

IRIS SUBMISSION MANUAL

Human Subjects Protection Program
UNIVERSITY OF LOUISVILLE 502.852.5188

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Sponsored Account Form

Guides

Human Research Protection Program Policy Manual

IRB Submission Life Cycle

Quality Improvement Program

Logging In

1. iris.louisville.edu
2. Log into iRIS with your assigned UofL userid and password. This will be the same password that is used to login to ULink.
 - a. If you are not a UofL employee (ex. KyOne employees, Norton employees, etc..) please contact the [Human Subjects Protection Program Office](#) for instructions on how to obtain a sponsored account.

Log In
Welcome to

UL OF
iRIS
integrated
Research
Information System

UserID:

Password:

Log In

[System/Browser Requirements](#)

LOGIN Issues? go to <https://iris.support.louisville.edu/jira/servicedesk/customer/portal/6>

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Version 10.03 Build 451 Updated 2016/04/18 14:19

Completing the Attestation and Disclosure Form (ADF)

1. Per the University [policy section 3.2](#), all research personnel are required to complete the Attestation and Disclosure Form (formerly the Conflict of Interest Form)
2. On the left of the page, hover the mouse over Conflict of Interest Forms
3. Select Attestation and Disclosure Form
4. Select Add a New Form

My Assistant

● Conflict of Interest Forms	Attestation and Disclosure Form
● My Grants and Contracts	Unpin Conflict of Interest from Content Dashboard
● Study Assistant	
Change your default Department	

Uploading a CV

1. Hover the pointer over “My Assistant”
2. Click on “My Account Information”

● My Assistant	My Account Information
● Conflict of Interest Forms	Organization Profile
● My Grants and Contracts	Announcements
● Study Assistant	Operating Procedures
Change your default Department	View Correspondence

3. Click on “Biosketch, CV, Pubs”

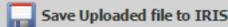
Profile	*Last Name:
Contact Management	Suffix:
Proposal Info	Prefix:
Other System IDs	Job Title:
Biosketch, CV, Pubs	Status:
Education History	Academic Position/Title:
Medical Licenses	Degree:
Signature	Gender:
Signoff Availability	Employee ID:
Vaccination History	Specialty:
Notes	Relationship to the

4. Click “Add CV or Biosketch”

Curriculum Vitae (CV) or Biosketch					+ Add CV or Biosketch
Remove	Edit	Document Type	Version Date	Title	View Document
No CV has been added.					

Publications					+ Add Publication
Remove	Edit	Publication Type	Publication date	Publication Title	View Attachment
No Publication has been added.					

5. Enter in the title of the CV
6. Enter a version date (today's date)
7. Click "Upload"
8. Browse for your CV on your computer
9. Click "Save Selected File"
10. Click "Save Uploaded File to iRIS"



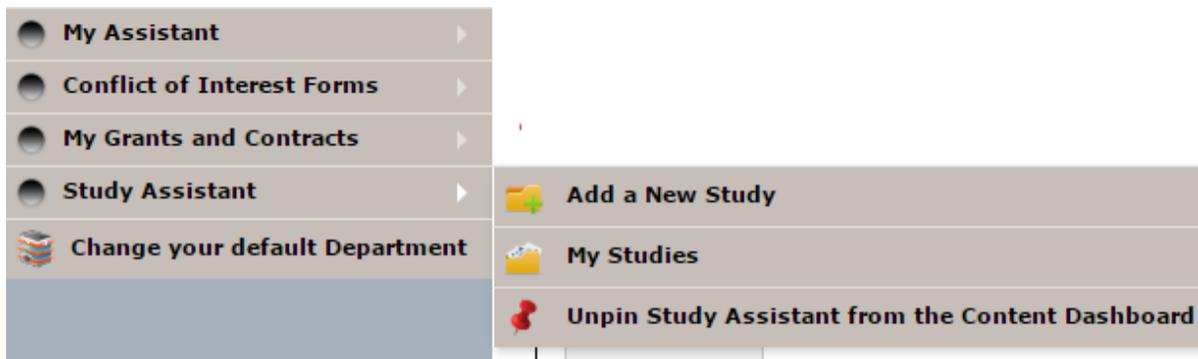
Edit the Document You Selected.

*Document Type:	<input checked="" type="radio"/> Curriculum Vitae (CV) <input type="radio"/> Biosketch						
*Title:	<input style="width: 90%;" type="text"/>						
Version Date:	<input style="width: 50%;" type="text"/> <input type="button" value="Calendar"/>						
	<input type="button" value="Upload..."/>						
Load the document into iRIS:	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Name</th> <th style="width: 25%;">View the Document</th> <th style="width: 25%;">Download the Document</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="text-align: center;">No Document has been uploaded.</td> </tr> </tbody> </table>	Name	View the Document	Download the Document	No Document has been uploaded.		
Name	View the Document	Download the Document					
No Document has been uploaded.							

Creating a New Study Submission

This process is repeated for submitting a Not Human Subject Research (NHSR) application, Institutional Authorization Agreement (IAA), and Emergency Use application.

1. Hover the pointer over "Study Assistant" on the left of the page
2. Select "Add a New Study"



3. Select "IRB Study Application"
4. Select "Start selected Application"




Please select a New Study Application from the list below:

Study Forms:

- IRB Study Application
- IACUC Application
- IBC Registration

5. Enter the full study title and the Short Study Title
6. Select "Save and Continue"
7. **NOTE:** The department of the person entering in the study will populate in this section. That might not be the same department as the Principal Investigator (PI). You **MUST** add the PI's department and then select it as the primary department. You **MUST ALSO** add any other institutional department. For example, Norton Healthcare, KyOne Health, ULH/James Graham Brown Cancer Center.

2.0 Add Department(s)

2.1 List the departments associated with this study. Add the Principal Investigator's department as the PRIMARY DEPARTMENT. For research conducted at a Norton facility add: Norton Healthcare. For research conducted at a Jewish Hospital/KyOne facility add: Ky One Health. For research conducted at University Hospital/James Graham Brown Cancer Center add: University Hospital:

Primary Dept?	Department Name			
<input type="checkbox"/>	<input checked="" type="radio"/>		<input type="button" value="+ Add"/>	<input type="button" value="X Remove"/>

8. Select Save and Continue
9. Add the PI, Additional Investigators and Research Support Staff.
 - a. **NOTE:** Research conducted at KyOne Health and Norton's facilities must include them as the Study Contact.
10. The rest of the questions will branch depending on the specifics of your study

Routing the Submission for Signoff (PI, Scientific Reviewer, and Department Chair)

1. After you select sign off and submit you will be prompted to add the Key Personnel required for routing and signoff.
 - a. **NOTE:** The PI is the only person that is required to be included in this section.
2. Select Save and Continue

Select the Key Personnel required for routing and signoff

Check the boxes next to the names of the personnel required for routing and signoff.

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		User Singleton	Principal Investigator

3. You are required to include a scientific reviewer and department chair sign off for all human subjects research submissions except for NHSR, Continuing Review, and Emergency Use submissions.
 - a. For some departments, this will be the same person. Please visit our [website](#) for a complete list.
4. If your Department Chair and Scientific Reviewer are not already listed on this page you must select "Add Signoff." Also, if the assigned persons here are incorrect you must change it to reflect the accurate individuals.

