IRIS SUBMISSION MANUAL

Human Subjects Protection Program

UNIVERSITY OF LOUISVILLE 502.852.5188

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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.

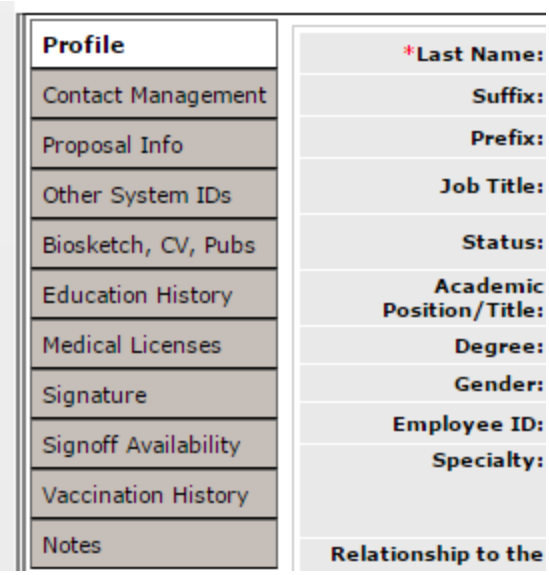
Completing the Attestation and Disclosure Form (ADF)

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

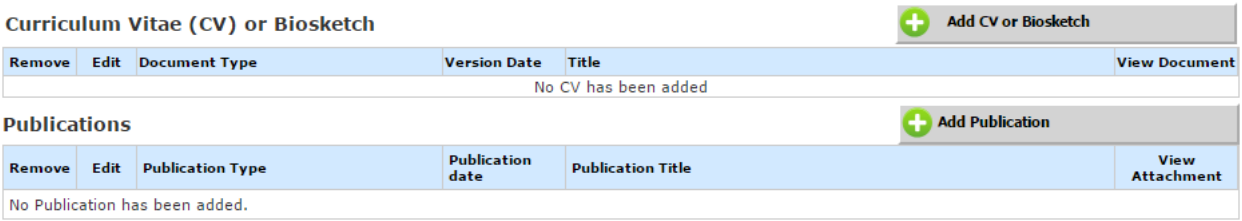
Uploading a CV

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

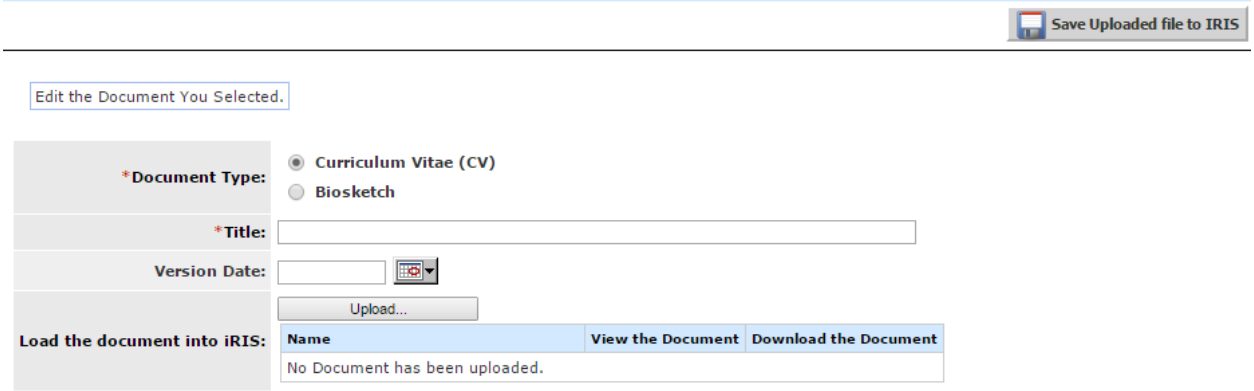
3. Click on “Biosketch, CV, Pubs”



4. Click “Add CV or Biosketch”



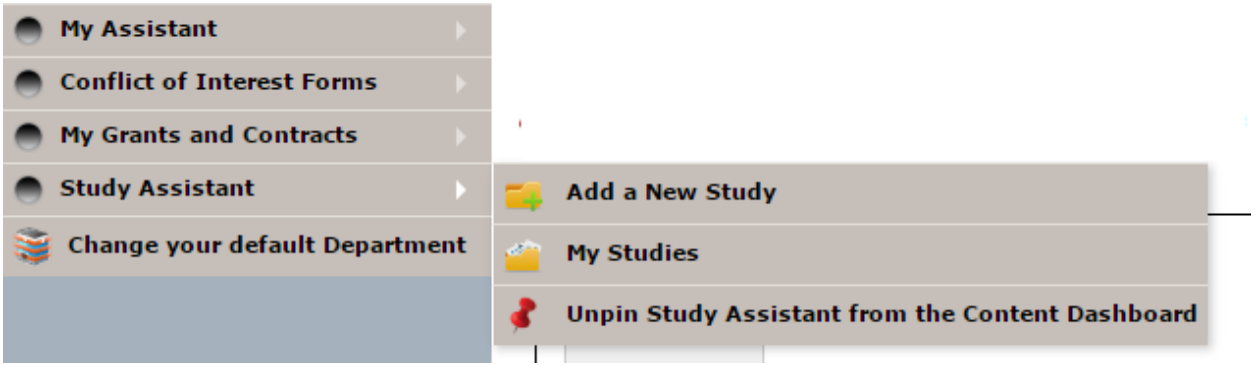
5. Enter in the title of the CV
6. Enter a version date (today's date)
7. Click "Upload"
8. Browse for your CV on your computer
9. Click "Save Selected File"
10. Click "Save Uploaded File to iRIS"



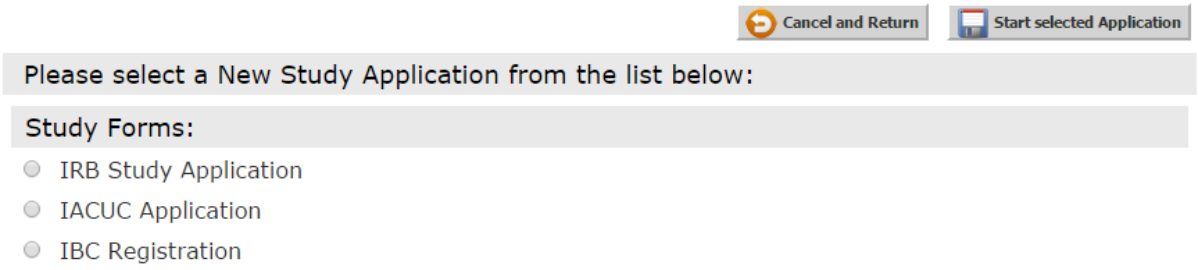
Creating a New Study Submission

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

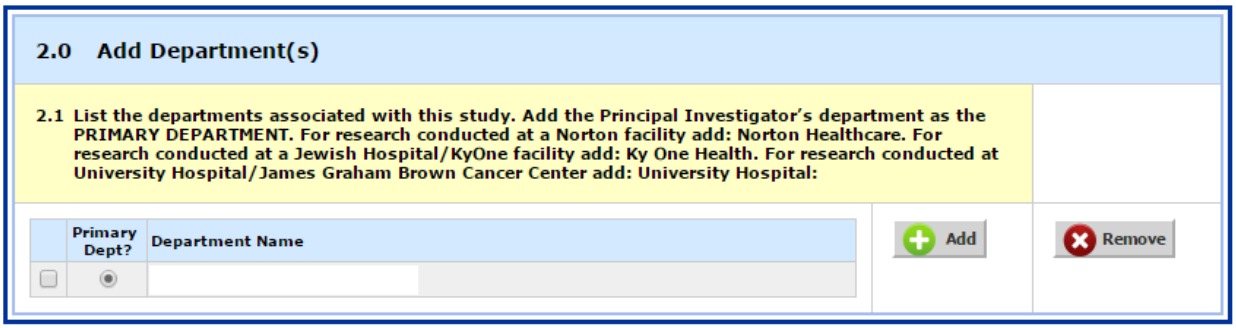
1. Hover the pointer over "Study Assistant" on the left of the page
2. Select "Add a New Study"



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



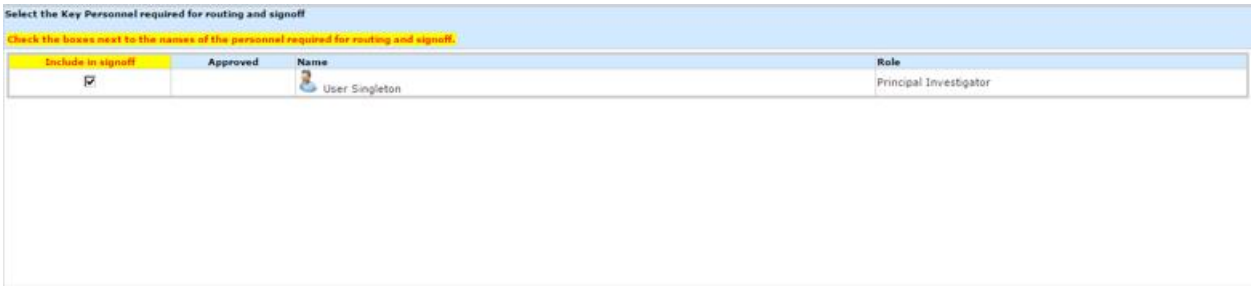
5. Enter the full study title and the Short Study Title
6. Select "Save and Continue"
7. **NOTE:** The department of the person entering in the study will populate in this section. That might not be the same department as the Principal Investigator (PI). You **MUST** add the PI's department and then 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.



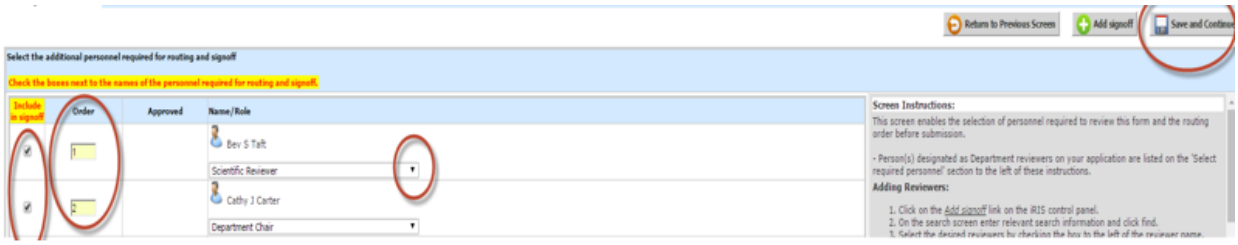
8. Select Save and Continue
9. Add the PI, Additional Investigators and Research Support Staff.
    a. **NOTE:** Research conducted at KyOne Health and Norton's facilities must include them as the Study Contact.
10. The rest of the questions will branch depending on the specifics of your study

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



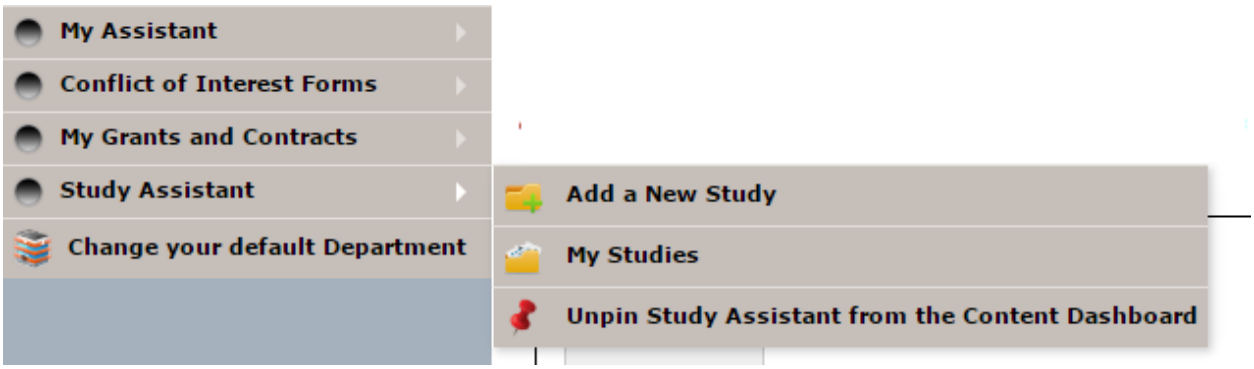
3. You are required to include a scientific reviewer and department chair sign off for all human subjects research submissions except for NHSR, Continuing Review, and Emergency Use submissions.
    a. For some departments, this will be the same person. Please visit our website for a complete list.
4. 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.



