting Signatures

Status Date

5/18/2007 10:24:46 AM

Board

Meeting Date

Approval Date

Expiration Date

Awaiting Signature

Scientific, Joe
Department, Jane

Select an Action:

Signature Memo

Notepad

Signature Memo

View

View Attachments / Forms

View History

Go

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

Verify Save
Close

Select a page below to edit

- Affirmation Page
- Scientific Review**

IRB PROTOCOL-SIGNATURE MEMO (07.0182)

Signature Type and Business Unit

Business Unit:
Library - LIB - Admin

Signature Type:
Scientific Review

AFFIRMATION

Please select one of the following options:

- ☐ Sign Protocol
- ☐ Return unsigned to the PI

SAVE WARNING

Please be sure to save your changes to this page before you move to another page or close the form.

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.

Verify Save
Close

Select a page below to edit

- Affirmation Page
- Scientific Review**

IRB PROTOCOL-SIGNATURE MEMO (07.0182)

SCIENTIFIC REVIEW

Will the research design yield valid results?

- ☐ Yes
- ☐ No

Please explain your answer:

Does the research utilize acceptable practice for the discipline?

- ☐ Yes
- ☐ No

Please explain your answer:

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.

Verify	Save
Close	

This box should pop up ➡

Click  then click 

(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**.

➡ Please select one of the following options:

☒ Sign Protocol

☐ Return unsigned to the PI

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

Click  then click 

12. You will see the list of studies again.

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

IRB PROTOCOL

	<u>Tracking #</u>	<u>PI</u>	<u>Title</u>	<u>Status</u>	<u>Status Date</u>
	07.0181	Noe, C	IRB Test Protocol #5	Awaiting Signatures	5/16/2007
	07.0182	Investigator, J	Sample Protocol 2	Awaiting Signatures	5/18/2007

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

Click on the link [Signature Memo](#).

IRB PROTOCOL

	<u>Tracking #</u>	<u>PI</u>	<u>Title</u>	<u>Status</u>	<u>Status Date</u>
	07.0181	Noe, C	IRB Test Protocol #5	Awaiting Signatures	5/16/2007
	07.0182	Investigator, J	Sample Protocol 2	Awaiting Signatures	5/18/2007
<div> <div>Expiration Date:</div> <div>Possibly Exempt?: No</div> </div>					
<div> <div>Task</div> <div>Signature Memo</div> </div>					
<div> <div>Created By</div> <div>J. Scientific</div> </div>					
<div> <div>Created On</div> <div>5/18/2007 11:52:56 AM</div> </div>					

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**

IRB PROTOCOL - Signature Memo

Tracking #

07.0182

PI

Investigator, Joe

Title

Sample Protocol 2

Version

2

Status

Awaiting Signatures

Status Date

5/18/2007 10:24:46 AM

Board

Meeting Date

Approval Date

Expiration Date

Awaiting Signature

Scientific, Joe
Department, Jane

RELATED MEMOS

*Please use the "Edit Memo" link below to edit (or reply) to the related memo. Use the "View Memo" link to view a read-only PDF version of the memo.

IRB PROTOCOL-SIGNATURE MEMO

	Tracking #	Created On	Created By
Edit Memo View Memo	07.0182	5/18/2007 11:40:28 AM	J. Scientific

Select an Action:

Send Signature Memo

Notepad

Send Signature Memo

Signature Memo

View

View Attachments / Forms


View History

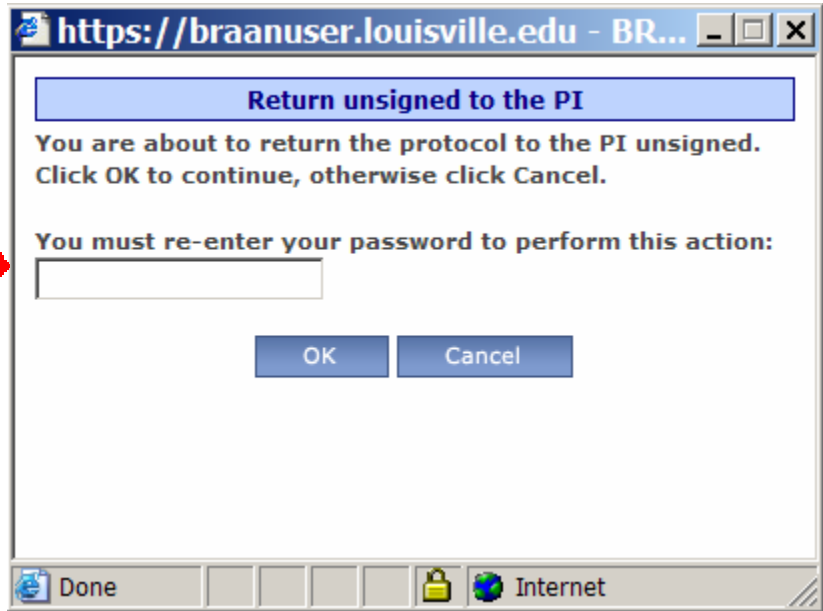
Go

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Release: 1.630.3 - Deployment Date: May 14, 2007

5. This box will popup.



Type in your password and click .



Return unsigned to the PI

You are about to return the protocol to the PI unsigned.
Click OK to continue, otherwise click Cancel.

You must re-enter your password to perform this action:

Done Internet

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

Activity List						
IRB PROTOCOL						
	Tracking #	PI	Title	Status	Status Date	Boa
+	07.0181	Noe, C	IRB Test Protocol #5	Awaiting Signatures	5/16/2007	

Joe Scientific
UofL - User
Collaborative Document
My Personal Info

Signature
▶ Activity List
Assign Proxy

Logout

CHAPTER 8. DEPARTMENT SIGNATURE

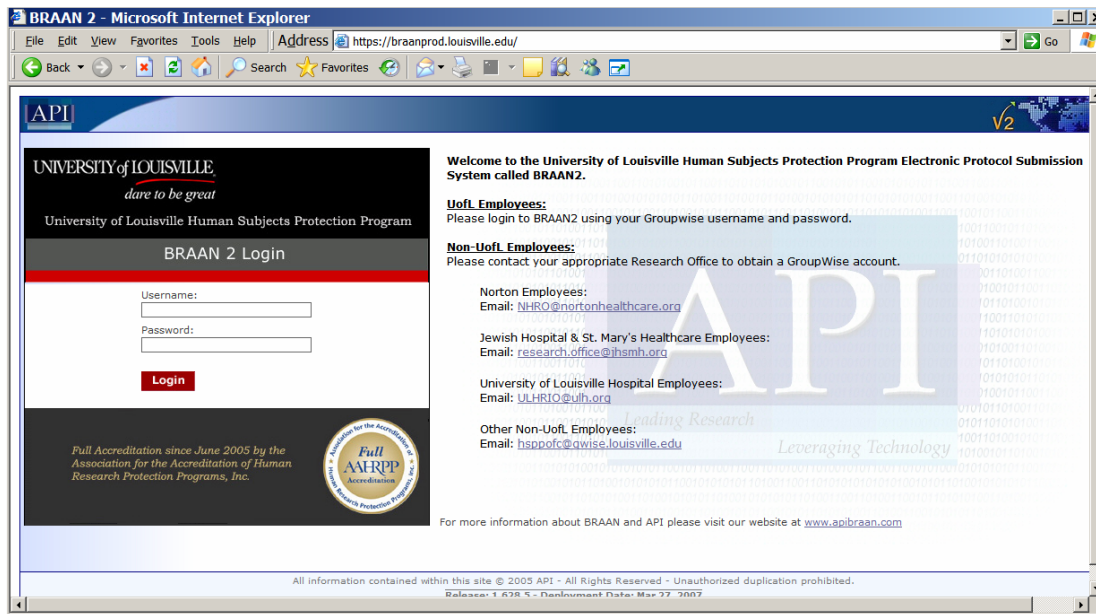
1. Go to the following website <https://braanprod.louisville.edu>