Select the additional personnel required for routing and signoff

Check the boxes next to the names of the personnel required for routing and signoff.

Include in signoff	Order	Approved	Name / Role
<input checked="" type="checkbox"/>	1		Dev S Tait Scientific Reviewer
<input checked="" type="checkbox"/>	2		Cathy J Carter Department Chair

Screen Instructions:
This screen enables the selection of personnel required to review this form and the routing order before submission.
Person(s) designated as Department reviewers on your application are listed on the "Select required personnel" section to the left of these instructions.
Adding Reviewers:
1. Click on the [Add signoff](#) link on the RIS control panel.
2. On the search screen enter relevant search information and click find.
3. Select the desired reviewers by checking the box to the left of the reviewer name.

5. Once those individuals have been selected, choose their correct role from the drop down list.
6. **NOTE:** The order does matter! The scientific reviewer must be selected as 1 and the Department Chair must be listed as 2. This is the order in which they will sign off after the PI signs off.
7. Mark the check boxes next to each name under the column "Include in signoff"
8. Select "Save and Continue"

Checking the Status of the Study

1. Once you have submitted, to check the where the study is in the review process click on "Study Assistant."

● My Assistant	▶
● Conflict of Interest Forms	▶
● My Grants and Contracts	▶
● Study Assistant	▶
● Change your default Department	▶
	<ul style="list-style-type: none"> ➤ Add a New Study ➤ My Studies ➤ Unpin Study Assistant from the Content Dashboard

2. Click “My Studies”
3. Select the pencil and paper icon under “Click to open”

View History	Click to open	View Details	Study Status	IRB Number	IRB Expiration	Short Study Title	Principal Investigator	Copy Study	Delete Study	Hide
			Pending - Submitted for Initial Review	16.0325		Expedited Bio	Singleton, User			
			Pending - Submitted for Initial Review	16.0324		FB DRUG	Singleton, User			

4. Click on the magnifying glass and paper icon, under the “Outstanding Submissions” section.

Study Status: Pending - Submitted for Initial Review **IRB Number :** 16.0325 **Study Title :** TEST Expedited Bio

Submissions **Study Management**

Protocol Items

- Protocol Items
- Study Application
- Informed Consent
- Other Study Documents
- Contract Documents

Submission Forms

- Forms
- Initial Review Submission Packet
- Serious Adverse Event Reporting Form
- IRB Amendment Form
- IRB Continuing Review Application
- IRB Deviation/Violation/Misc.
- IRB Emergency Use Followup Report
- IRB UPIRTSO Form

Submissions History

Study Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
	338010	Click on the hyperlink to edit/view the submission. Initial Review Submission Packet	<input type="button" value="Retract Submission"/>

5. This section allows you to see where in the review pipeline your study is. If you select the people icons you can see if the PI, Scientific Reviewer, or Department Chair has signed off.
 - a. **Note:** The date on the top is the date that the submission was received. The date on the bottom is when the task was completed (ex. The top date is the date the PI received it to sign off. The bottom date is the date the PI signed off on the submission.).

Status	View Details	Date Received / Date Completed	Event Description
		06/08/2016 11:41 AM EDT	Christina L LaDuke as Dept_Chr-Scientific_Rvwr review and apply signoff
		06/08/2016 11:40 AM EDT 06/08/2016 11:40 AM EDT	Assign Department Personnel for Signoff
		06/08/2016 11:41 AM EDT 06/08/2016 11:41 AM EDT	User Singleton as Principal Investigator review and apply signoff
		06/08/2016 11:40 AM EDT 06/08/2016 11:40 AM EDT	Initial Review Submission Packet is waiting to be submitted

Answering Stipulations

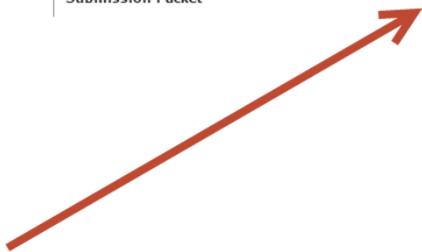
1. Click to open the study
2. Located in “Outstanding Submissions,” click on “Respond to Review” to open the Review Response Form

Study Status: Stipulations Required	IRB Number : 16.0311	Study Title : TEST
	IRB Expiration Date: 05/08/2017	

Submissions	Study Management
--------------------	-------------------------

Protocol Items Protocol Items <input type="radio"/> Study Application <input type="radio"/> Informed Consent <input type="radio"/> Other Study Documents <input type="radio"/> Contract Documents	<input type="radio"/> Submissions History <input type="radio"/> Study Correspondence
---	---

Submission Forms Forms <input type="radio"/> Initial Review Submission Packet <input type="radio"/> Serious Adverse Event Reporting Form <input type="radio"/> IRB Amendment Form <input type="radio"/> IRB Continuing Review Application <input type="radio"/> IRB Deviation/Violation/Misc. <input type="radio"/> IRB Emergency Use Followup Report <input type="radio"/> IRB UPIRTSO Form	<table border="1"> <tr> <th>Track Location</th> <th>Ref Number</th> <th>Request Type</th> <th>Process Submission</th> </tr> <tr> <td></td> <td>338350</td> <td> Click on the hyperlink to edit/view the submission. Institutional Review Board has requested a Submission Response for Initial Review Submission Packet </td> <td>Respond to Review</td> </tr> </table>	Track Location	Ref Number	Request Type	Process Submission		338350	Click on the hyperlink to edit/view the submission. Institutional Review Board has requested a Submission Response for Initial Review Submission Packet	Respond to Review
Track Location	Ref Number	Request Type	Process Submission						
	338350	Click on the hyperlink to edit/view the submission. Institutional Review Board has requested a Submission Response for Initial Review Submission Packet	Respond to Review						



To Remove an Attachment

1. Click “Remove Component”
2. Accept or Deny the stipulation
3. Provide an explanation on how you addressed the stipulation

Stipulation 1 out of 4:

Description:
Please remove Study Doc Two

Stipulation Type: (Stipulation must be addressed)

Links to Components (These are the items that are linked to this stipulation)	Operation	Component Name	Action	Status
	Remove Attachment	Study Document Study Doc Two (Version 1.0)	Remove Component	Pending

Do you accept this Stipulation?
 N/A Yes No

Provide an explanation on how you addressed this Stipulation:

To Edit a Document

1. Click "Revise Linked"

Stipulation 2 out of 4:

Description:
Please edit Consent One

Stipulation Type: (Stipulation must be addressed)

Links to Components (These are the items that are linked to this stipulation)	Operation	Component Name	Action	Status
	Modify Existing Attachment	Study Consent One (Version 1.0)	Revise Linked Add/Select Existing Add a New Consent	Pending

Do you accept this Stipulation?
 N/A Yes No

Provide an explanation on how you addressed this Stipulation:

2. On the pop up window, select "Create Revision"

Select Existing or Create Revised Study Consent							
Select	Show all Versions	Edit	Version	Title	Checked Out By	Checked Out Date	Create Revision
Already Submitted			1.0	Consent One			

3. Select “Check-out Document”

Study Consent Revision:	
* Consent Title:	Consent One
Version Number:	1 .1
* Version Date:	07/14/2016 
Category:	--none--
* Language:	English
* Reconsent Required:	<input type="radio"/> Yes <input checked="" type="radio"/> No
* Reconsent Reason:	<input type="text"/>
Description:	<input type="text"/>
Check-out the Document to your workstation for editing:	<input type="button" value="Check-out Document..."/>
<input type="button" value="Save Consent"/>	

4. Wait until the document downloads
 - a. For Chrome users: This document will download to the bottom of the screen.
 - b. For Internet Explorer users:
 - c. For Firefox users:
 - d. For Safari users:
5. Click to open the document that has just downloaded
6. Select “Complete Check Out”

Download the Study Document

Back

INSTRUCTIONS

Step 1:

If your browser blocks pop - ups, then after a few moments a bar similar to the one shown below may appear in your browser.