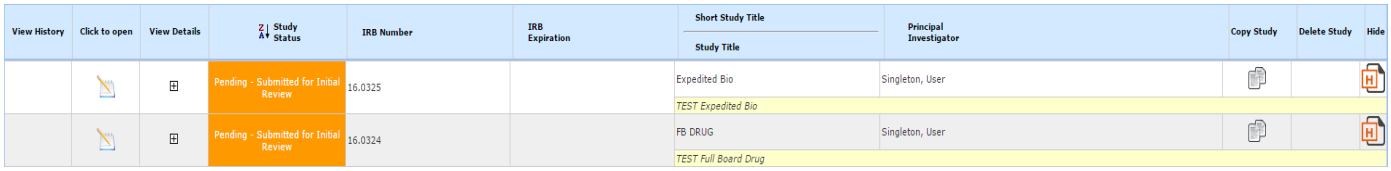
5. Once those individuals have been selected, choose their correct role from the drop down list.
6. **NOTE:** The order does matter! The scientific reviewer must be selected as 1 and the Department Chair must be listed as 2. This is the order in which they will sign off after the PI signs off.
7. Mark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

Checking the Status of the Study

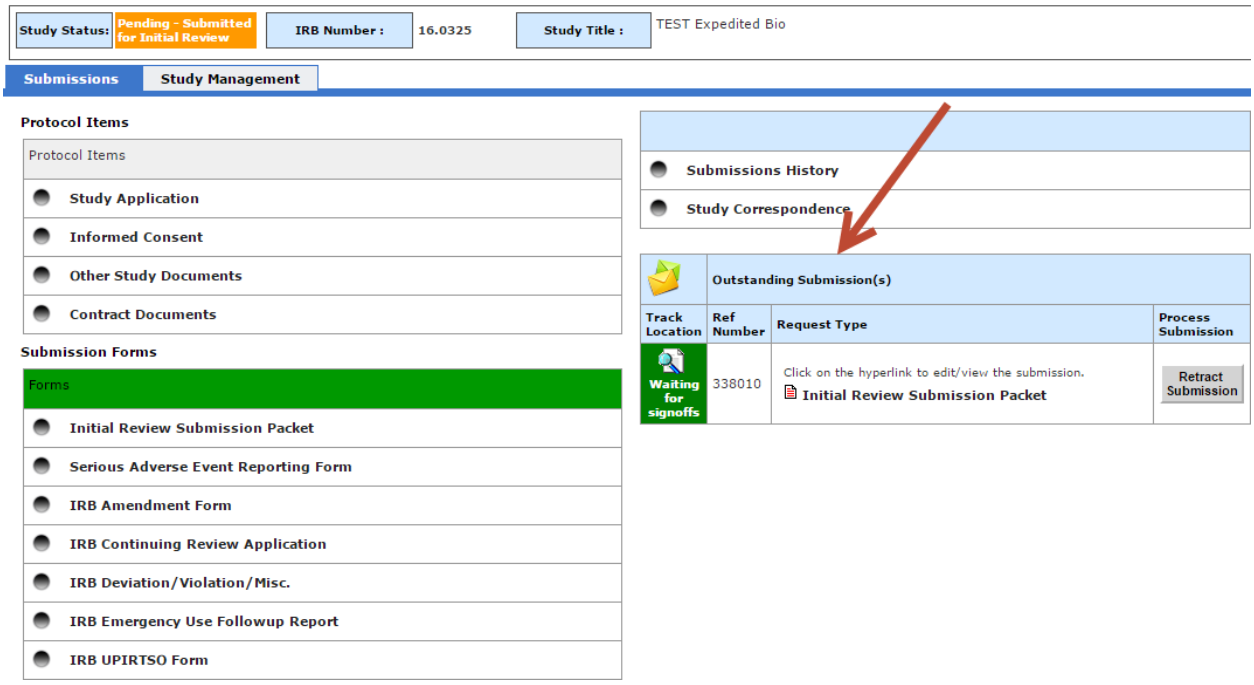
1. Once you have submitted, to check the where the study is in the review process click on "Study Assistant."



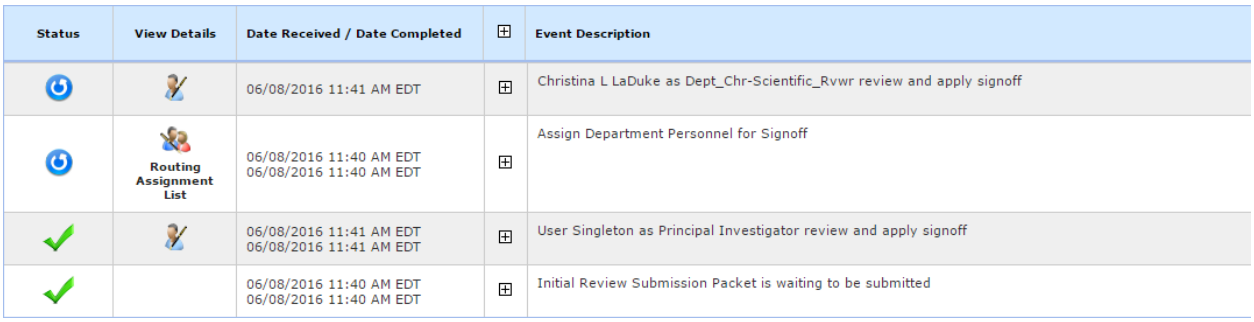
2. Click “My Studies”
3. Select the pencil and paper icon under “Click to open”



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

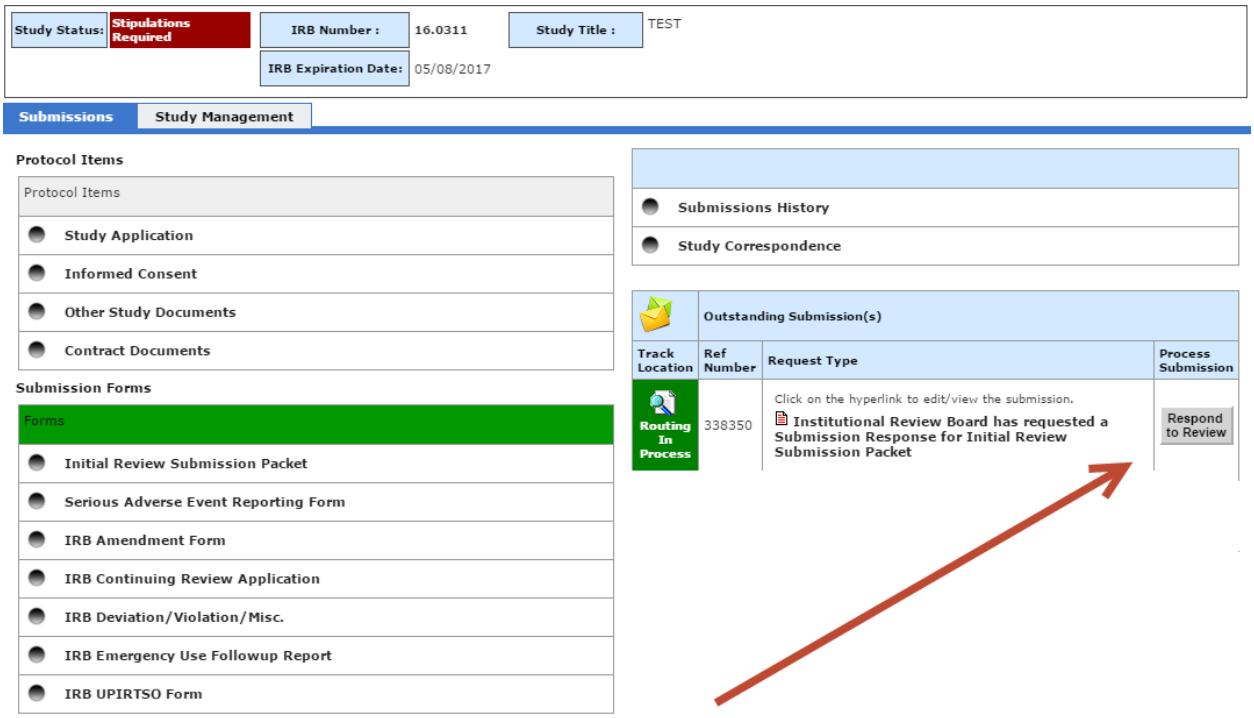


5. This section allows you to see where in the review pipeline your study is. If you select the people icons you can see if the PI, Scientific Reviewer, or Department Chair has signed off.
    a. **Note:** The date on the top is the date that the submission was received. The date on the bottom is when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