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

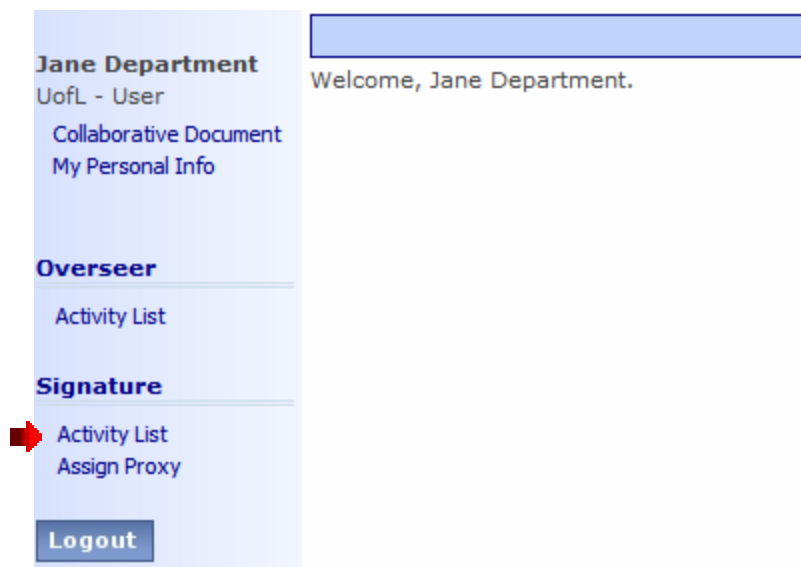
Your Password is your GroupWise password.



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.

IRB PROTOCOL

	<u>Tracking #</u>	<u>PI</u>	<u>Title</u>	<u>Status</u>	<u>Status Date</u>
+	07.0181	Noe, C	IRB Test Protocol #5	Awaiting Signatures	5/16/2007
+	07.0182	Investigator, J	Sample Protocol 2	Awaiting Signatures	5/18/2007

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.](#)

IRB PROTOCOL

	<u>Tracking #</u>	<u>PI</u>	<u>Title</u>	<u>Status</u>	<u>Status Date</u>	<u>Board</u>	<u>Meeting Date</u>
+	07.0181	Noe, C	IRB Test Protocol #5	Awaiting Signatures	5/16/2007		
<div> <div>Expiration Date:</div> <div>Possibly Exempt?: No</div> <div> <div>Task</div> <div>Awaiting Your Signature</div> </div> <div> <div>Created By</div> <div>C. Noe</div> </div> <div> <div>Created On</div> <div>5/16/2007 3:36:42 PM</div> </div> <div>LIB - Admin</div> </div>							

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

IRB PROTOCOL - Awaiting Your Signature

Tracking #

07.0181

PI

Noe, Christina

Title

IRB Test Protocol #5

Version

1

Status

Awaiting Signatures

Status Date

5/16/2007 3:36:30 PM

Board

Meeting Date

Approval Date

Expiration Date

Document Signed By

Scientific, Joe

Awaiting Signature

Department, Jane

Select an Action:

Notepad

Notepad

Signature Memo

View

View Attachments / Forms

View History

Go

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  then click 

8. You will see the list of studies again.

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

 **IRB PROTOCOL**

	<u>Tracking #</u>	<u>PI</u>	<u>Title</u>	<u>Status</u>	<u>Status Date</u>
	07.0181	Noe, C	IRB Test Protocol #5	Awaiting Signatures	5/16/2007
	07.0182	Investigator, J	Sample Protocol 2	Awaiting Signatures	5/18/2007

9. A box will appear under the study.

Click on the link [Signature Memo](#).

IRB PROTOCOL

Tracking #

PI

Title

Status

Status Date

Board

Meeting Date

07.0181

Noe, C

IRB Test Protocol #5

Awaiting Signatures

5/16/2007

Expiration Date:

Possibly Exempt?: No

Task

Created By

Created On

Signature Memo

J. Department

5/21/2007 4:11:03 PM

LIB - Admin

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**

IRB PROTOCOL - Signature Memo

Tracking # 07.0181
PI Noe, Christina
Title IRB Test Protocol #5
Version 1
Status Awaiting Signatures
Status Date 5/16/2007 3:36:30 PM
Board
Meeting Date
Approval Date
Expiration Date
Document Signed By Scientific, Joe
Awaiting Signature Department, Jane

RELATED MEMOS
*Please use the "Edit Memo" link below to edit (or reply) to the related memo. Use the "View Memo" link to view a read-only PDF version of the memo.