Simply click on the bar and a small drop down list will appear. Click **Download File** from the list of options.



Step 2:

In a few moments, your browser will prompt you to either **Open** or **Save** the file (see example below).

Note: this is not the actual File Download box, it is only a picture. In order to Check - out the document and edit it, you will need to **Save** it to your workstation.



To do so, click **Save**. This will open up a window similar to the one shown below that allows you to choose where in your workstation you would like to save the document.

Once you've selected where you will save the document, click **Save**. After this, the Download Complete box will appear as shown below. From here you can choose to open the document to edit it, open the folder that contains the document, or Close the Download Complete box to edit the document later.

Step 3:

IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete box that you click the **Complete Checkout** button in iRIS. This allows you to check the document (or upload the document) back into iRIS once you've finished editing it. To cancel the Document Check - Out, click **Cancel**. Note: If you've already saved the file to your computer, the file will remain in your computer, however you will simply lose the option of checking the document back in.

7. Make your revisions to the document and save somewhere on your computer
8. Select "Check-in Document" and update the "Version Date" If re-consenting is required please fill out that portion as well.

Consent Title:	Consent One
*Version Date:	07/14/2016  
Category:	--none--
Description:	
*Version Number:	1 .1
* Language:	English
* Reconsent Required:	<input type="radio"/> Yes <input checked="" type="radio"/> No 
Reconsent Reason:	
This document is currently checked out by:	User Singleton at 07/14/2016 02:01 PM EDT 
Check-in when you are done editing to upload the document back into iRIS.	<input type="button" value="Check-in Document..."/>
Revert to the document stored in iRIS.	<input type="button" value="Undo Check-out Document..."/>
Comments:	

To edit the Application

1. Click “Revise Existing”

⚠ Stipulation 3 out of 4:

Description:
Please edit section 4 of the application.

Stipulation Type: (Stipulation must be addressed)

Operation	Component Name	Action	Status
Modify Existing Attachment	IRB Study Application (Version 1.3)	Select Already prepared Revise Existing	Pending

Do you accept this Stipulation?
 N/A Yes No

Provide an explanation on how you addressed this Stipulation:

(Note: A red arrow in the original image points to the "Revise Existing" button in the table above.)

2. Click “OK” to adding a revision.

iris-user.louisville.edu says: ✕

Confirm the adding a revision.
Are you sure you want to create a revision?

3. Make the change to the section that needs to be revised
4. Click “Save and Continue to Next Section” until you are routed back to the Review Response Submission Form

Stipulation 3 out of 4:

Description:
Please edit section 4 of the application.

Stipulation Type: (Stipulation must be addressed)

Operation	Component Name	Action	Status
 Modify Existing Attachment	IRB Study Application (Version 1.3)	 Compare Application Version	 Completed
	IRB Study Application (Version 1.4)		

Do you accept this Stipulation?
 N/A Yes No

Provide an explanation on how you addressed this Stipulation:

Rich text editor toolbar with options for text formatting (bold, italic, underline, font color, background color, text color, font size, bullet points, numbered lists, indent, outdent, link, unlink, insert link, insert image, insert table, insert video, insert audio, insert code, insert link, insert image, insert table, insert video, insert audio, insert code).

5. Accept or Deny the stipulation
6. Provide an explanation on how you addressed the stipulation

To add a New Document

1. Scroll down to the bottom of the Review Response Submission Form
2. You will see the Revised Submission Materials section
3. Click "Revise Submission"

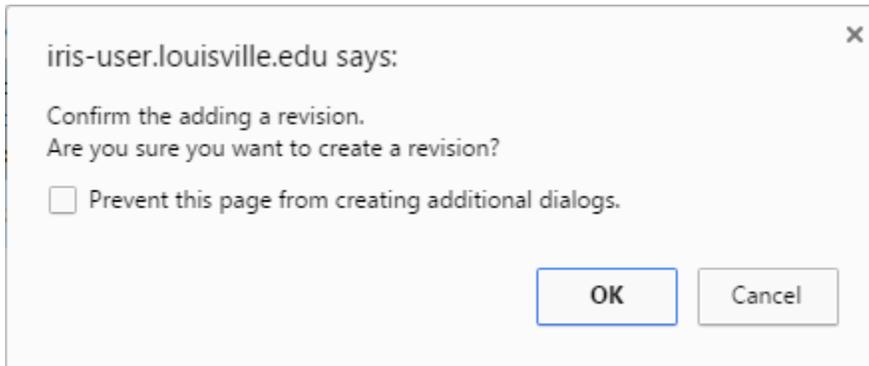
Revised Submission Materials

use the below submission components to modify the items for revision.

Expand All Compare Item(s) Revise Submission Create PDF Packet

Compare	Include in PDF Packet	Remove	Revisions	All Submission Components Previous Rounds & Currently Attached
Submission Form(s)				
<input type="checkbox"/>	<input type="checkbox"/>			Review Response Submission Form - (Version 1.0 (Incomplete)) (Parent of the submission package) - Submitted in round(s) Currently attached
<input type="checkbox"/>	<input type="checkbox"/>			Initial Review Submission Packet - (Version 2.0) - Submitted in round(s) Currently attached,1
Application				
<input type="checkbox"/>	<input type="checkbox"/>			IRB Study Application - (Version 1.4) - Submitted in round(s) Currently attached
Consent Form(s)				
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Consent One (English) - (Version 1.1) - Submitted in round(s) Currently attached
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Consent Four (English) - (Version 1.0) - Submitted in round(s) Currently attached,1
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Consent Three (English) - (Version 1.0) - Submitted in round(s) Currently attached,1
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Consent Two (English) - (Version 1.0) - Submitted in round(s) Currently attached,1
Document(s)				
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Study Doc Two - (Version 1.0) - Submitted in round(s) Currently attached,1
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Study Doc One - (Version 1.0) - Submitted in round(s) Currently attached,1

- Click "Ok" to adding a new revision



- Scroll down to either "Consent and HIPAA Documents" or "Other Study Documents"
- Click on "Add a New Consent" or "Add a New Document"

1.10 Consent and HIPAA Documents

1.11 * Attach all Informed Consent and HIPAA documents for this protocol:
When possible, attach Word documents instead of PDFs.