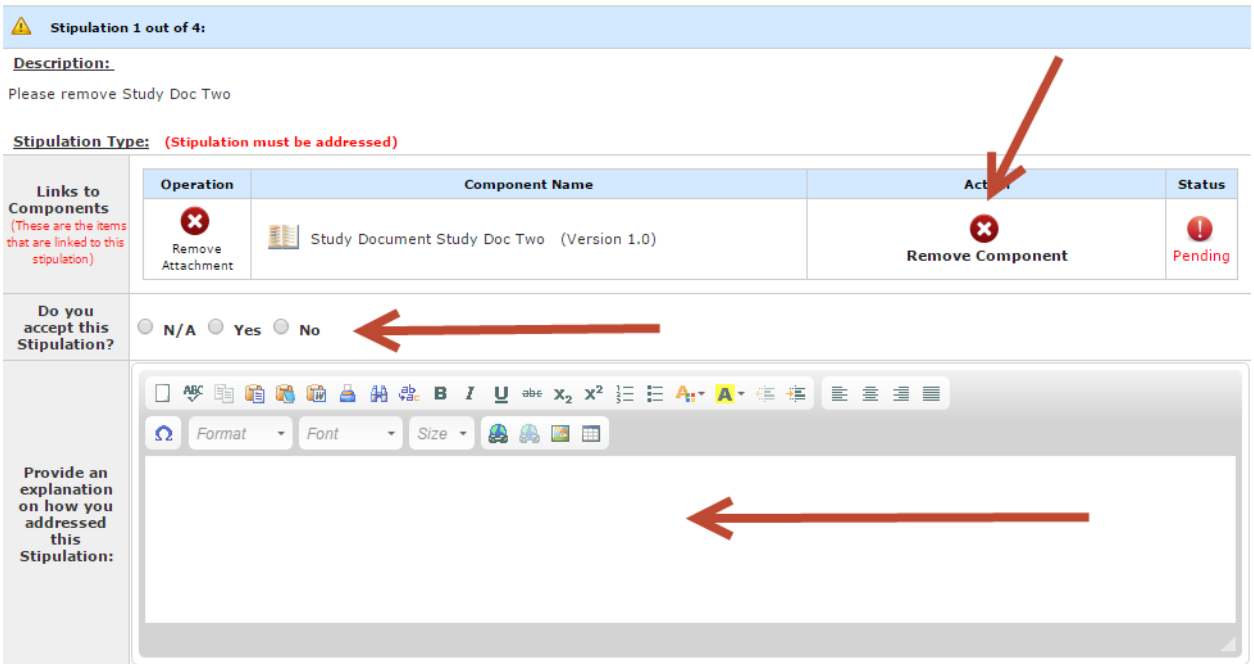
Answering Stipulations

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



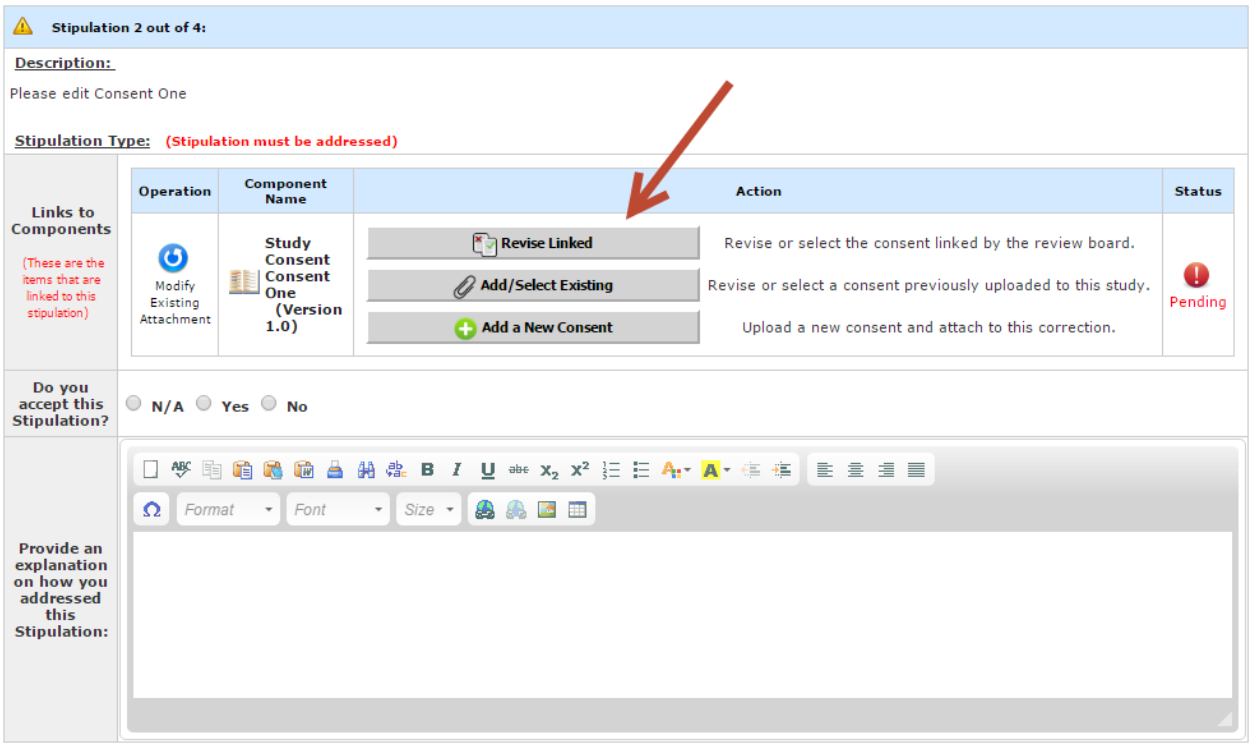
To Remove an Attachment

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

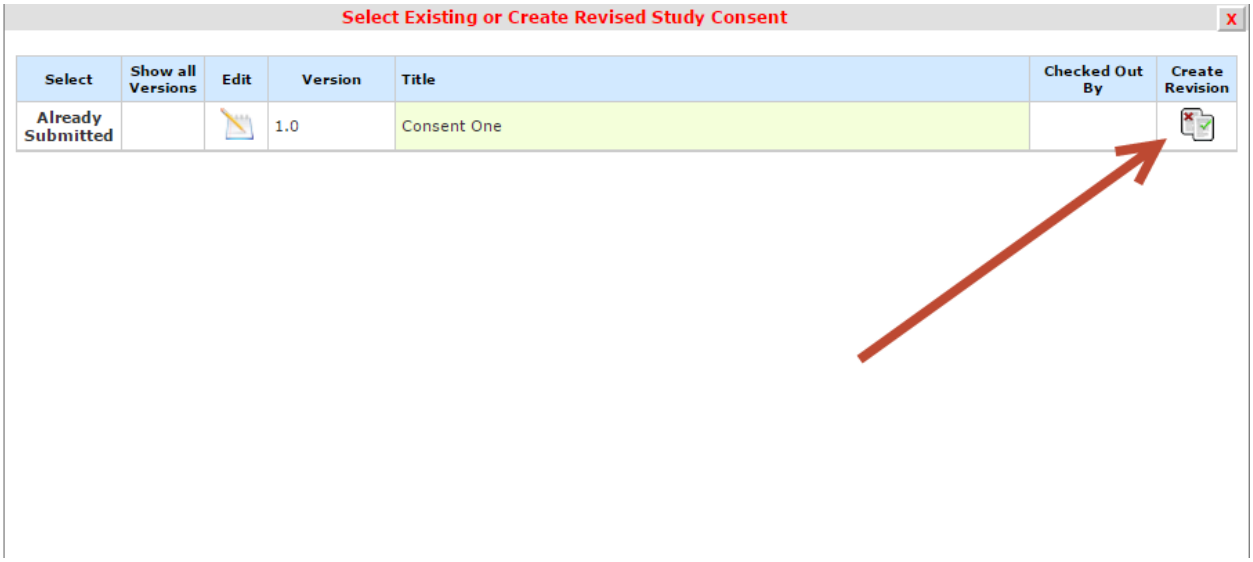


To Edit a Document

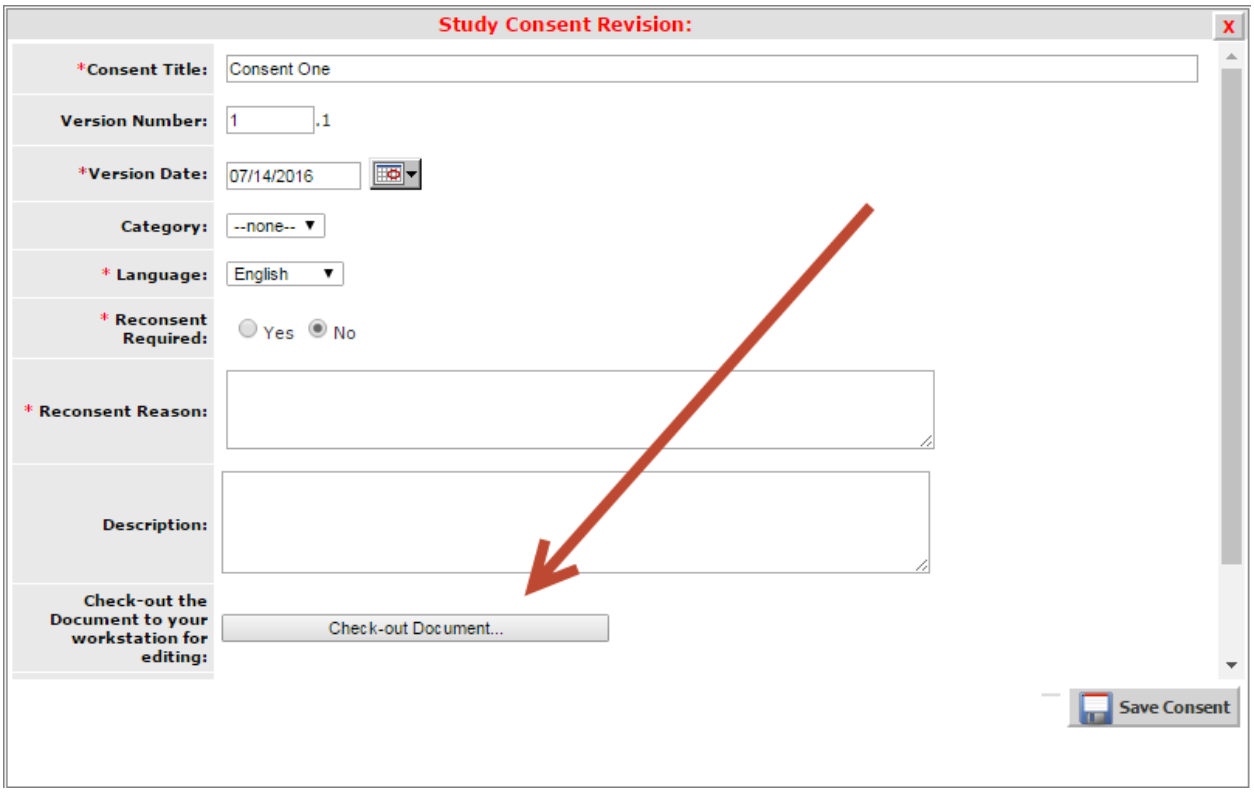
1. Click “Revise Linked”



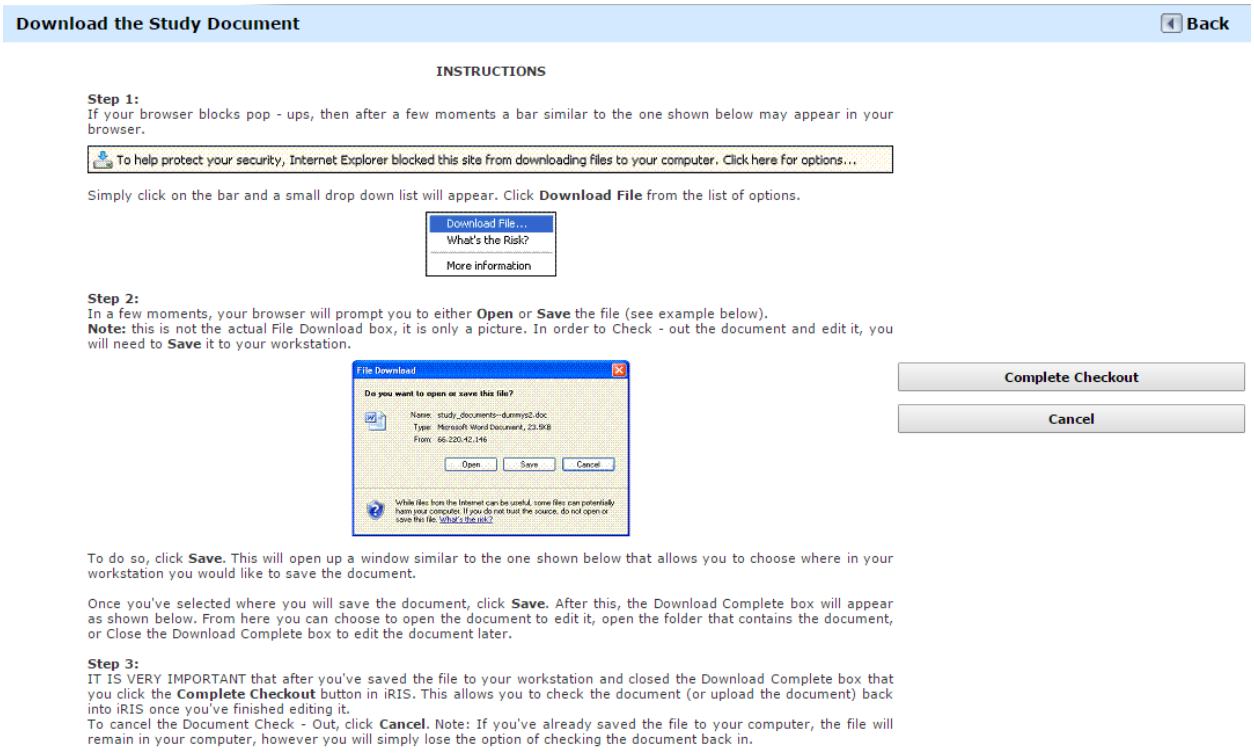
2. On the pop up window, select “Create Revision”



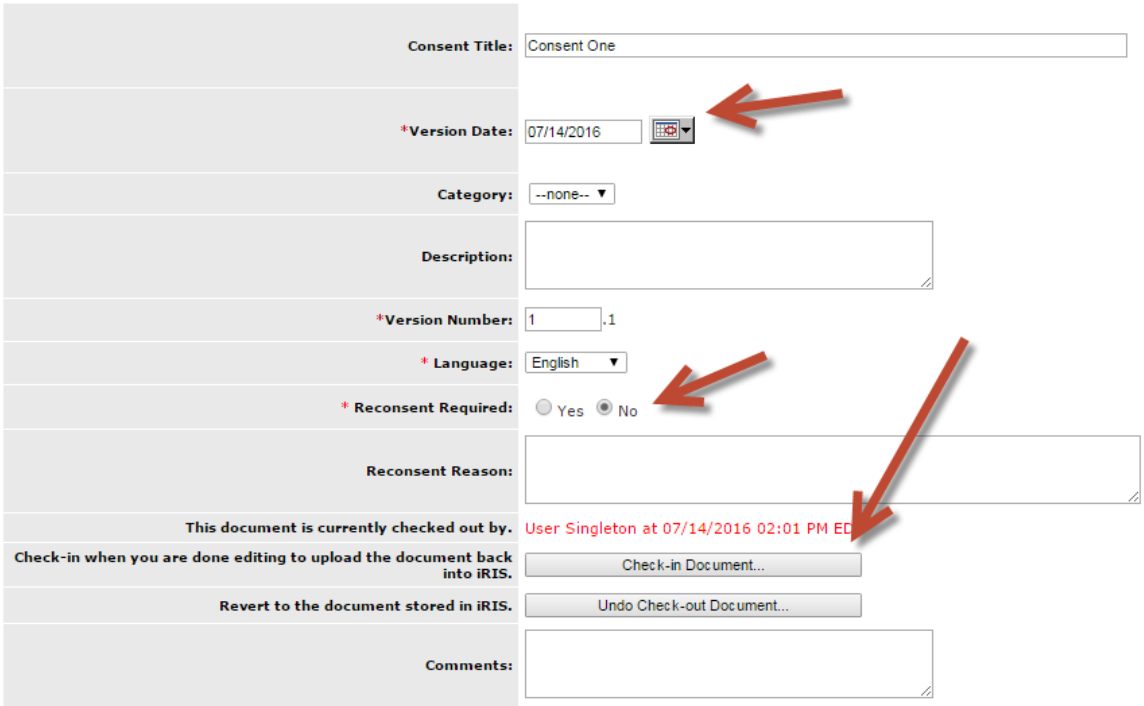
3. Select “Check-out Document”



