

University of Louisville Human Subjects Protection Program Instructions to submit a protocol in BRAAN2

STEP ONE

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

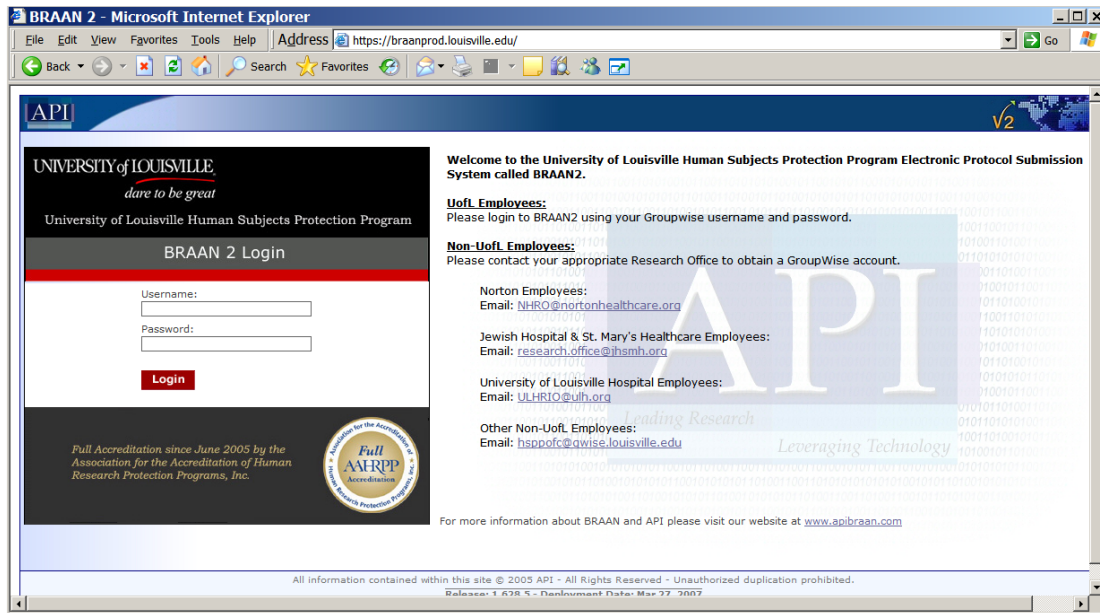
STEP TWO

Login to BRAAN2:

Your username is your GroupWise address before the @ sign.

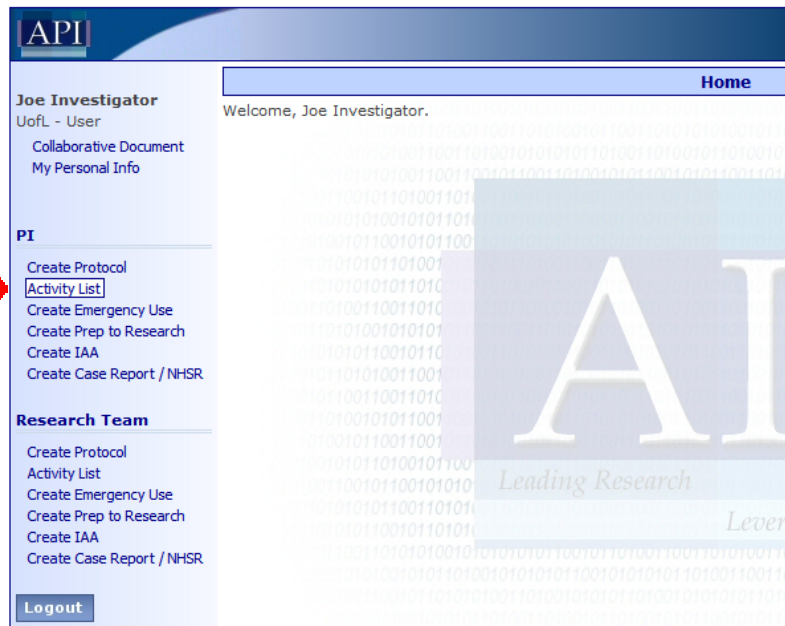
Example: if your email is jdburk04@louisville.edu, your username is jdburk04

Your Password is your GroupWise password.



STEP THREE

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 PI group.**




University of Louisville Human Subjects Protection Program Instructions to submit a protocol in BRAAN2

STEP FOUR

You will now see a list of all studies where you are listed as the PI.