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
	1.0	Consent Four		English				70.86 KB
	1.0	Consent Three		English				62.12 KB
	1.0	Consent Two		English				52.00 KB
	1.1	Consent One		English				2.21 MB

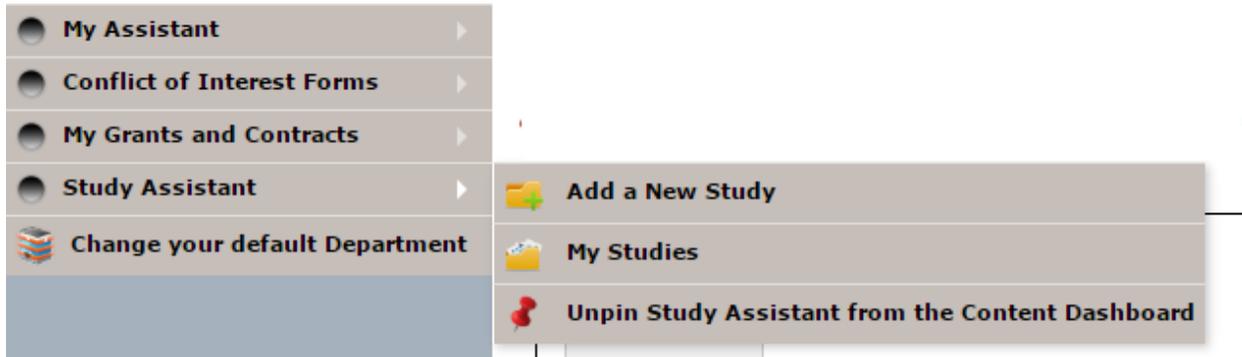
1.12 Other Study Documents

1.14 Attach all other study documents (e.g. research proposal or protocol, grant, billing compliance form, investigators brochure, recruitment materials, data collection forms, study handouts or other documents related to this submission):

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	1.0	Study Doc Two					363.44 KB
	1.0	Study Doc One					134.04 KB

Finding Stamped Documents

NOTE: You must **ALWAYS** use the most current stamped documents when consenting subjects.



1. Click “My Studies”
2. Select the pencil and paper icon under “Click to open”

View History	Click to open	View Details	Study Status	IRB Number	IRB Expiration	Short Study Title Study Title	Principal Investigator	Copy Study	Delete Study	Hide
			Approved	16.0290	02/14/2017	EXPEDITED KES 2/8/2016 EXPEDITED KES 2/8/2016	Singleton, Kristyn E Elizabeth			
			Approved	16.0311	05/08/2017	Full board test - 5-9-2016 Full board test - 5-9-2016 - BAD	Dearinger, User			

3. Click on Informed Consent or Other Study Documents
4. Click on the PDF icon to access your stamped documents.
 - a. The most recent document will have the most recent approval date.

	View History	Edit/View	Title	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document	Hide
<input type="checkbox"/>			Partial Waiver 5-10-2016	2.1 05/10/2016	English			Approved	05/09/2016	05/08/2017			
<input type="checkbox"/>			Consent 5-9-2016	1.1 05/09/2016	English								

Submitting an Amendment

The following are the most common amendments that are received but, this is not an exhaustive list. Please look to Appendix A for a more comprehensive list.

Personnel Change

1. Select IRB Amendment Form once you have opened the study you wish to submit the amendment for

Study Status:	Approved	IRB Number :	16.0311	Study Title :
		IRB Expiration Date:	05/08/2017	

Submissions **Study Management**

Protocol Items

Protocol Items
<input type="radio"/> Study Application
<input type="radio"/> Informed Consent
<input type="radio"/> Other Study Documents
<input type="radio"/> Contract Documents

Submission Forms

Forms
<input type="radio"/> Initial Review Submission Packet
<input type="radio"/> Serious Adverse Event Reporting Form
<input type="radio"/> IRB Amendment Form
<input type="radio"/> IRB Continuing Review Application
<input type="radio"/> IRB Deviation/Violation/Misc.
<input type="radio"/> IRB Emergency Use Followup Report
<input type="radio"/> IRB UPIRTSO Form

2. Select "Add a New Form"

--	--	--	--

List of records associated with form: IRB Amendment Form.
To view previous versions click on the folder icon .

4 result(s) found...

3. Continue with the form and select "Personnel Change" for question 1.2
4. Select "Save and Continue"
5. This screen will populate the box for you to **add or remove** personnel.
 - a. **NOTE: YOU DO NOT HAVE TO ADD EVERYONE THAT WAS ALREADY APPROVED ON THE STUDY EXCEPT FOR THE PI.** This is only for new, unapproved team members.
6. Depending on the role of the individual, select the section to add the personnel but clicking on the "Add" button
 - a. **NOTE:** If the individual you are adding is going to be making any submissions in iRIS (ex. a regulatory coordinator or study coordinator) add them to Research Staff and give them the designation of KSP in the drop down box.
 - b. **NOTE:** Please ensure that the individuals you are adding have already completed their required training, attached their CV, and submitted their ADF.

- 1.0 Amendment
- 2.0 Personnel Change
- 3.0 Attachments

2.0 Personnel Change

2.1 Personnel Change (please be sure to update Waivers and/or Consents when you add or remove personnel)

***Please add a Principal Investigator for the study:**

+ Add

If applicable, please select the Protocol Staff personnel:

A) Additional Investigators + Add

B) Research Staff + Add ✖ Remove

Singleton, User

***Please add a Study Contact:**

+ Add

The Project Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

Please select any existing Personnel you wish to remove:

+ Select

7. To **remove** personnel from the study, click on the “Select” button at the bottom of the box.
8. Choose the individual you wish to remove.

Save Selections

<input type="checkbox"/>	Name	Role on the Study
<input type="checkbox"/>	User Dearing	Principal Investigator
<input checked="" type="checkbox"/>	User Dearing	Study Contact
<input type="checkbox"/>	User Singleton	Co-Investigator

9. Select “Save Selections”
10. Select “Save and Continue”

Print Friendly
Save Section
Save and Continue to Next Section

Section view of the Form

Entire view of the Form

1.0 Amendment

2.0 Personnel Change

3.0 Attachments

2.0 Personnel Change

2.1 Personnel Change (please be sure to update Waivers and/or Consents when you add or remove personnel)

***Please add a Principal Investigator for the study:**

+ Add

If applicable, please select the Protocol Staff personnel:

A) Additional Investigators + Add

B) Research Staff + Add ✖ Remove

Singleton, User

***Please add a Study Contact:**

+ Add

The Project Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

Please select any existing Personnel you wish to remove:

Dearing, User Study Contact

+ Select
✖ De-select

Protocol Change (Application Change)

1. After opening a study, select “IRB Amendment Form.”

Study Status: Approved	IRB Number : 16.0311	Study Title :
	IRB Expiration Date: 05/08/2017	

Submissions **Study Management**

Protocol Items

Protocol Items
<input type="radio"/> Study Application
<input type="radio"/> Informed Consent
<input type="radio"/> Other Study Documents
<input type="radio"/> Contract Documents

Submission Forms

Forms
<input type="radio"/> Initial Review Submission Packet
<input type="radio"/> Serious Adverse Event Reporting Form
<input type="radio"/> IRB Amendment Form
<input type="radio"/> IRB Continuing Review Application
<input type="radio"/> IRB Deviation/Violation/Misc.
<input type="radio"/> IRB Emergency Use Followup Report
<input type="radio"/> IRB UPIRTSO Form

2. Select “Add a New Form”

--	--	--	--

List of records associated with form: IRB Amendment Form.
To view previous versions click on the folder icon .