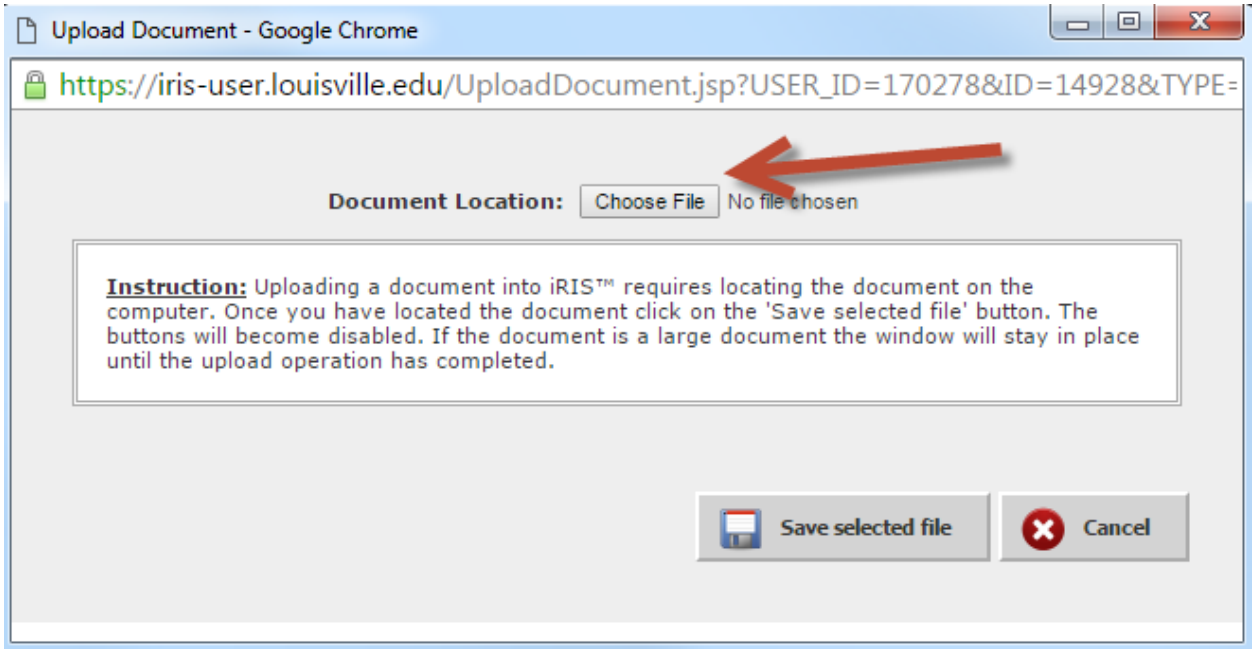
4. Wait until the document downloads
    a. For Chrome users: This document will download to the bottom of the screen.
    b. For Internet Explorer users:
    c. For Firefox users:
    d. For Safari users:
5. Click to open the document that has just downloaded
6. Select “Complete Check Out”



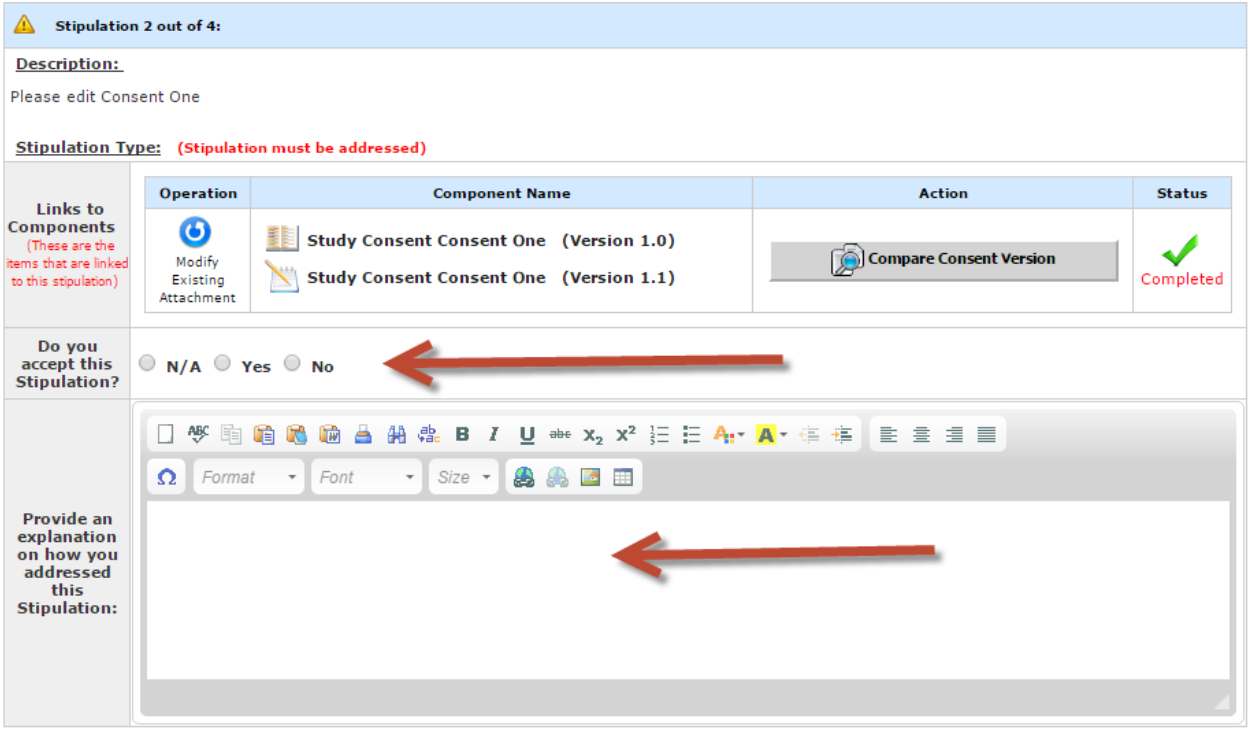
7. Make your revisions to the document and save somewhere on your computer
8. Select “Check-in Document” and update the “Version Date” If re-consenting is required please fill out that portion as well.



9. Select “Choose File” to browse your computer for the file

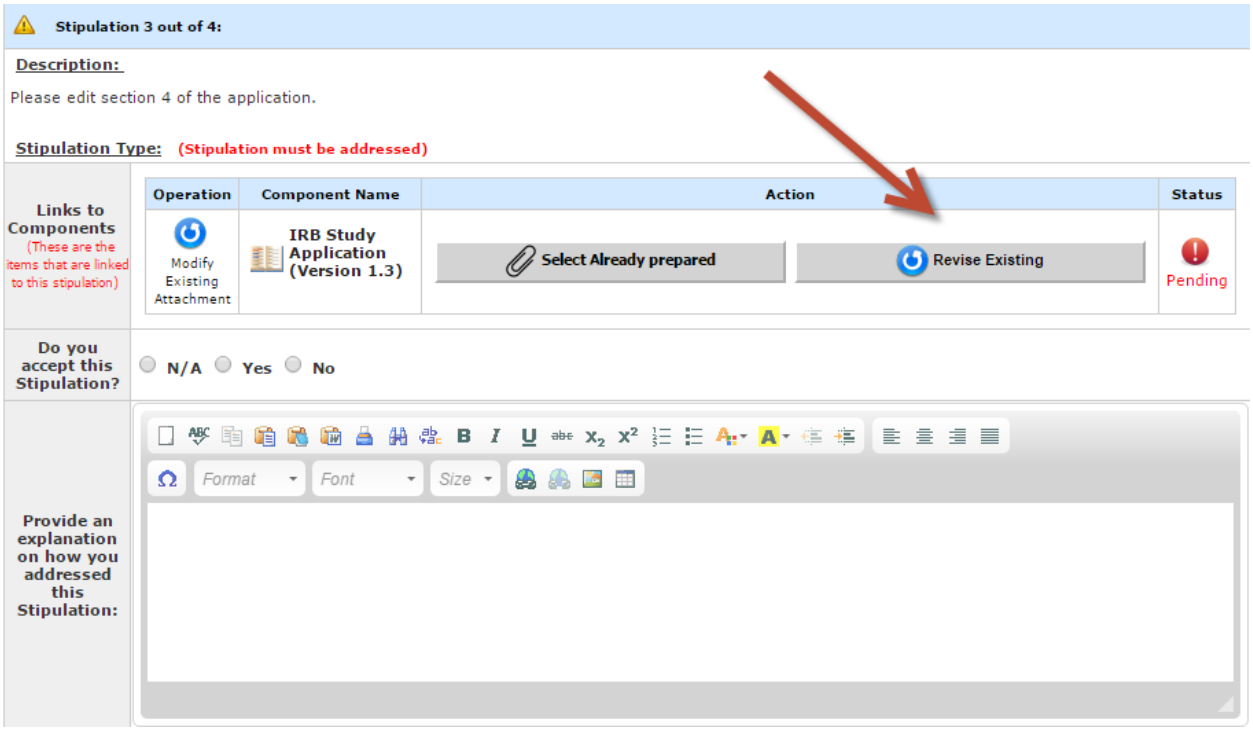


10. Select “Save selected file”
11. Once back to the Review Response Submission Form, you will see that the stipulation has been completed with a green check mark.
12. Accept or Deny the stipulation
13. Provide an explanation on how you addressed the stipulation.

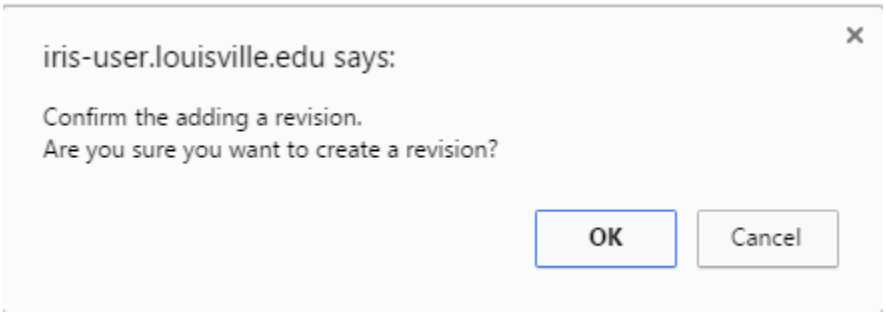


To edit the Application

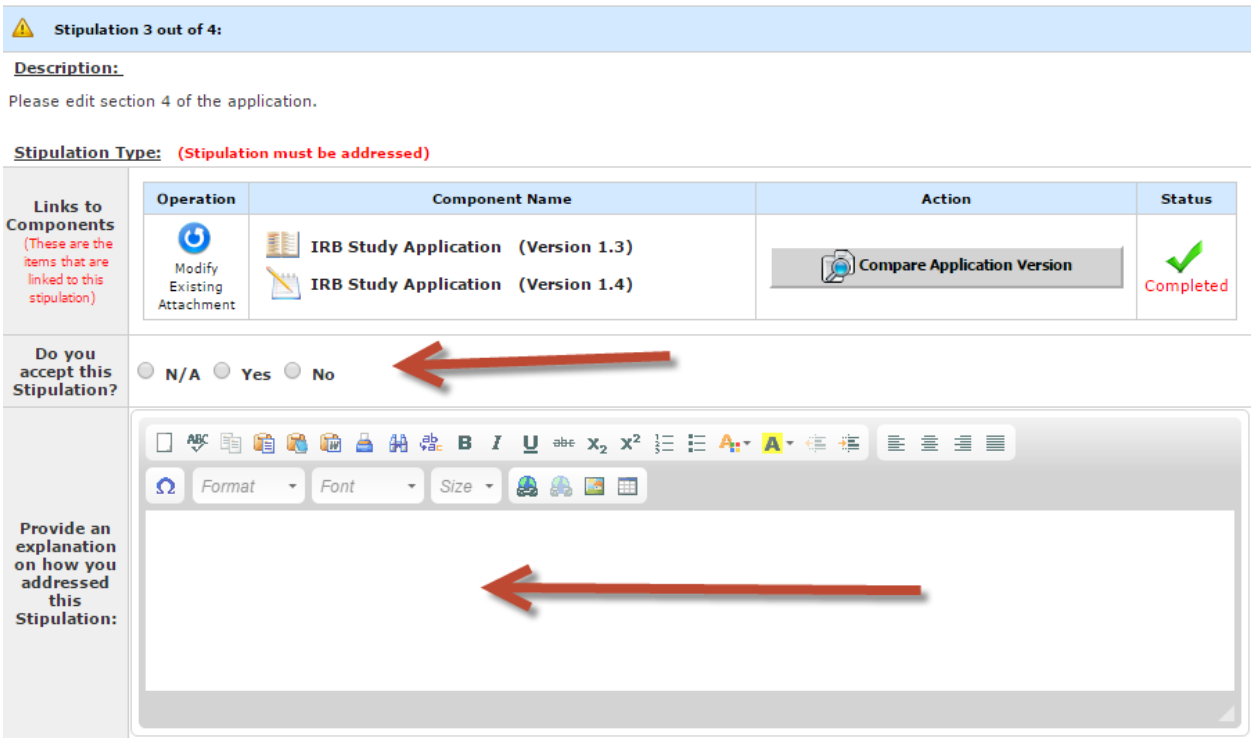
1. Click “Revise Existing”