IRB PROTOCOL-SIGNATURE MEMO			
	Tracking #	Created On	Created By
View Memo	07.0181	5/21/2007 3:52:22 PM	J. Scientific
Edit Memo View Memo	07.0181	5/21/2007 4:07:32 PM	J. Department

Select an Action 

- Notepad
- Send Signature Memo**
- Signature Memo
- View
- View Attachments / Forms
- View History

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Release: 1.630.3 - Deployment Date: May 14, 2007

15. This box will popup.

Type in your GroupWise password and click

OK


BRAAN 2 - Sign Protocol - Microsoft Internet Explorer

Sign Protocol

I affirm that this application is within the academic and/or clinical scope of this Department/Division. In addition, I certify that adequate space and resources are available to conduct this research.

You must re-enter your password to perform this action:

OK Cancel

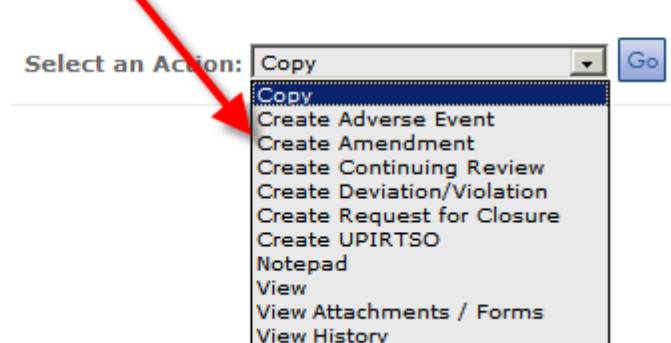
Done  Trusted sites

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:

**For post approval actions,
please choose from one of the
following options**




Select an Action: Copy

- Copy
- Create Adverse Event
- Create Amendment
- Create Continuing Review
- Create Deviation/Violation
- Create Request for Closure
- Create UPIRTSO
- Notepad
- View
- View Attachments / Forms
- View History

Go

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:



Verify Save Close


Deviation / Violation / Miscellaneous

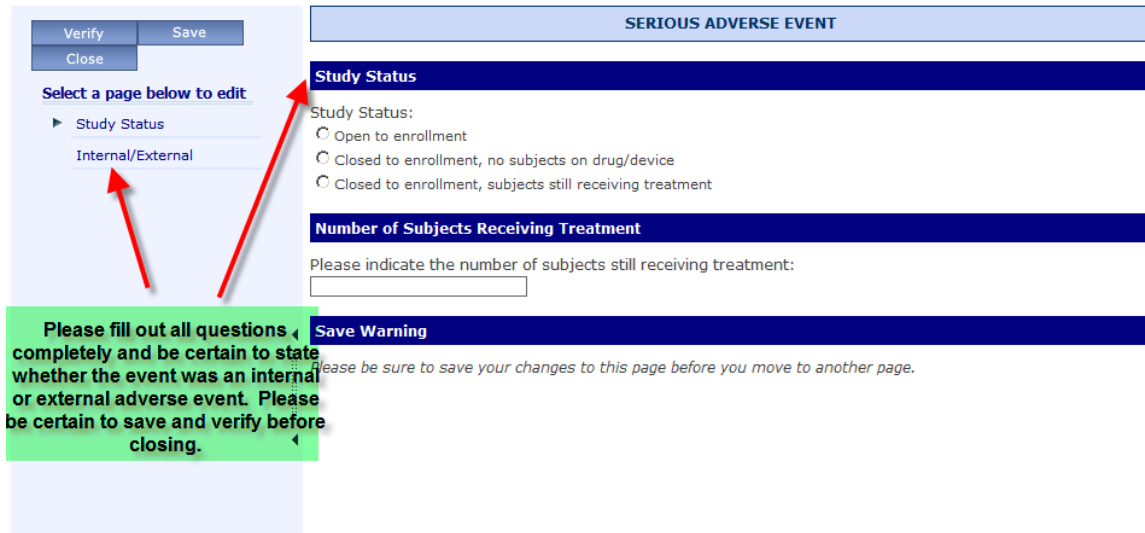
Describe the violation, deviation or other event:

Please be certain to fill out the form completely and to save and click verify before closing the form.

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.