4 result(s) found...

3. Continue with the form and select “Protocol Change” for question 1.2
4. Answer the following questions as they pertain to your study
5. If this study is changing anything in the application (ex. study sites, study billing information, enrollment of special populations—prisoners, wards of state, etc., funding source) you **MUST** edit the application.
 - a. Select the “Click here to attach the application” button for question 2.4

2.4 Application changes	
Click here to attach the application.	
No Application has been associated with this submission.	

- b. Select “Add Revision”

Attaching Study Application
✕

Select the application that you would like to attach and then click Save Attachment

Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
<input type="radio"/>			IRB Study Application (Version 1.2)	No	 Add Revision

- c. Select “Ok” to the popup asking you to acknowledge creating a new version of the application

Confirm the adding a revision.
Are you sure you want to create a revision?

OK

Cancel

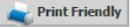
- d. Make any needed changes to application.
- i. **NOTE:** Some changes (ex. adding special population groups) will require you to answer additional questions that you did not have to answer before.
- e. Click “Save and Continue to Next Section” until you reach the end of the initial application
- f. The new application will be now be attached with a new version number

2.4 Application changes

Click here to attach the application.

Remove	Show Rev.	Edit/View	Version	Title
			1.3	IRB Study Application (Version 1.3) - Attached

6. If this Protocol/Application Amendment also changes something in the written protocol **or** the informed consent you **MUST** attach this as well
- Select "Save and Continue to Next Section" from section 2 of the amendment form

 Print Friendly
  Save Section
  Save and Continue to Next Section

Section view of the Form

- 1.0 Amendment
- 2.0 Protocol Change
- 3.0 Attachments

Entire view of the Form

3.0 Attachments

3.1 Please attach (if applicable):

- Revised Protocol
- Revised Consent Forms
- Revised Assent Forms
- Revised Preamble
- Revised HIPAA Documents (don't forget to make personnel changes on the Partial Waiver form)
- Revised Investigator's Brochure
- DSMB Report
- External SAE Report
- Any other documents related to this amendment

When possible, attach Word documents instead of PDFs.

 Select or Revise Existing
 Add a New Document
 Add Multiple Documents

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

- To edit an already existing document (approved with a previous submission) click "Select or Revise Existing"
- Select "Create Revision" on the document you wish to edit
- Change the version date to the current date
- Select "Check Out Document"
- Wait until the document downloads to your computer
 - For Chrome Users: This document will download to the bottom of the screen.
 - For Internet Explorer Users: Select "Open" to the pop-up at the bottom of the screen. You can also click "Save" to save a copy on your computer. You will then have to go to that location to access the document.
 - For Firefox Users: Select "Open with: Microsoft Word" and then select "Ok"
 - For Safari Users:
- Click to open the document that has just downloaded
- Select "Complete Check Out"

Version 9/7/2016

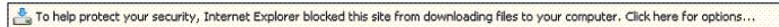
Download the Study Document

Back

INSTRUCTIONS

Step 1:

If your browser blocks pop - ups, then after a few moments a bar similar to the one shown below may appear in your browser.



Simply click on the bar and a small drop down list will appear. Click **Download File** from the list of options.

**Step 2:**

In a few moments, your browser will prompt you to either **Open** or **Save** the file (see example below).

Note: this is not the actual File Download box, it is only a picture. In order to Check - out the document and edit it, you will need to **Save** it to your workstation.



Complete Checkout

Cancel

To do so, click **Save**. This will open up a window similar to the one shown below that allows you to choose where in your workstation you would like to save the document.

Once you've selected where you will save the document, click **Save**. After this, the Download Complete box will appear as shown below. From here you can choose to open the document to edit it, open the folder that contains the document, or Close the Download Complete box to edit the document later.

Step 3:

IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete box that you click the **Complete Checkout** button in iRIS. This allows you to check the document (or upload the document) back into iRIS once you've finished editing it. To cancel the Document Check - Out, click **Cancel**. Note: If you've already saved the file to your computer, the file will remain in your computer, however you will simply lose the option of checking the document back in.

- i. Make your revisions to the document and save somewhere on your computer
- j. Select "Check-in Document"

Study Document Revision:	
* Document Title:	Protoc of revised 5-9-2016
Version Number:	2 .1
* Version Date:	05/09/2016 
Category:	Protocol
Description:	<div style="border: 1px solid gray; height: 40px;"></div>
This document is currently checked out by.	User Singleton at 06/10/2016
Check-in when you are done editing upload the document back into iRIS.	<input type="button" value="Check-in Document..."/>
Revert to the document stored in iRIS.	<input type="button" value="Undo Check-out Document..."/>
Comments:	<div style="border: 1px solid gray; height: 30px;"></div>

- k. Select "Choose File" to browse your computer for the file
- l. Select "Save selected file"

Document Location: No file chosen

Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

m. To add a new document that was **not** previously submitted/reviewed select “Add a New Document”

Section view of the Form

- 1.0 Amendment
- 2.0 Protocol Change
- 3.0 Attachments

Entire view of the Form

3.0 Attachments

3.1 Please attach (if applicable):

- Revised Protocol
- Revised Consent Forms
- Revised Assent Forms
- Revised Preamble
- Revised HIPAA Documents (don't forget to make personnel changes on the Partial Waiver form)
- Revised Investigator's Brochure
- DSMB Report
- External SAE Report
- Any other documents related to this amendment

When possible, attach Word documents instead of PDFs.

Select or Revise Existing
 Add a New Document
 Add Multiple Documents

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
✖	2.1	Protocol revised 5-9-2016	Protocol				 52.90 KB

n. Enter the document title, upload the document, and Select “Save Document”

Version 9/7/2016

Study Document Add: X

* Document Title:	<input style="width: 80%;" type="text"/>
* Select the document to upload:	<input type="button" value="Choose File"/> No file chosen
* Version Number:	<input style="width: 50px;" type="text" value="1"/> . <input style="width: 20px;" type="text" value="0"/>
* Version Date:	<input style="width: 80px;" type="text" value="06/10/2016"/> <input type="button" value="Calendar"/>
Category:	<input style="width: 80%;" type="text" value="--none--"/> ▼
Description:	<div style="border: 1px solid gray; height: 40px;"></div>
Comments:	<div style="border: 1px solid gray; height: 40px;"></div>

7. Once the documents have been added/revised select "Save and Continue to Next Section"
8. Answer the rest of the questions and submit

Study Closure

1. Open the study, click "IRB Amendment Form"

Study Status: Approved	IRB Number : 16.0311	Study Title :
	IRB Expiration Date: 05/08/2017	

Submissions
Study Management

Protocol Items

Protocol Items
<input type="radio"/> Study Application
<input type="radio"/> Informed Consent
<input type="radio"/> Other Study Documents
<input type="radio"/> Contract Documents

Submission Forms

Forms
<input type="radio"/> Initial Review Submission Packet
<input type="radio"/> Serious Adverse Event Reporting Form
<input type="radio"/> IRB Amendment Form
<input type="radio"/> IRB Continuing Review Application
<input type="radio"/> IRB Deviation/Violation/Misc.
<input type="radio"/> IRB Emergency Use Followup Report
<input type="radio"/> IRB UPRTSO Form

2. Select “Add a New Form”



Copy Form Add a New Form Compare Two Versions Delete Selected Form(s)

i List of records associated with form: IRB Amendment Form.
To view previous versions click on the folder icon .