2. Click “Ok” to adding a revision.



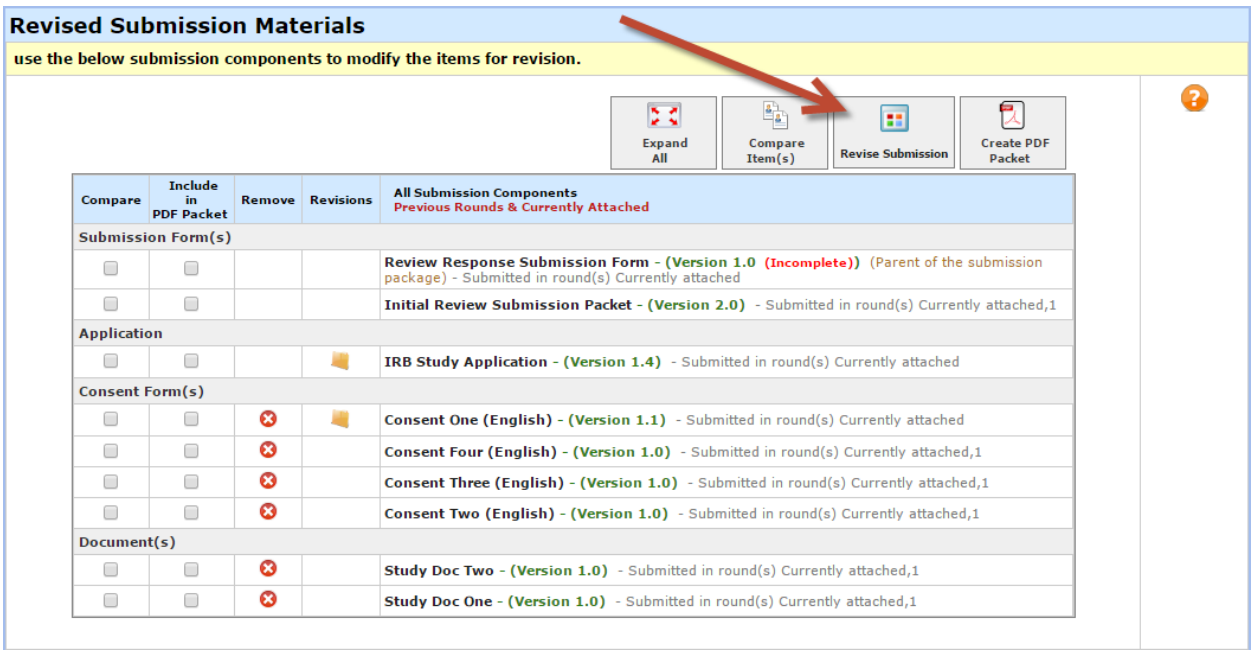
3. Make the change to the section that needs to be revised
4. Click “Save and Continue to Next Section” until you are routed back to the Review Response Submission Form



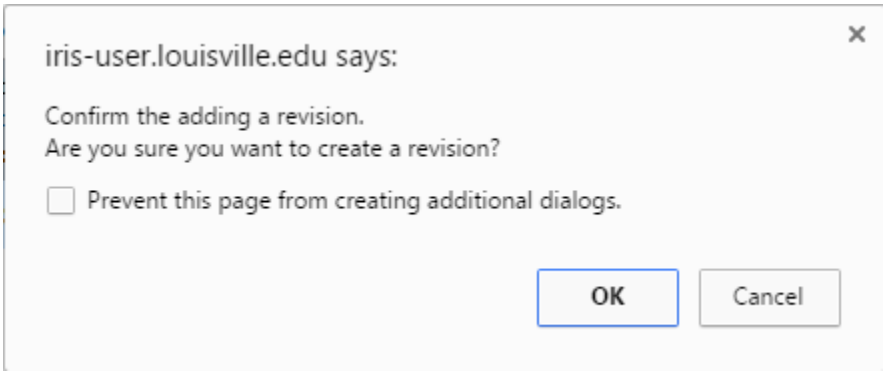
5. Accept or Deny the stipulation
6. Provide an explanation on how you addressed the stipulation

To add a New Document

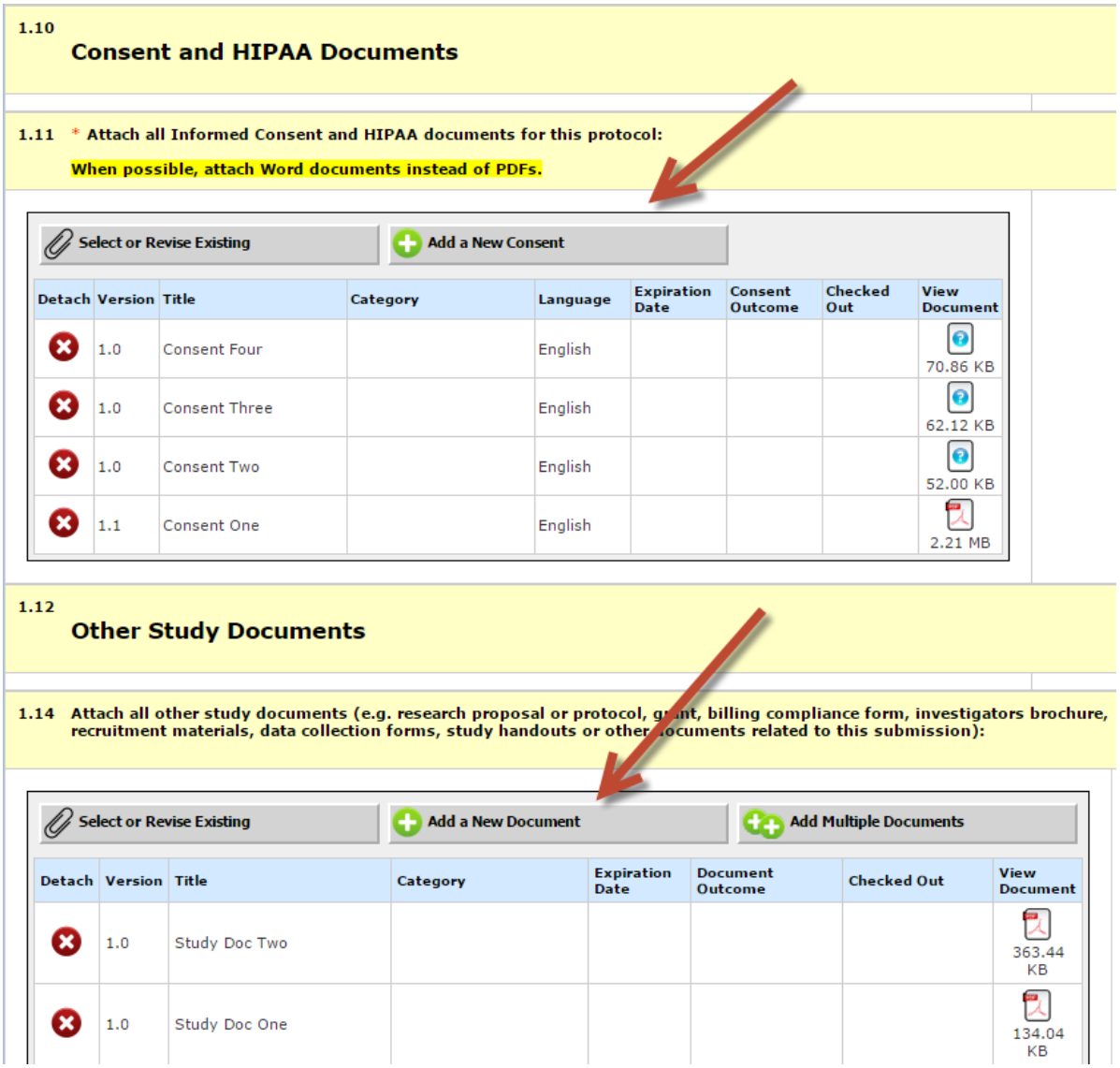
1. Scroll down to the bottom of the Review Response Submission Form
2. You will see the Revised Submission Materials section
3. Click “Revise Submission”



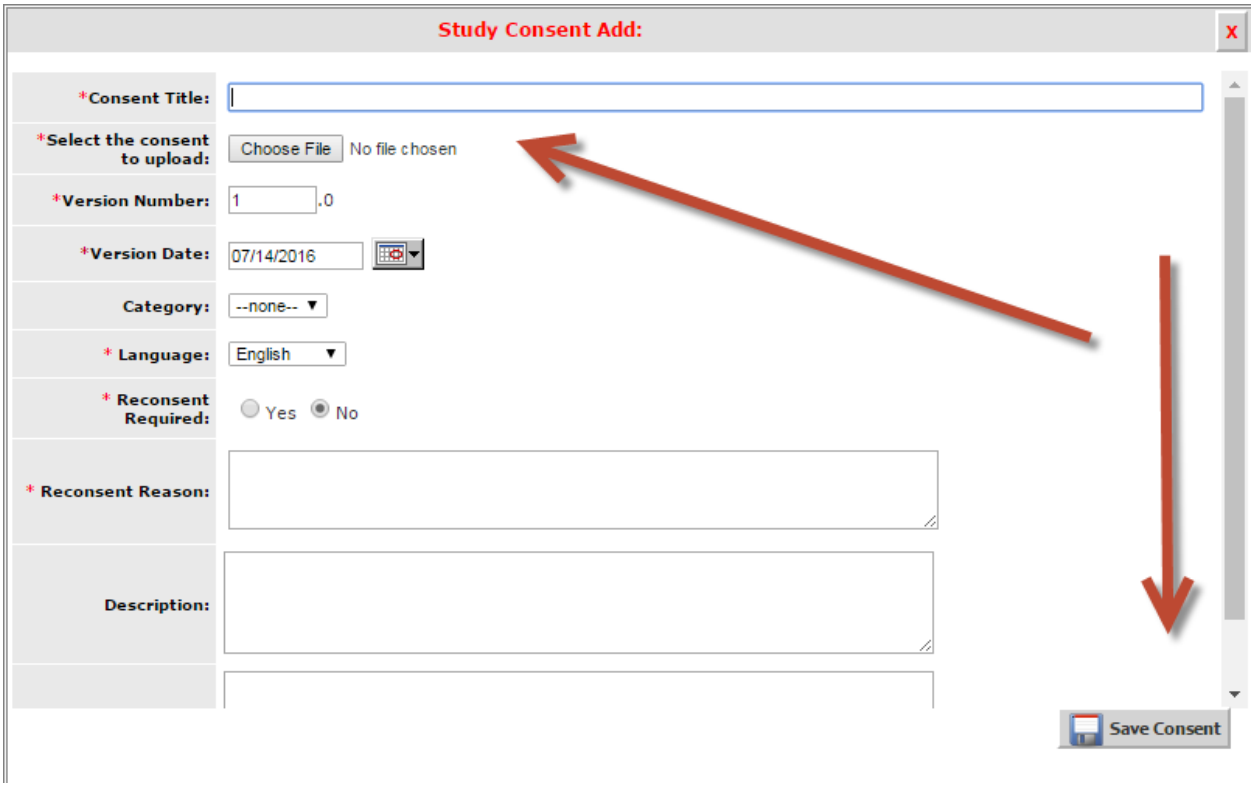
4. Click “Ok” to adding a new revision



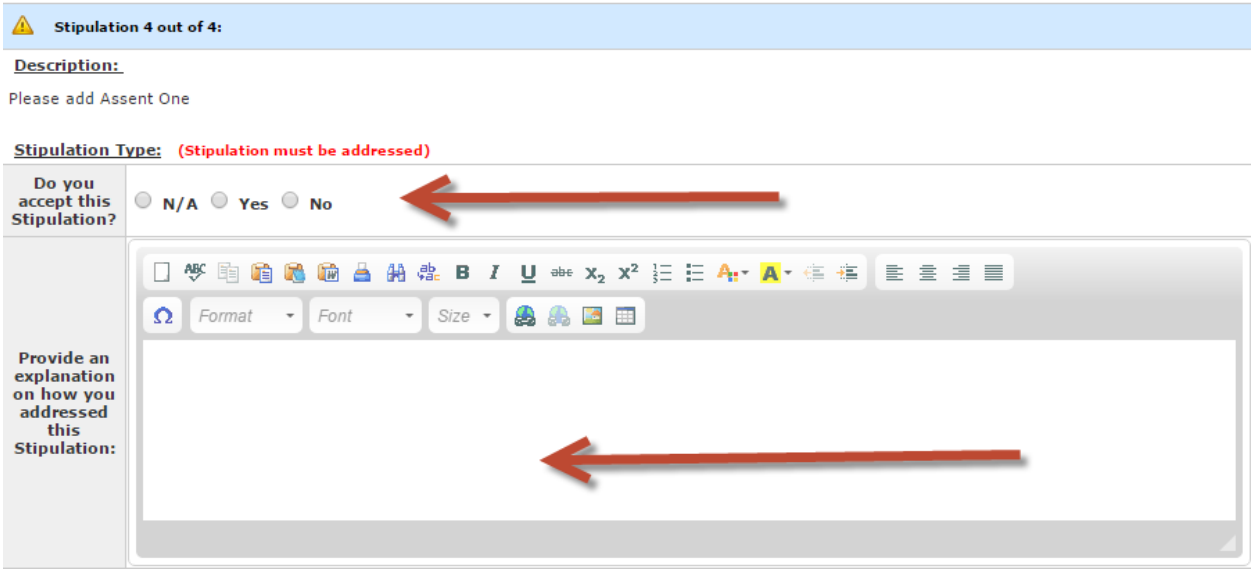
5. Scroll down to either “Consent and HIPAA Documents” or “Other Study Documents”
6. Click on “Add a New Consent” or “Add a New Document”