Verify Save
Close

Select a page below to edit

- Study Status
- Internal/External

SERIOUS ADVERSE EVENT

Study Status

Study Status:

- ☐ Open to enrollment
- ☐ Closed to enrollment, no subjects on drug/device
- ☐ Closed to enrollment, subjects still receiving treatment

Number of Subjects Receiving Treatment

Please indicate the number of subjects still receiving treatment:

Save Warning


Please be sure to save your changes to this page before you move to another page.

Please fill out all questions completely and be certain to state whether the event was an internal or external adverse event. Please be certain to save and verify before closing.

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.

Verify Save
Close

Select a page below to edit

- Instructions
- UPIRTSO**

Be sure to read the instructions carefully and to fill out the UPIRTSO page completely. Please save and verify this document before closing.

UPIRTSO

Instructions

Reminders

- Always use BRAAN navigational buttons. Never use your web browser to navigate within BRAAN.
- Always use the **SAVE** and **CLOSE** buttons within BRAAN to exit a document or close a screen. Never use the X on the top of the window to close the screen.
- Remember to click on the **SAVE** button before closing and exiting documents or moving to a new page.

Visibility Rules


- In order to minimize the need for you to read questions that do not pertain to your study, BRAAN utilizes "visibility rules". These rules cause new sections or questions to appear (become visible) based on your answers to previous questions.
- After you complete and save a page, please review the page to see if any new questions appear in **red text**. Please answer these questions and click **SAVE** before moving on to the next page.

Attachments

- When you come to a section that allows you to attach files, you must click on the **SAVE** button before attaching your file(s).
- Always enter a description of the file you are attaching.

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.

The screenshot shows a web browser window titled "BRAAN 2 - Protocol Actions - UofL - User - Microsoft Internet Explorer". The address bar shows the URL: <https://braanuser.louisville.edu/Protocols/TaskDetails.aspx?ActivityId=347077&a>. The page content is divided into a left sidebar and a main content area.

Left Sidebar:

- API**
- Erin Perkins
UofL - User
Collaborative Document
My Personal Info
- IRB Coordinator**
 - Activity List
 - Reviewer Feedback Report
 - Final Decision Notification Log
 - Meeting Managers
- PI**
 - Create Protocol
 - Activity List
 - Create Emergency Use
 - Create Prep to Research
 - Create IAA
 - Create Case Report / NHR
- Research Team**
 - Create Protocol
 - Activity List
 - Create Emergency Use
 - Create Prep to Research
 - Create IAA
 - Create Case Report / NHR
- Signature**
 - Activity List

Main Content Area:

IRB PROTOCOL - Details

Tracking # 07.0183

PI Noe, Christina

Title A Randomized Phase 3 Study of PXXY in Combination with Cisplatin and Xeplant in Subjects with Advanced Metastatic Cancer

Version 1

Status Approved

Status Date 5/30/2007 3:33:02 PM

Board Biomedical

Meeting Date

Approval Date

Expiration Date

Select an Action:

- Copy
- Create Adverse Event
- Create Amendment
- Create Continuing Review
- Create Deviation/Violation
- Create Request for Closure
- Create UPIRTSO
- Notepad
- View
- View Attachments / Forms
- View History

Enter the information in the applicable fields in the Amendment Form **and** make changes in the protocol. , , and 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.

Verify Save
Close

Select a page below to edit
Instructions
Amendment
PI Attestations
Attachments

AMENDMENT (07.0183)

Type of Amendment

Type of Amendment:

☐ Personnel Change

☐ Protocol Change

☐ Enrollment Closure

☐ P.I. Request for Hold

☒ Other

Informed Consent Changes

Does the proposed amendment affect the informed consent?

☐ Yes

☐ No

Verify

Select a page below to edit
INSTRUCTIONS
SECTION 1:
*Title
SECTION 2:
*PI
*Primary IRB Contact
*Key Personnel
SECTION 3:
*Research Nature
*Sponsored
*Review Type
*Resubmission

IRB PROTOCOL (07.0183)

Principal Investigator/Project Director (PI/PD)

Click "Add New" below to add the Principal Investigator.

[Noe, Christina](#) [Delete](#)

Students cannot be Principal Investigators. If this is a student study, please enter the Faculty Advisor as the PI and enter the student as the Primary IRB Contact.