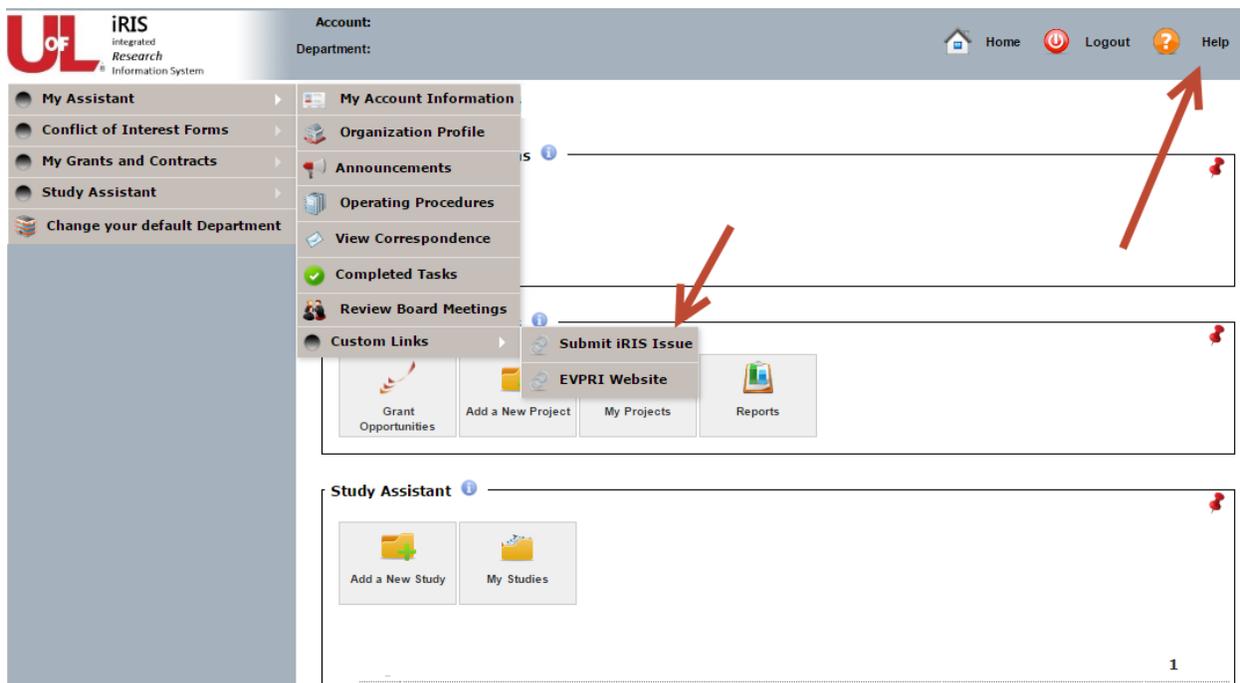
4 result(s) found...

3. Continue with the form and select “Study Closure” for question 1.2
4. Answer the following questions as they pertain to your study

Training—Submitting a Ticket for Update

If you have completed the required Human Subjects and HIPAA trainings (see HSPPO [website](#)) and iRIS is still indicating that you do not have adequate training, please use the instructions below to file a ticket to get this resolved.

1. Click on either the “Help” button or My Assistant—Custom Links—Submit iRIS Issue



UL iRIS
Integrated Research Information System

Account: _____
Department: _____

Home Logout Help

My Assistant

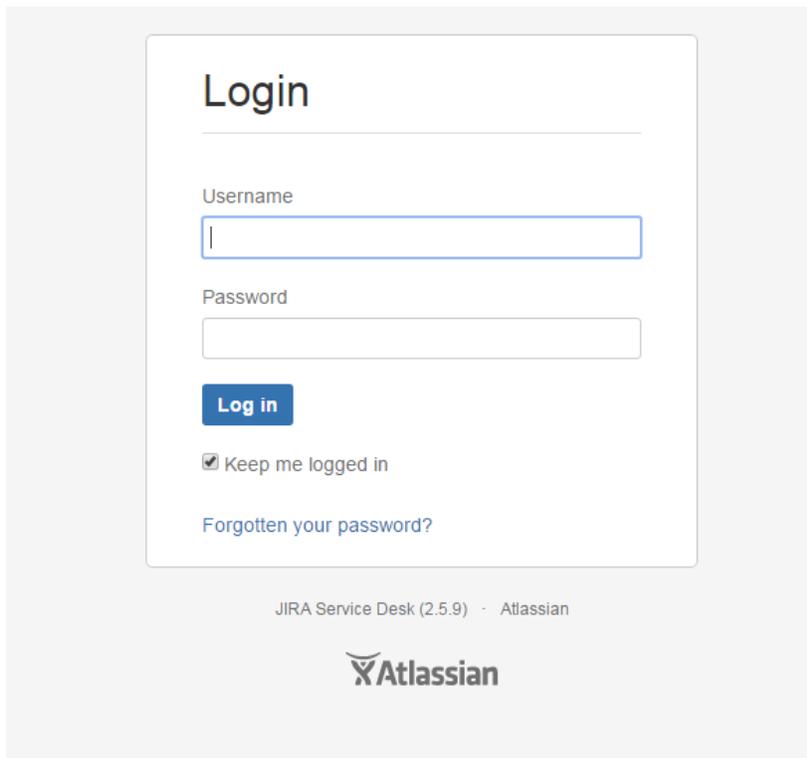
- My Account Information
- Organization Profile
- Announcements
- Operating Procedures
- View Correspondence
- Completed Tasks
- Review Board Meetings
- Custom Links
 - Submit iRIS Issue
 - EVPRI Website
 - Grant Opportunities
 - Add a New Project
 - My Projects
 - Reports

Study Assistant

- Add a New Study
- My Studies

1

2. This will route to the following page.
 - a. You must log in with your UofL userid and password. Just like you would log into iRIS.



3. Click on “Training Update Request”



Welcome! You can raise a iRIS Issues request from the options provided.

Q Find a solution

- iRIS User**
 - Module Administration
 - System Administration
-  **Add a Sponsor**
Use this option to request that a new sponsor be added to iRIS
-  **Report Login Problem**
Use this option to report inability to log into iRIS
-  **Training Update Request** 
Use this option to request that training be updated in iRIS
-  **Report iRIS Issue**
Use this option to report a non-functional aspect of iRIS
-  **Ask a Question**
Use this option to ask a general iRIS question.