7. Title the consent/document
8. Select “Choose File” to upload the document
9. Click “Save Document”

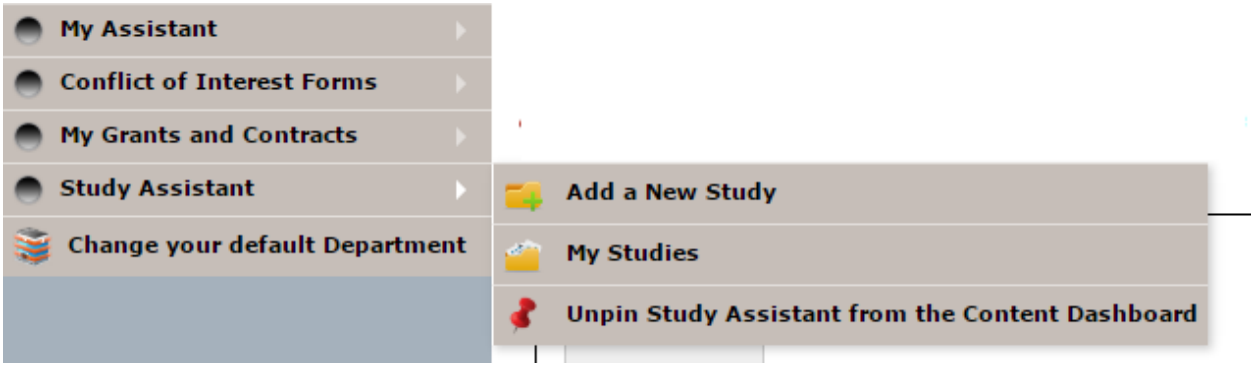


10. Click “Save and Continue to Next Section”
11. Click “Exit Form”
12. Accept or Deny the stipulation
13. Provide an explanation on how you addressed the stipulation

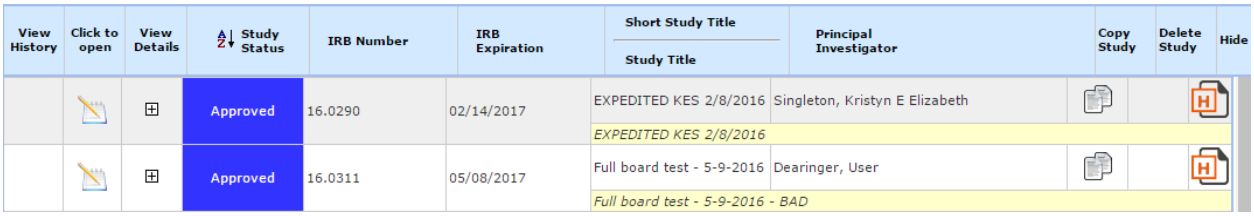


Finding Stamped Documents

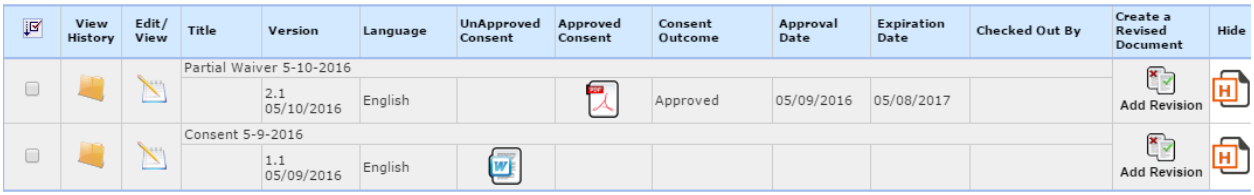
NOTE: You must ***ALWAYS*** use the most current stamped documents when consenting subjects.



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



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.

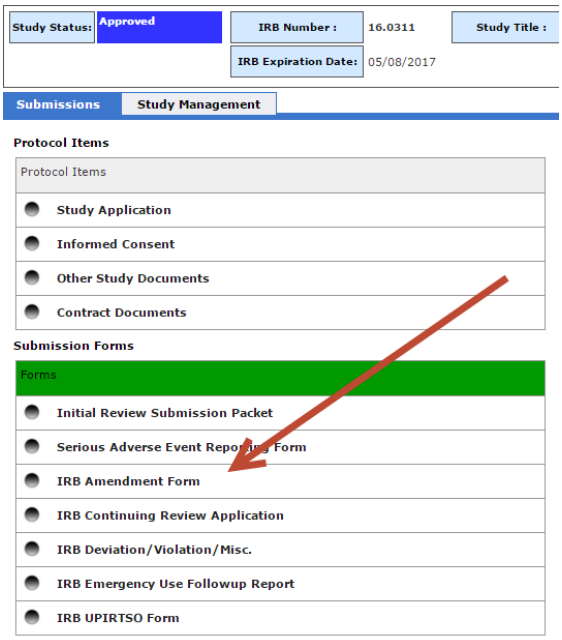


Submitting an Amendment

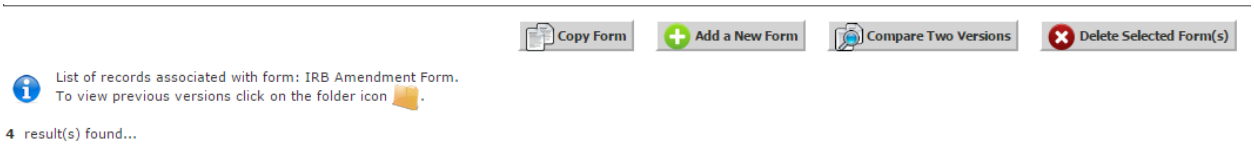
The following are the most common amendments that are received but, this is not an exhaustive list. Please look to Appendix A for a more comprehensive list.

Personnel Change

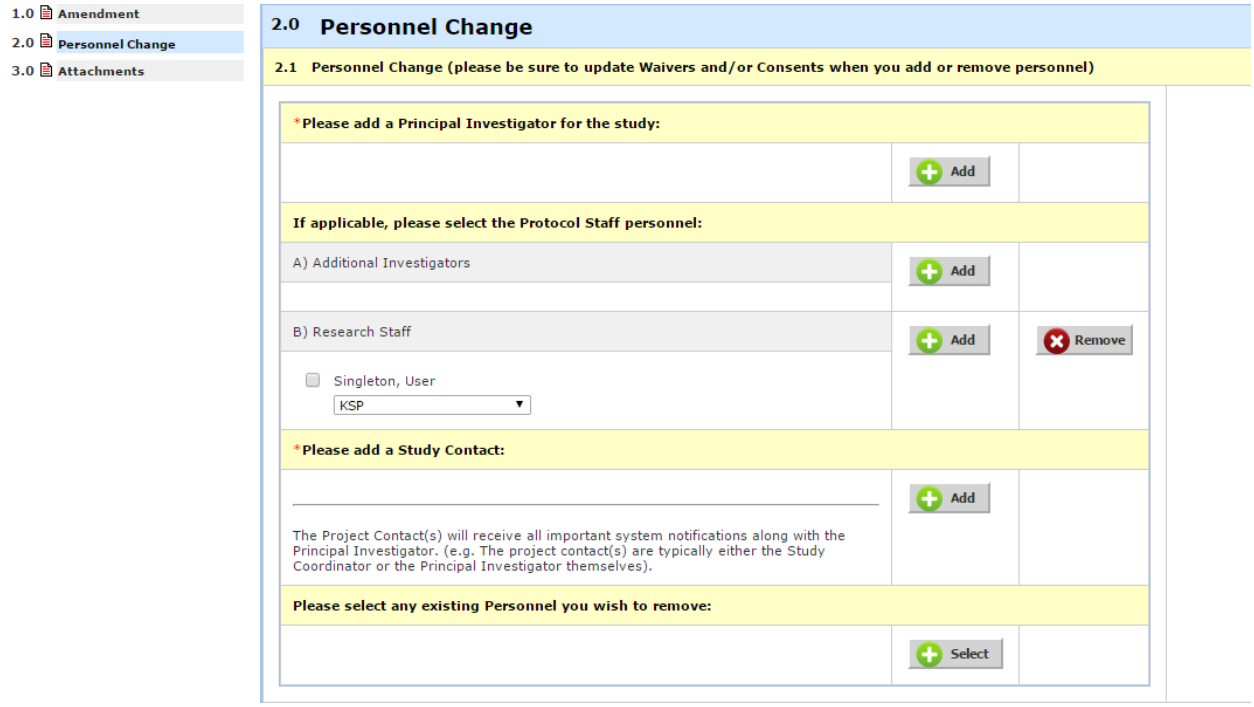
1. Select IRB Amendment Form once you have opened the study you wish to submit the amendment for



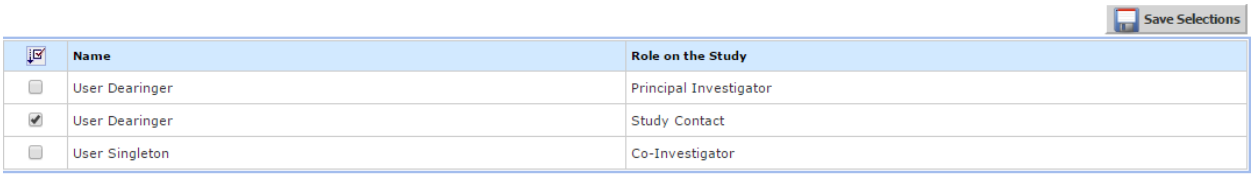
2. Select “Add a New Form”



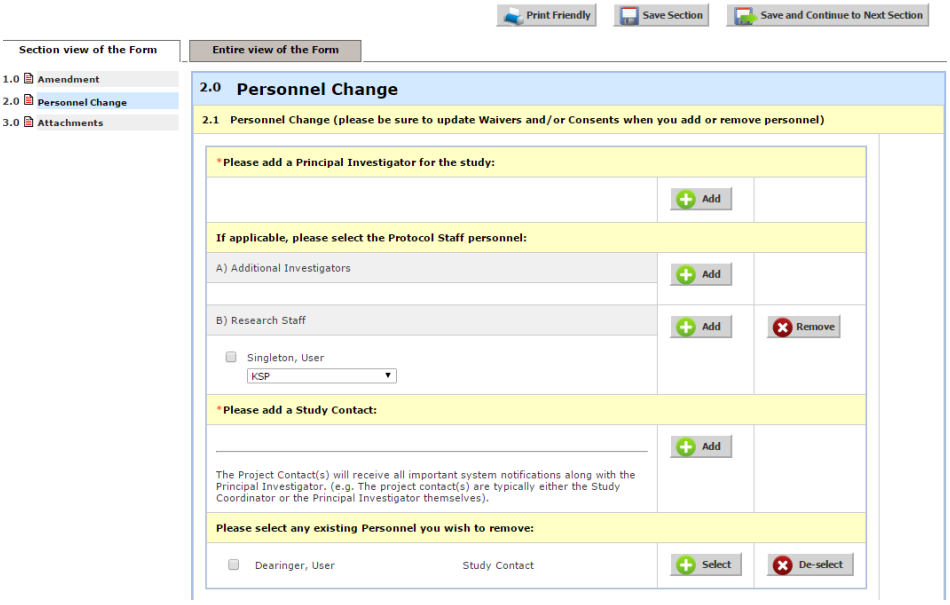
3. Continue with the form and select “Personnel Change” for question 1.2
4. Select “Save and Continue”
5. This screen will populate the box for you to **add or remove** personnel.
    a. **NOTE: YOU DO NOT HAVE TO ADD EVERYONE THAT WAS ALREADY APPROVED ON THE STUDY EXCEPT FOR THE PI.** This is only for 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.



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.

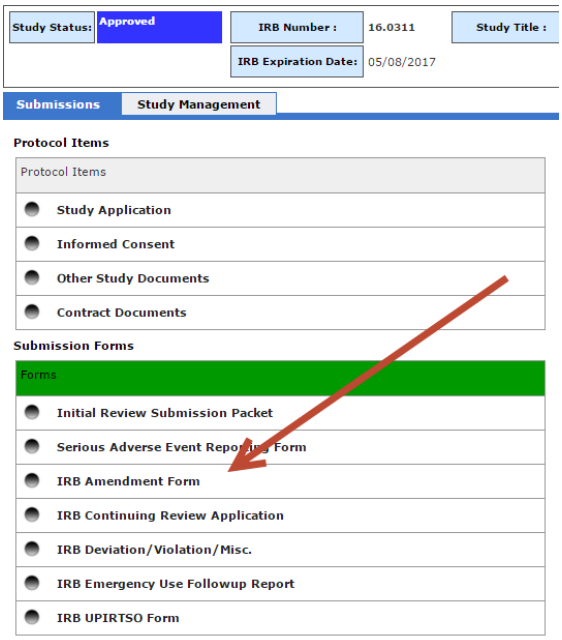


9. Select "Save Selections"
10. Select "Save and Continue"

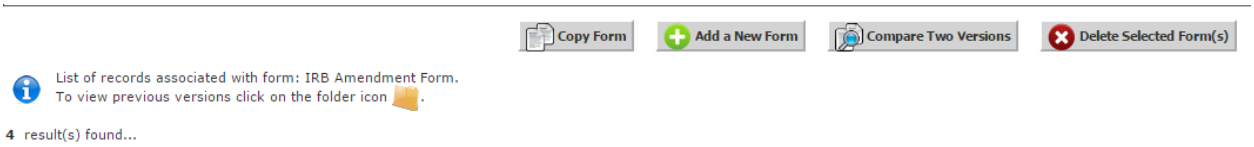


Protocol Change (Application Change)