SAVE NOW

Primary IRB Contact

To designate an individual other than the P.I. as the Primary IRB Contact, please click "Add New" below:

[Add New](#)

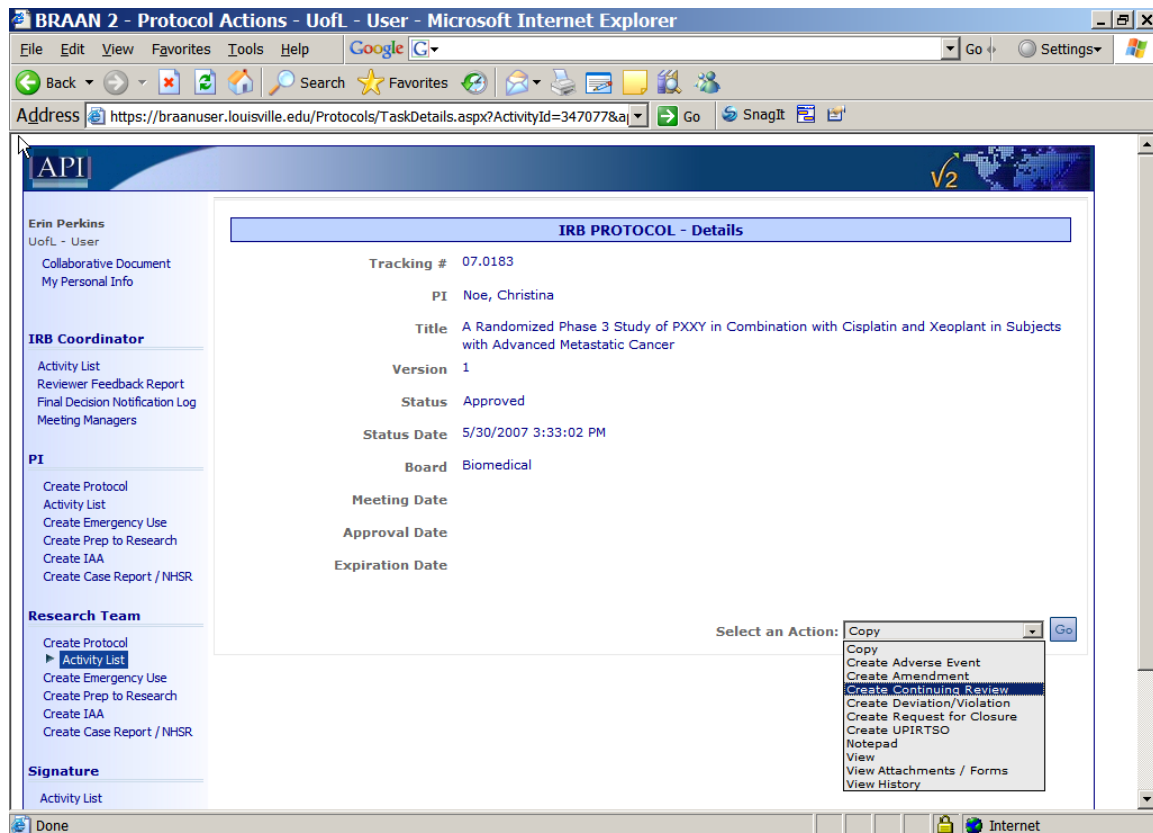
Amendments are submitted and routed for review like other documents:

Activity List							
+ Filter							
AMENDMENT							
	Tracking #	PI	Title	Status	Status Date	Board	Meeting Date
	H-3010	Kemperman, L	IRB Protocol Workflow Demo - F...	New	10/27/2006	Board Blue	
IRB PROTOCOL							
	Tracking #	PI	Title	Status	Status Date	Board	Meeting Date
	H-3010	Kemperman, L	IRB Protocol Workflow Demo - F...	Suspended	10/27/2006	Board Blue	

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.

The image displays two screenshots of the BRAAN2 system interface, showing the continuation review process.