4. Describe what you are requesting in the box. If you have completed your CITI training, attach your completion report in the “Attachment” section.
5. Click “Create”
6. You will receive a response to your UofL email address



iRIS Help Center / iRIS Issues

Training Update Request

Describe the training information that is missing from iRIS

Please provide as much detail as possible, including the name(s) of individual(s) completing the training, course titles, approximate completion date(s), affected study(ies)

Attachment (optional)

Choose file(s)

Create Cancel

Please attach any completion reports or other documentation of completed training that can assist in the resolution of the issue.

Training—iRIS Report for Personnel Training/CV/ADF

The easiest way to check a member of your study team’s training, CVs, or Attestation and Disclosure form is to run the report out of iRIS. Note: An individual’s CV will not appear if they did not enter the version date.

1. Log into iRIS
2. Click on “My Grants and Contracts”
3. Click on “Reports”

The screenshot shows the iRIS navigation menu. On the left, there is a vertical list of menu items: My Assistant, Conflict of Interest Forms, My Grants and Contracts, Study Assistant, and Change your default Department. On the right, a secondary menu is expanded, showing options: Grant Opportunities, Add a New Project, My Projects, Find a Project, Reports, and Unpin My Grants and Contracts from the Content Dashboard. A large red arrow points from the top right towards the 'Reports' option in the secondary menu.

4. Click “Current Training,” any of the ADF reports, or “Active CVs—within the last two years”

5. Click “Run Report”

6. The PDF will pop up in a separate screen. Scroll through or click Ctrl+F (Mac Command+F) to look up the individual.

Training—Apex Reports

Apex reports is another option for research teams to check the training of individuals in their department. This report has the ability to search with more criteria. Similar with iRIS Reports, you cannot search by name.

1. Go to the website: <https://apex.louisville.edu>
2. Log in with your UL userid and password.
3. Currently there are two reports that are available: Current ADF Status and Current Research Training

4. Select a report. Enter in the search criteria you wish to use and click refresh.

Home > Current Research Training

Parameters Refresh Print Reset

UofL ID Separate multiple IDs with a comma Department Training Category

Expire Days Unit / School

Training—Adding Personnel to a Study

You can check training for individuals that you are trying to add to your protocol; this can be at the time of initial submission or during a personnel amendment.

1. In the “Assign key study personnel (KSP) access to the study” section (this is located in both the initial application and the amendment form), click on the “Add User” button.

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 RESEARCH NATURE AND APPLICATION TYPES
5.0 SPONSOR
6.0 STUDY SITES
7.0 REVIEW TYPE

3.0 Assign key study personnel(KSP) access to the study

3.1 * Please add a Principal Investigator for the study:

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

B) Research Support Staff

3.3 * Please add a Study Contact:

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

2. Search for the individual.

Directory Browse/Find:

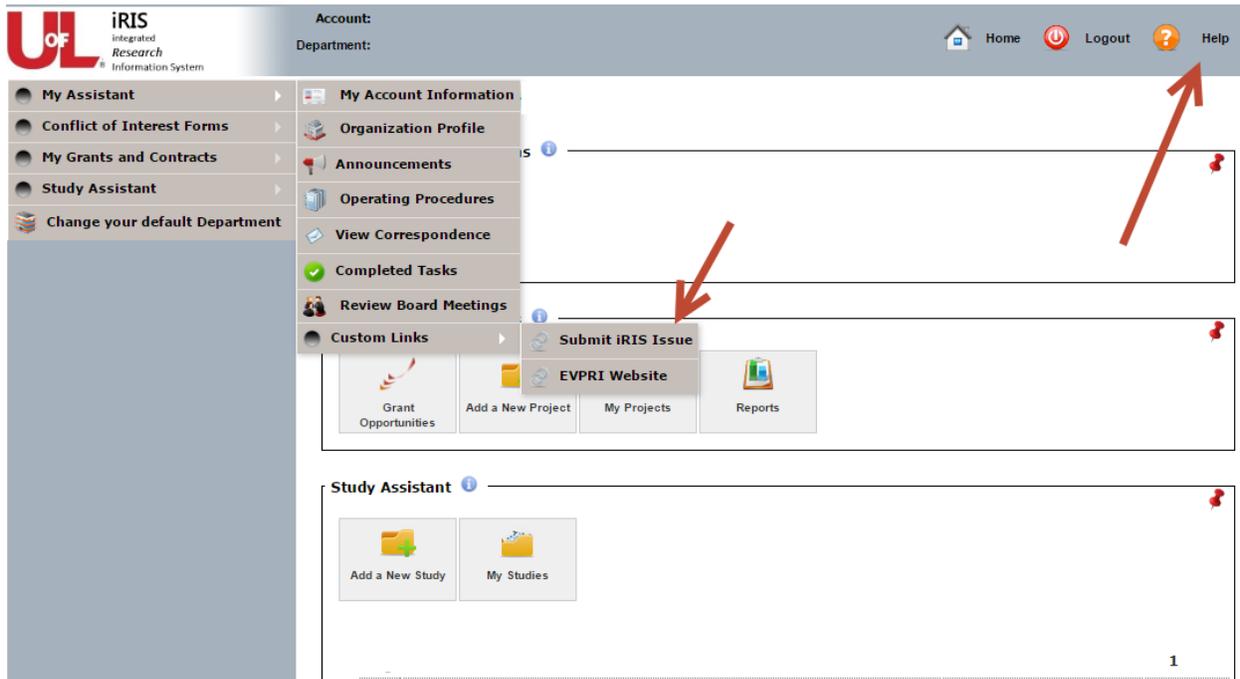
Last Name: (You may enter a partial name to search)
 First Name:
 by Department:
 Search From: iRIS Database LDAP Directory

3. Click on the “Training” icon next to the person that you are adding.

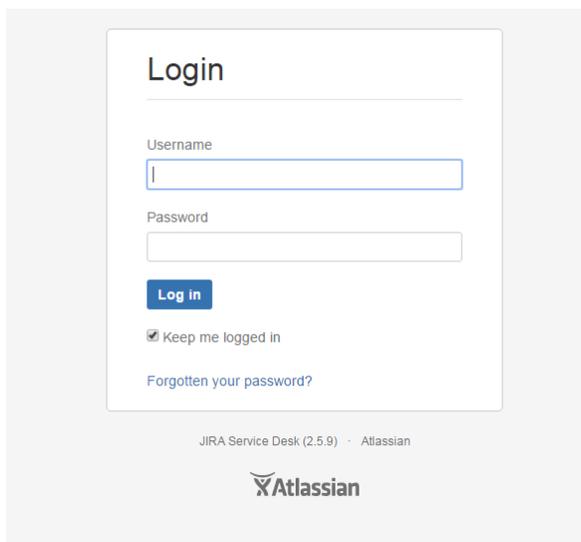
Adding a Sponsor to iRIS

If you notice that your sponsor information (name) is not pulling up in the application form, the sponsor may not be in the system. You must request that the sponsor be added to iRIS by submitting a ticket to the iRIS administrators.