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

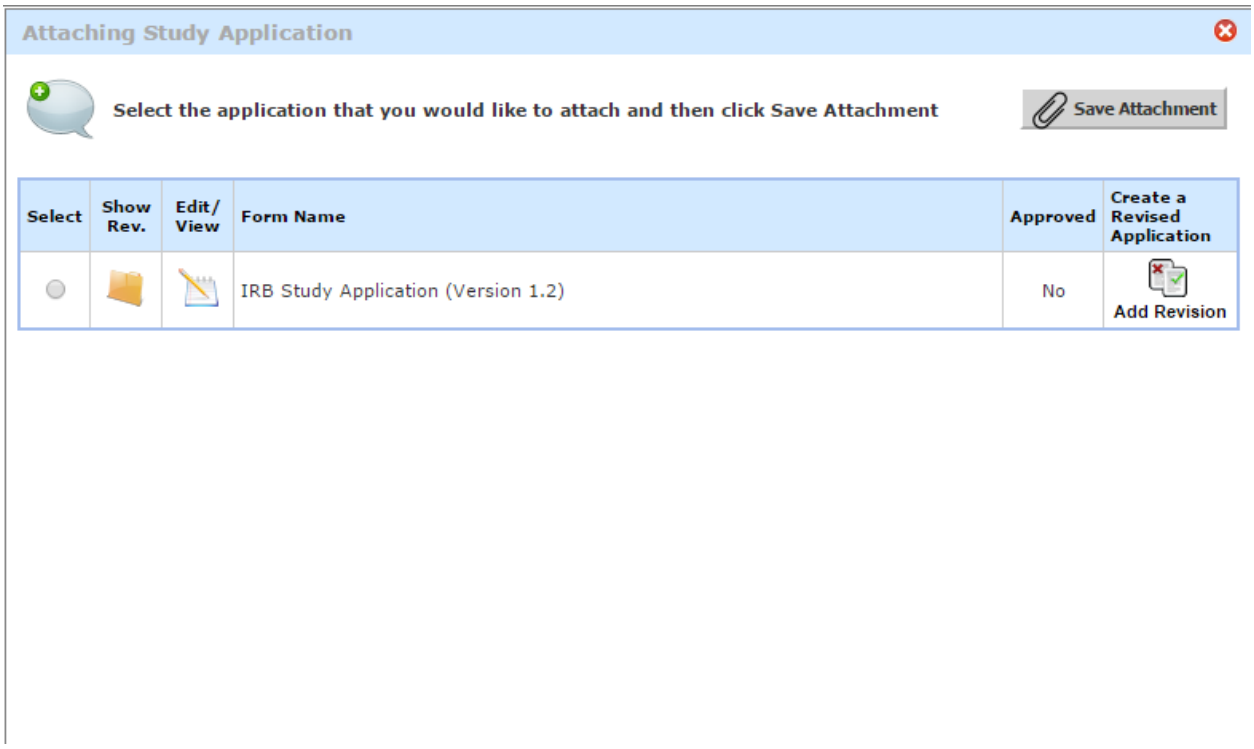


2. Select “Add a New Form”

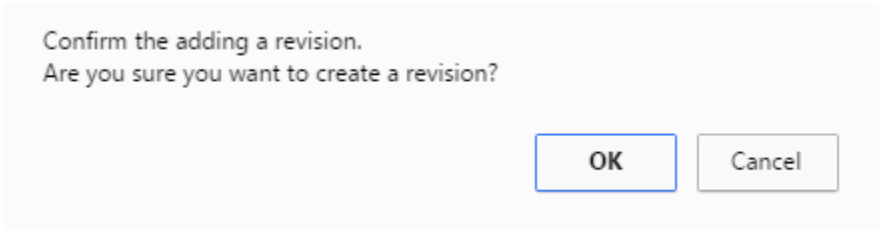


3. Continue with the form and select “Protocol Change” for question 1.2
4. Answer the following questions as they pertain to your study
5. If this study is changing anything in the application (ex. study sites, study billing information, enrollment of special populations—prisoners, wards of state, etc.,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

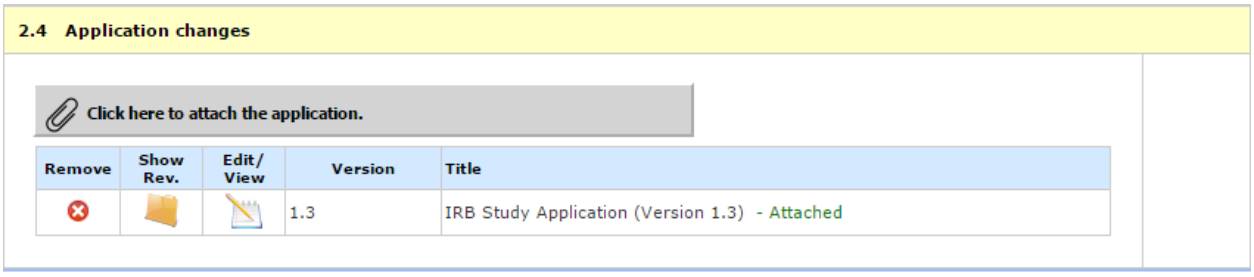
    b. Select “Add Revision”



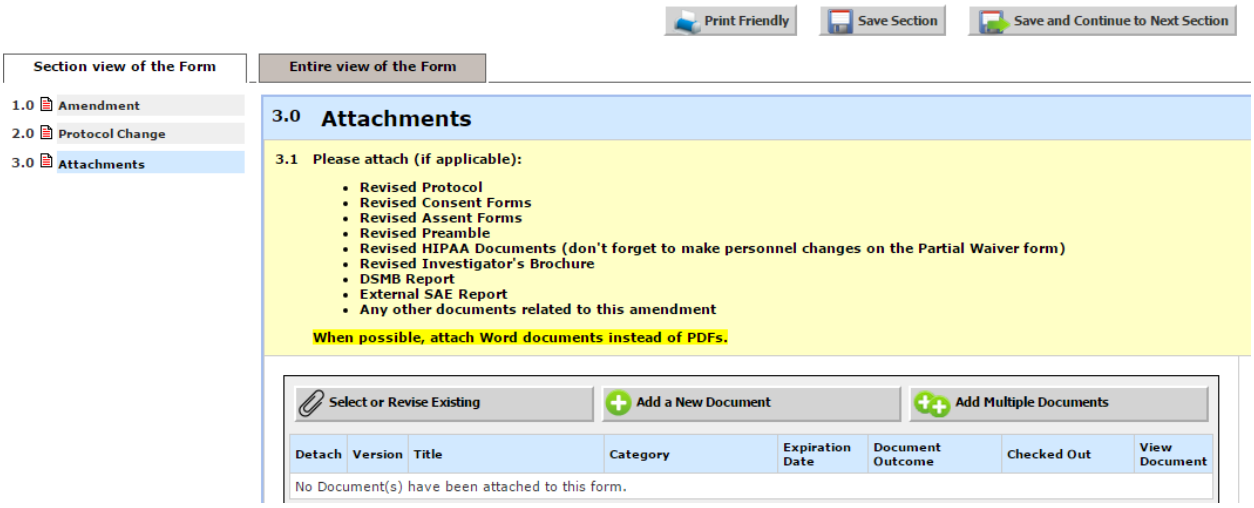
c. Select "Ok" to the popup asking you to acknowledge creating a new version of the application



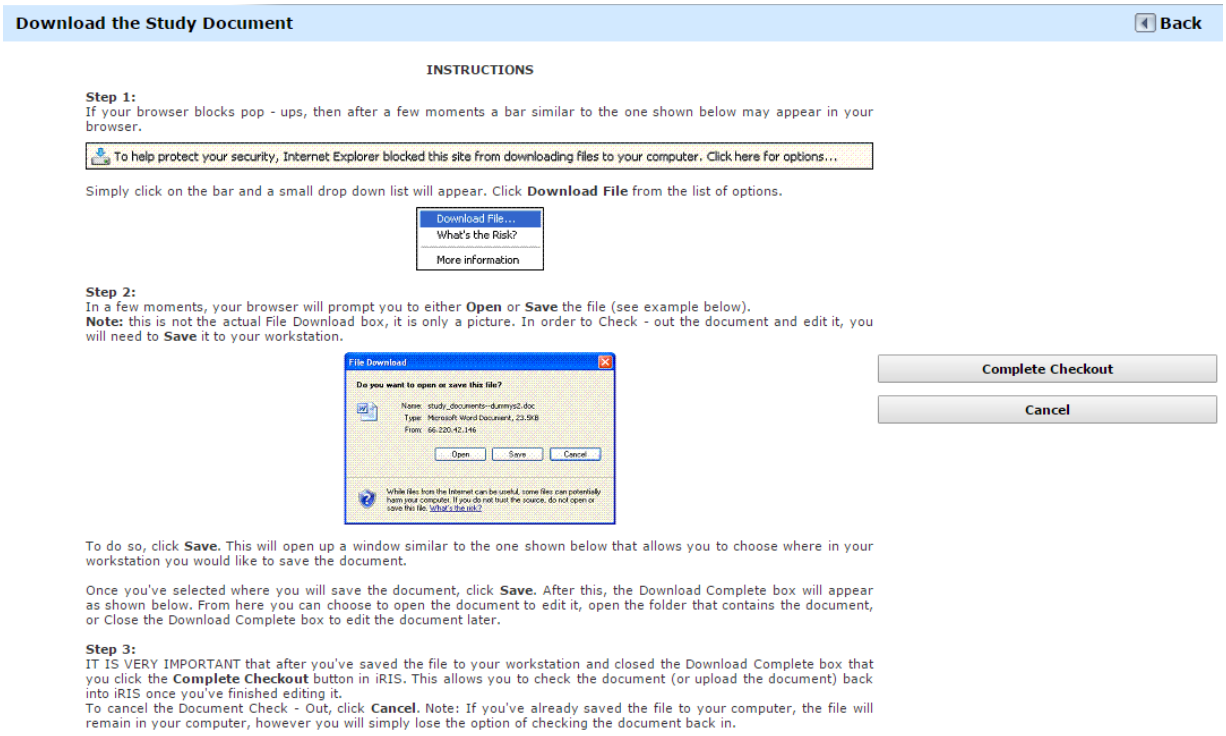
d. Make any needed changes to application.
    i. **NOTE**: Some changes (ex. adding special population groups) will require you to answer additional questions that you did not have to answer before.
e. Click "Save and Continue to Next Section" until you reach the end of the initial application
f. The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



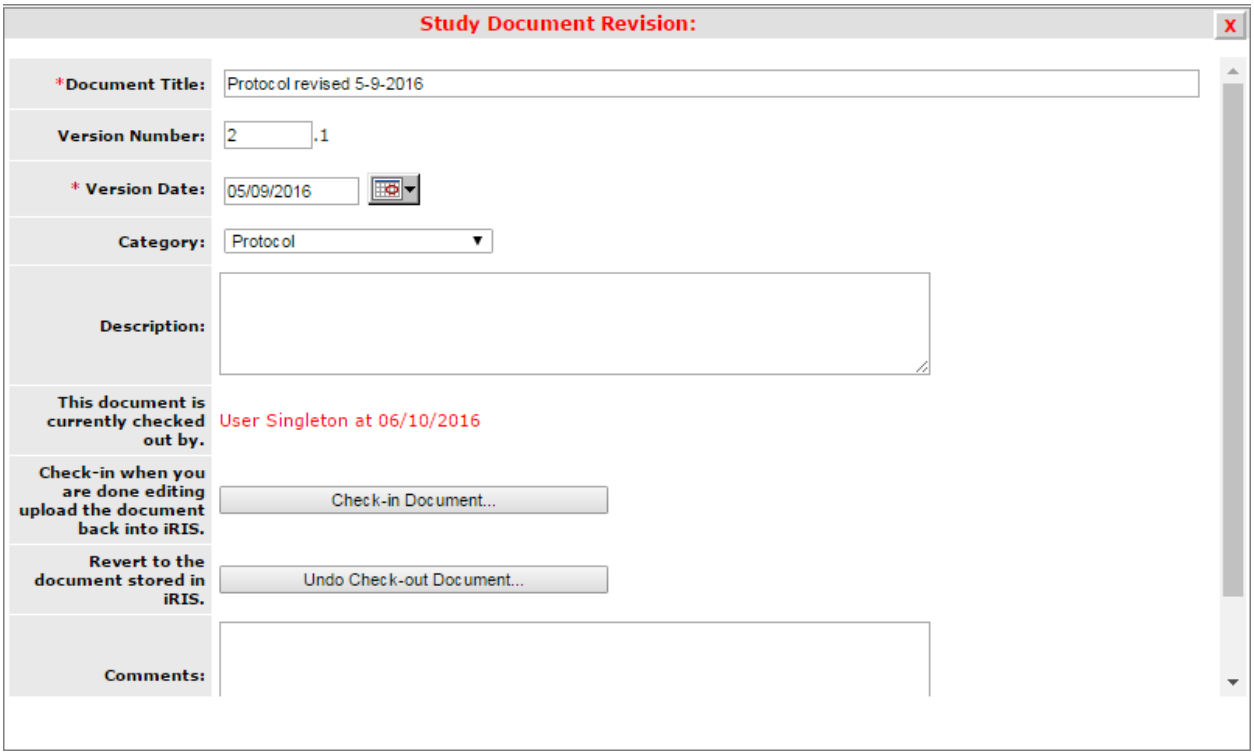
6. If this Protocol/Application Amendment also changes something in the written protocol **or** the informed consent you **MUST** attach this as well
    a. Select "Save and Continue to Next Section" from section 2 of the amendment form