Locate the study you need to submit and **click on the [None](#) link.**


IRB PROTOCOL					
	<u>Tracking #</u>	<u>Principal Investigator</u>	<u>Title</u>	<u>Status</u>	<u>Status Date</u>
	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

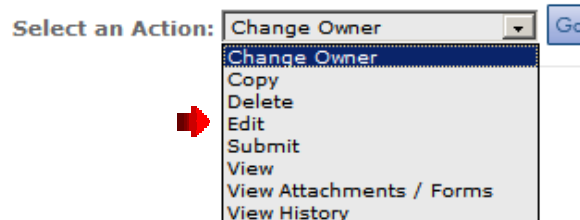
STEP FIVE

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 **



University of Louisville Human Subjects Protection Program Instructions to submit a protocol in BRAAN2

STEP SIX

The Protocol will be displayed.

- Click on Section 2.

Verify Save
Close

Select a page below to edit

INSTRUCTIONS

SECTION 1:
*Title

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

IRB PROTOCOL

Principal Investigator/Project Director (PI/PD)

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

[Investigator, Joe](#) [Delete](#)

Students cannot be Principal Investigators. If this is a student as the PI and enter the student as the Primary IRB Contact.

SAVE NOW

You will see your name with a red flag to the left. **Please click on your name.**

STEP SEVEN

A new page will open up showing all of the Principal Investigator Information. Please scroll to the bottom of the page where you will see the following COI question.

Significant Financial Conflict of Interest (COI)

Please check the box below if one of the following two statements are true:

1. I do not have a Conflict of Interest with this study.
2. I have a Conflict of Interest with this study that has been "managed" according to the University's Policy for Oversight of Individual Financial Interests in Research.

Check the box

Click on **Save** in the upper left hand corner of the screen

STEP EIGHT

Click on the **Verify Button** to the left of the save button. (to verify PI information)

Verify Save
Close

Principal

Principal Investigator

PI Name:
Enter last and first name and click 'Search'

Last: F

This box should pop up

BRAAN 2 - Verification Errors - ...

Verification Errors

No Errors Found

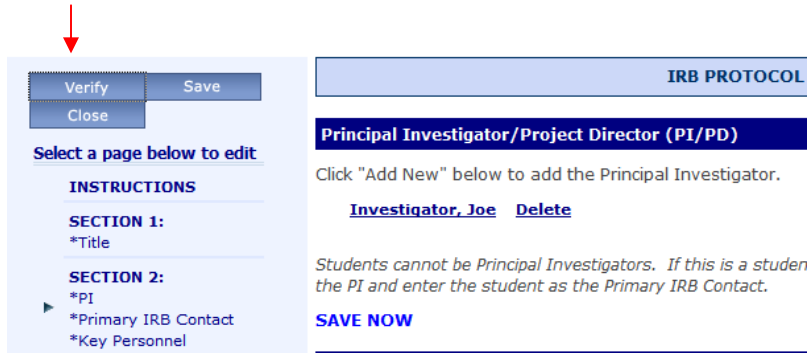
Click **Save** then click **Close**

University of Louisville Human Subjects Protection Program Instructions to submit a protocol in BRAAN2

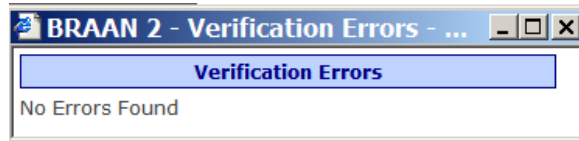
STEP NINE


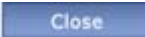
You should be back to the IRB Protocol and the red flag that was next to your name should be gone.

Click on the Verify Button (to verify Protocol)



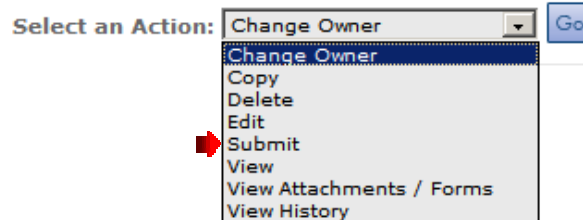
This box should pop up →



Click  then click 

STEP TEN

Open the "Select an Action" drop down list and click Submit.

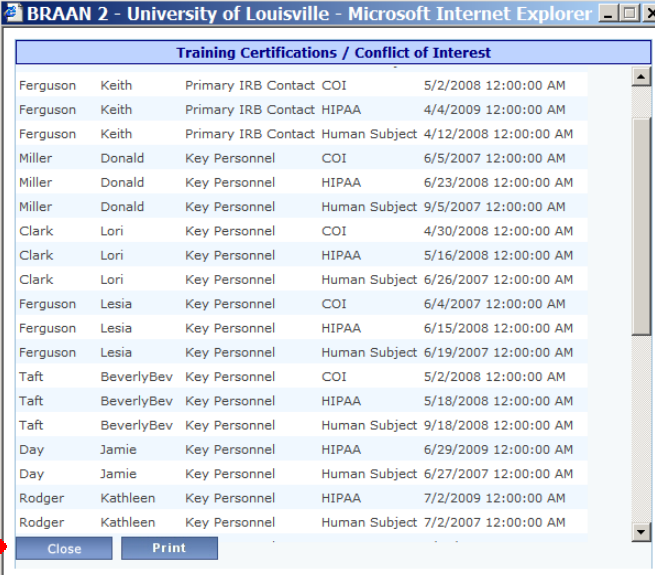


University of Louisville Human Subjects Protection Program Instructions to submit a protocol in BRAAN2

STEP ELEVEN

A box will popup letting you know if all of the personnel on the study have completed their training and Conflict of Interest Form*.