1. Click on the “Help” button or My Assistant—Custom Links—Submit iRIS Issue



2. This route will take you to the following page.
 - a. You must log in with your UofL userid and password. Just like you would in iRIS.



3. Click on “Add a Sponsor”

UNIVERSITY OF iRIS Help Center
LOUISVILLE iRIS Issues

Welcome! You can raise a iRIS Issues request from the options provided.

iRIS User

[Module Administration](#)

[System Administration](#)



Add a Sponsor
Use this option to request that a new sponsor be added to iRIS



Report Login Problem
Use this option to report inability to log into iRIS



Training Update Request
Use this option to request that training be updated in iRIS



Report iRIS Issue
Use this option to report a non-functional aspect of iRIS



Ask a Question
Use this option to ask a general iRIS question.

4. Include the name of the entity, full address, and web address, if applicable.
5. Click "Create"
6. You will be notified by the System Administration team via UL email once this task has been completed.

 [iRIS Help Center](#) / [iRIS Issues](#)
Add a Sponsor

Description

Please provide the following: full legal name of entity; full address; web address, if applicable.

Create [Cancel](#)

Submitting a Continuing Review (CR)

1. Click "Study Assistant"
2. Click "My Studies"
3. Click "Open"
4. Click "IRB Continuing Review Application" to open a CR form.

Submission Forms

Forms	
<input type="radio"/>	Initial Review Submission Packet
<input type="radio"/>	Serious Adverse Event Reporting Form
<input type="radio"/>	IRB Amendment Form
<input type="radio"/>	IRB Continuing Review Application
<input type="radio"/>	IRB Deviation/Violation/Misc.
<input type="radio"/>	IRB Emergency Use Followup Report
<input type="radio"/>	IRB UPIRTSO Form

5. Click "Add a New Form"

 Copy Form
 Add a New Form
 Compare Two Versions
 Delete Selected Form(s)

 List of records associated with form: IRB Continuing Review Application.
To view previous versions click on the folder icon .

 result(s) found

6. Answer the questions as they pertain to your study.
7. **NOTE:** If there are any changes to study personnel please update this in the CR application. There is a questions specifically for this. If you study as a Complete/Partial Waiver, please attach an updated copy of your document with the accurate listing of study team members.

Submitting a Deviation

1. Click "Study Assistant"
2. Click "My Studies"
3. Click "Open"
4. Click "IRB Deviation/Violation/Misc"

Submission Forms

Forms	
<input type="radio"/>	Initial Review Submission Packet
<input type="radio"/>	Serious Adverse Event Reporting Form
<input type="radio"/>	IRB Amendment Form
<input type="radio"/>	IRB Continuing Review Application
<input type="radio"/>	IRB Deviation/Violation/Misc.
<input type="radio"/>	IRB Emergency Use Followup Report
<input type="radio"/>	IRB UPIRTSO Form

5. Click “Add a New Form”

 Copy Form
  Add a New Form
  Compare Two Versions
  Delete Selected Form(s)

 List of records associated with form: IRB Continuing Review Application.
 To view previous versions click on the folder icon .

 result(s) found

6. Answer the questions as they pertain to your study

Submitting an Unanticipated Problem Involving Risks to Subjects or Others

1. Click “Study Assistant”
2. Click “My Studies”
3. Click “Open”
4. Click “IRB UPIRTSO Form”

Submission Forms

Forms	
<input type="radio"/>	Initial Review Submission Packet
<input type="radio"/>	Serious Adverse Event Reporting Form
<input type="radio"/>	IRB Amendment Form
<input type="radio"/>	IRB Continuing Review Application
<input type="radio"/>	IRB Deviation/Violation/Misc.
<input type="radio"/>	IRB Emergency Use Followup Report
<input type="radio"/>	IRB UPIRTSO Form

5. Click “Add a New Form”

 Copy Form
  Add a New Form
  Compare Two Versions
  Delete Selected Form(s)

 List of records associated with form: IRB Continuing Review Application.
 To view previous versions click on the folder icon 📁.

 2 result(s) found

6. Answer the questions as they pertain to your study

Appendix A--Link to IRB Resources

Please use the links below to access helpful links for guiding your through the policies and regulations of human subjects research. If you have any questions please call the University of Louisville Human Subjects Protection Program Office, 502.852.5188 or email hsppofc@louisville.edu

UofL Human Subjects Protection Program Office--<http://louisville.edu/research/humansubjects/>

Biomedical Templates (ex. Consent and Research Authorization, Assents, HIPAA Complete Waiver, Billing Compliance Table, etc.)-- <http://louisville.edu/research/humansubjects/templates/biomedical-forms>

Social/Behavioral/Educational Templates (ex. Preamble, Informed Consent, Info for research conducted in JCPS system, Certification of Accuracy for Translation, etc.)--
<http://louisville.edu/research/humansubjects/templates/sbe-forms>

Sponsored Account Form--

http://louisville.edu/research/humansubjects/templates/SponsoredAccountRequestForm_2142014.pdf

Guides (Internal and External Policies and Instructions) —

<http://louisville.edu/research/humansubjects/policies/guides>

Guides

#001	Additional Protections for Minors – FDA	#017	Informed Consent- Dos and Don'ts
#002	Additional Protections for Minors- OHRP	#018	Informed Consent- Minors
#003	Additional Protections for Pregnant Women, Fetuses, and Neonates	#019	Informed Consent- Required Criteria
#004	Additional Protections for Research Involving Prisoners	#020	Informed Consent- Waiver of Consent
#005	Definitions	#021	Informed Consent- Optional Consent within Main Consent
#006	Approved Sources of Public Use Data	#022	IRB- Approval Criteria
#007	Common Terms and Acronyms	#023	IRB- Events that Require Prompt Reporting to the IRB
#008	Conflicting Interests of IRB Members	#024	IRB- Review Fees
#009	Emergency Use of a Test Article	#025	Is My Project Research?
#010	Exempt Review Categories	#026	What Qualifies as Human Subjects Research?
#011	Expedited Review Categories	#027	Quality Assurance - Quality Improvement
#012	FDA- Special Considerations for the Oversight of Research of FDA-Regulated Drugs or Devices	#028	Significant and Non-Significant Devices
#013	FDA-IND Application Guidance	#029	Recruitment Tools
#014	Federal Agencies- Additional Reporting Requirements	#030	Paying Human Subjects
#015	Federal Grants and IRB Review	#031	Utilizing the NCI CIRB-Guidance for Investigators
#016	HIPAA and PHI	#032	Acronyms and Hyperlinks
		#033	Documents Stamped by the IRB

Human Research Protection Program Policy Manual (IRB Investigator’s Guide and IRB SOPs) -- <http://louisville.edu/research/humansubjects/policies/hrpp-policies>

IRB Submission Life Cycle-- <http://louisville.edu/research/humansubjects/lifecycle>

(ex. Consent Process Documentation example, SAE Log Template, Eligibility Checklist, Drug Dispensing Log, etc.)-- <http://louisville.edu/research/humansubjects/qip>