Top Screenshot: CONTINUING REVIEW (07.0183)

On the left, there is a sidebar with buttons: **Verify**, **Save**, and **Close**. Below these is a section titled "Select a page below to edit" with a list of options: **Instructions**, **Expedited Review**, **Study Information**, **Subject Information**, **Compliance**, **Conflict of Interest**, and **Additional Information**.

The main content area is titled **CONTINUING REVIEW (07.0183)**. It contains two sections:

- Expedited Yes/No**: A section with a question: "If this study was originally approved through the Expedited Review procedure, continuation review will usually also be approved through the Expedited Review procedure. Is this continuation request being submitted for Continuing Review under Expedited Review procedures?" with radio button options for **Yes** and **No**.
- Check Questions**: A section with instructions: "After you complete and **SAVE** this page, please review the page to see if any new questions appear in **red text**. If there are new questions, please answer these questions and click **SAVE** before moving on to the next page."

Bottom Screenshot: IRB PROTOCOL (07.0183)

On the left, there is a sidebar with a **Verify** button. Below it is a section titled "Select a page below to edit" with a list of options: **INSTRUCTIONS**, **SECTION 1: *Title**, **SECTION 2: *PI, *Primary IRB Contact, *Key Personnel**, **SECTION 3: *Research Nature, *Sponsored, *Review Type, *Destination**.

The main content area is titled **IRB PROTOCOL (07.0183)**. It contains a section titled **Title of Protocol** with instructions: "Please enter the title of the protocol in the box below and then click 'Save' in the upper left corner of your screen." Below the instructions is a text input field containing the following text:

A Randomized Phase 3 Study of PXXY in Combination with Cisplatin and Xeoplant in Subjects with Advanced Metastatic Cancer

Continuation reviews 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.

Verify Save

Close

Select a page below to edit

- Instructions
- Title & PI
- Study Location(s)
- EU Notification
- EU Determination

Please read the instructions and fill out all questions in each section completely.

EMERGENCY USE

Instructions

Emergency Use (EU)

The **Study Title** and **PI Name** are **required** for BRAAN to save and file the document in the appropriate place. Please be sure that these fields are completed before exiting the document.

Reminders

Always use BRAAN navigational buttons. Never use your web browser to navigate within BRAAN.

Always use the **SAVE** and **CLOSE** buttons within BRAAN to exit a document or close a screen. Never use the X on the top of the window to close the screen.

Remember to click on the **SAVE** button before closing and exiting documents or moving to a new page.

Attachments

When you come to a section that allows you to attach files, you must click on the **SAVE** button before attaching your file(s).

Always enter a description of the file you are attaching.

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.

The screenshot displays the BRAAN2 IAA (IRB Authorization Agreement) form. On the left is a navigation sidebar with buttons for 'Verify', 'Save', and 'Close'. Below these is a section titled 'Select a page below to edit' containing a list of steps: 'Instructions', 'Title & PI', 'Study Location(s)', 'IRB Authorization Agreement', 'IRB Authorization Agreement Study Information', and a red warning message: 'Complete each field entirely. Remember to SAVE and VERIFY before closing.' The main content area is titled 'IAA' and features a 'TITLE' section with a 'Title:' label and a large text input field. Below this is a 'SAVE NOW' button. The 'PRINCIPAL INVESTIGATOR' section includes a prompt to 'Click 'Add New' to add the Principal Investigator' and an 'Add New' link. Another 'SAVE NOW' button is present. The 'PRIMARY STUDY CONTACT' section is partially visible at the bottom, with a prompt to 'Is someone from the research team (other than the P.I.) designated as the primary contact for...'. The interface uses a blue and white color scheme with a vertical scrollbar on the right.

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.

The screenshot shows the BRAAN2 Case Report/NHSR application form. On the left is a navigation menu with buttons for 'Verify', 'Save', and 'Close'. Below these are links for 'Select a page below to edit', 'Instructions', 'Title & PI', 'Study Location(s)', and 'Case Report / NHSR'. A red text box in the menu area says 'Fill out each section completely. Remember to SAVE and VERIFY before closing.' The main form area has a title bar 'CASE REPORT/NHSR' and a section titled 'TITLE' with a text input field. Below this is a 'SAVE NOW' button. The next section is titled 'AUTHOR/PI' with a text input field and a link 'Add New'. Another 'SAVE NOW' button is at the bottom.