If no-one is expired you can close this box and continue with the submission.



Training Certifications / Conflict of Interest				
Ferguson	Keith	Primary IRB Contact	COI	5/2/2008 12:00:00 AM
Ferguson	Keith	Primary IRB Contact	HIPAA	4/4/2009 12:00:00 AM
Ferguson	Keith	Primary IRB Contact	Human Subject	4/12/2008 12:00:00 AM
Miller	Donald	Key Personnel	COI	6/5/2007 12:00:00 AM
Miller	Donald	Key Personnel	HIPAA	6/23/2008 12:00:00 AM
Miller	Donald	Key Personnel	Human Subject	9/5/2007 12:00:00 AM
Clark	Lori	Key Personnel	COI	4/30/2008 12:00:00 AM
Clark	Lori	Key Personnel	HIPAA	5/16/2008 12:00:00 AM
Clark	Lori	Key Personnel	Human Subject	6/26/2007 12:00:00 AM
Ferguson	Lesia	Key Personnel	COI	6/4/2007 12:00:00 AM
Ferguson	Lesia	Key Personnel	HIPAA	6/15/2008 12:00:00 AM
Ferguson	Lesia	Key Personnel	Human Subject	6/19/2007 12:00:00 AM
Taft	BeverlyBev	Key Personnel	COI	5/2/2008 12:00:00 AM
Taft	BeverlyBev	Key Personnel	HIPAA	5/18/2008 12:00:00 AM
Taft	BeverlyBev	Key Personnel	Human Subject	9/18/2008 12:00:00 AM
Day	Jamie	Key Personnel	HIPAA	6/29/2009 12:00:00 AM
Day	Jamie	Key Personnel	Human Subject	6/27/2007 12:00:00 AM
Rodger	Kathleen	Key Personnel	HIPAA	7/2/2009 12:00:00 AM
Rodger	Kathleen	Key Personnel	Human Subject	7/2/2007 12:00:00 AM

(Note: If anyone shows that their training or COI is expired you will not be able to submit the protocol. In order to submit the protocol that person will need to update whatever is expired. If you need to submit the protocol right away, you can remove that person from the protocol temporarily. Once the protocol is approved you can add the person back via an amendment.)*

***This is NOT the same COI that you checked off in Step #7.**

COI here refers to [The Disclosure of Significant Financial Interest Form](#) which is located on the [Office of Research Integrity Website](#).

Direct link to the [Disclosure of Significant Financial Interest Form](https://webapp.louisville.edu/coldfusion2/webs/VPR_SFI_2008/admin/default.htm)
(https://webapp.louisville.edu/coldfusion2/webs/VPR_SFI_2008/admin/default.htm)

Once you fill out the form, it will take at least 24 hours for the Office of Research Integrity to update the database that links to BRAAN2.

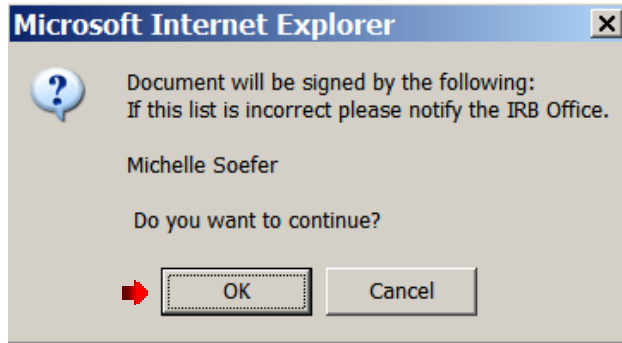
All requests for expedited updates or questions regarding COI should be directed to the Office of Research Integrity, Service Account at oriuofl@gwise.louisville.edu

**University of Louisville Human Subjects Protection Program
Instructions to submit a protocol in BRAAN2**

STEP TWELVE

Another box will pop up letting you know who in your department will need to sign the protocol.

Assuming this is correct; you can click OK and continue.



STEP THIRTEEN (IMPORTANT!!)

It should only take a couple of minutes for the status of your study to change from "New" to "Awaiting Signatures".

If the status of the study does not change to Awaiting Signatures you have not submitted the study! Please return to STEP TEN.