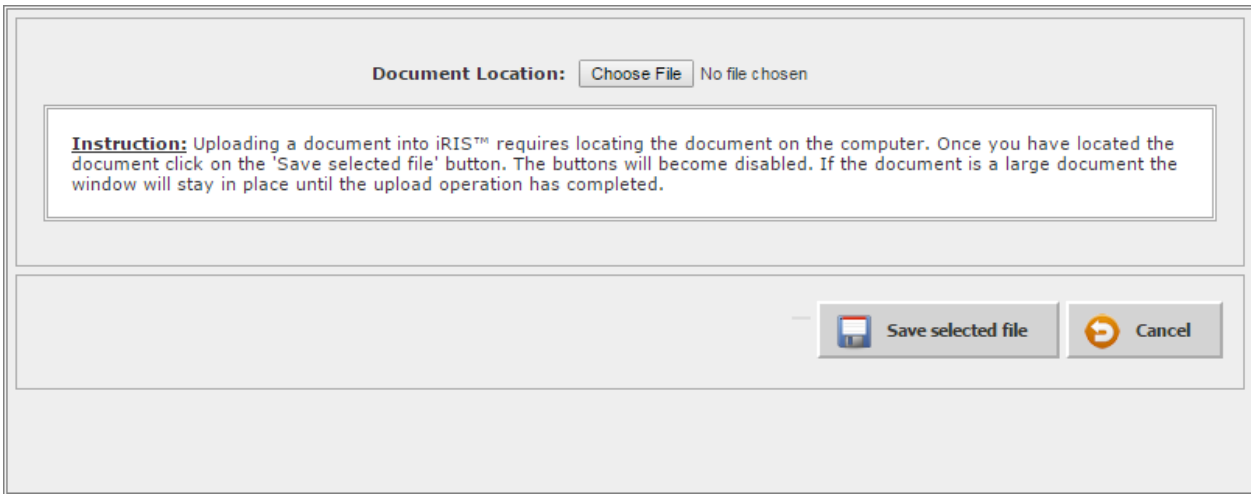
    b. To edit an already existing document (approved with a previous submission) click "Select or Revise Existing"
    c. Select "Create Revision" on the document you wish to edit
    d. Change the version date to the current date
    e. Select "Check Out Document"
    f. Wait until the document downloads to your computer
        i. For Chrome Users: This document will download to the bottom of the screen.
        ii. 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.
        iii. For Firefox Users: Select "Open with: Microsoft Word" and then select "Ok"
        iv. For Safari Users:
    g. Click to open the document that has just downloaded
    h. Select "Complete Check Out"



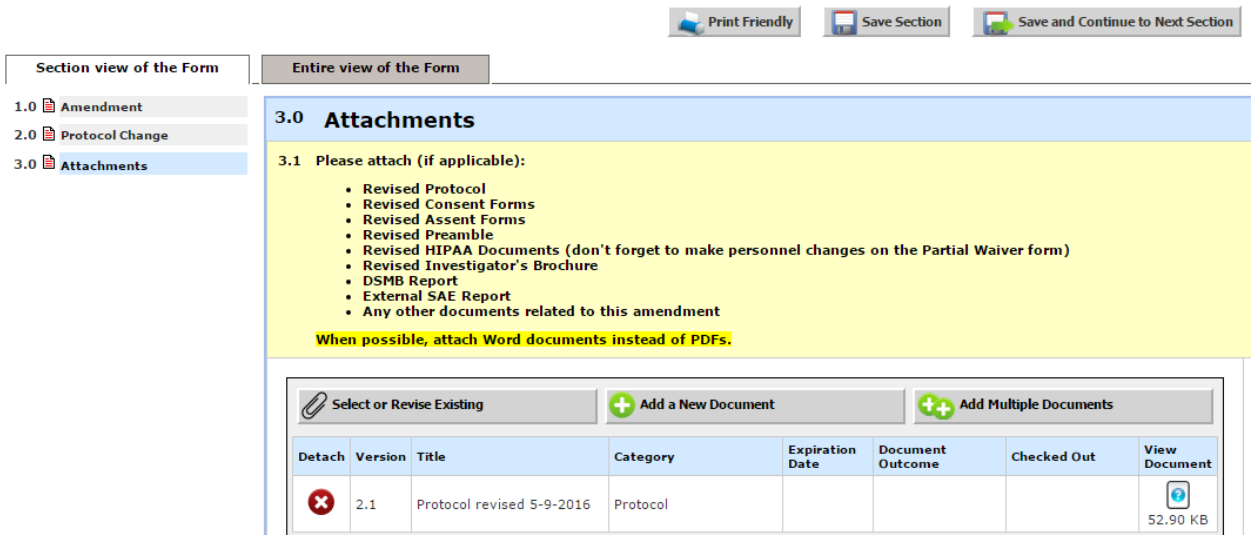
i. Make your revisions to the document and save somewhere on your computer
j. Select “Check-in Document”



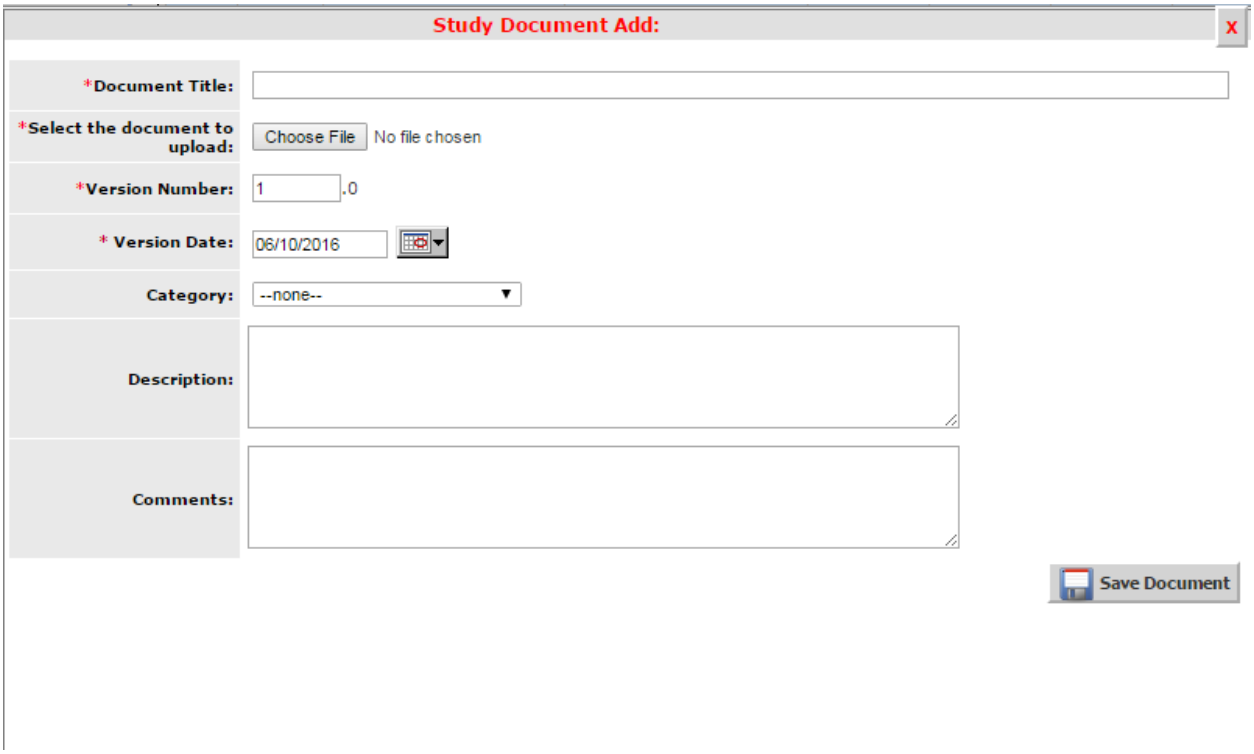
k. Select “Choose File” to browse your computer for the file
l. Select “Save selected file”



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



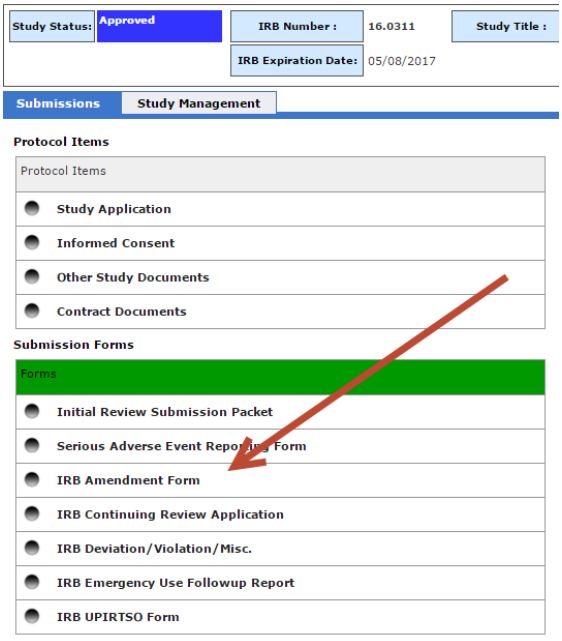
n. Enter the document title, upload the document, and Select "Save Document"



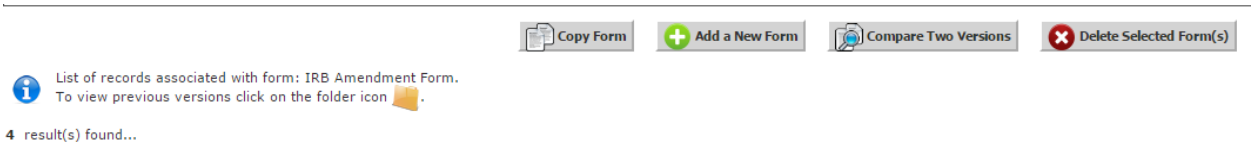
7. Once the documents have been added/revised select "Save and Continue to Next Section"
8. Answer the rest of the questions and submit

Study Closure

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



2. Select “Add a New Form”

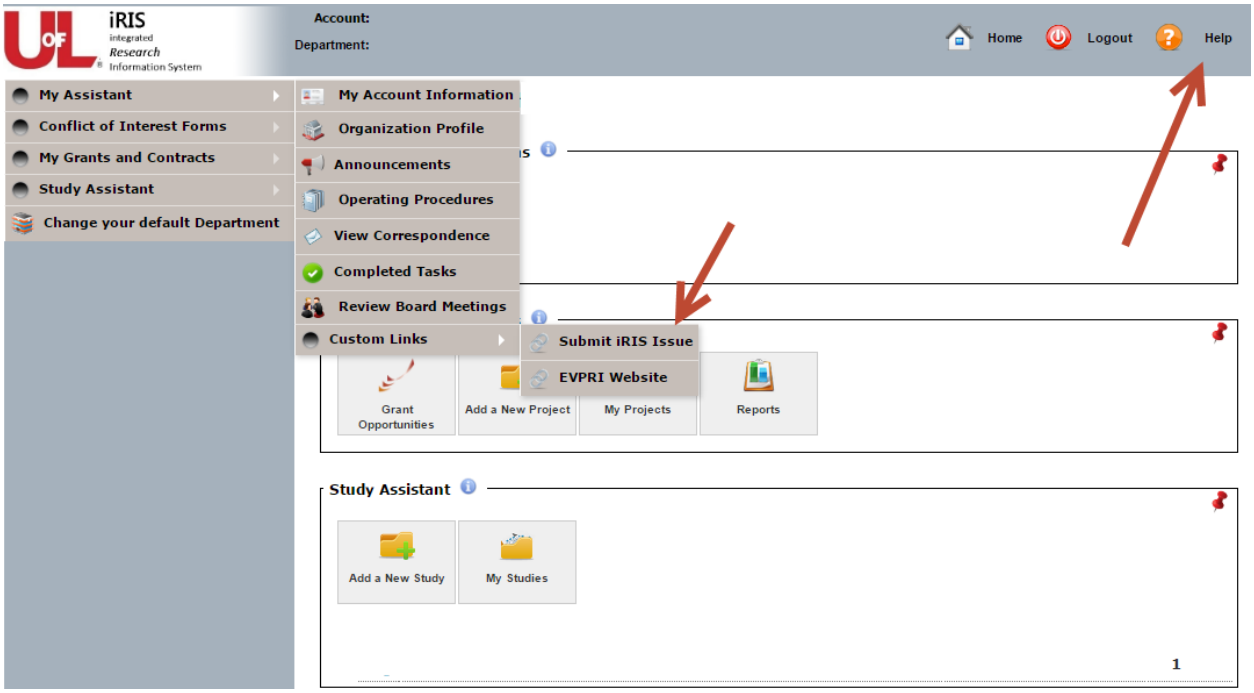


3. Continue with the form and select “Study Closure” for question 1.2
4. Answer the following questions as they pertain to your study

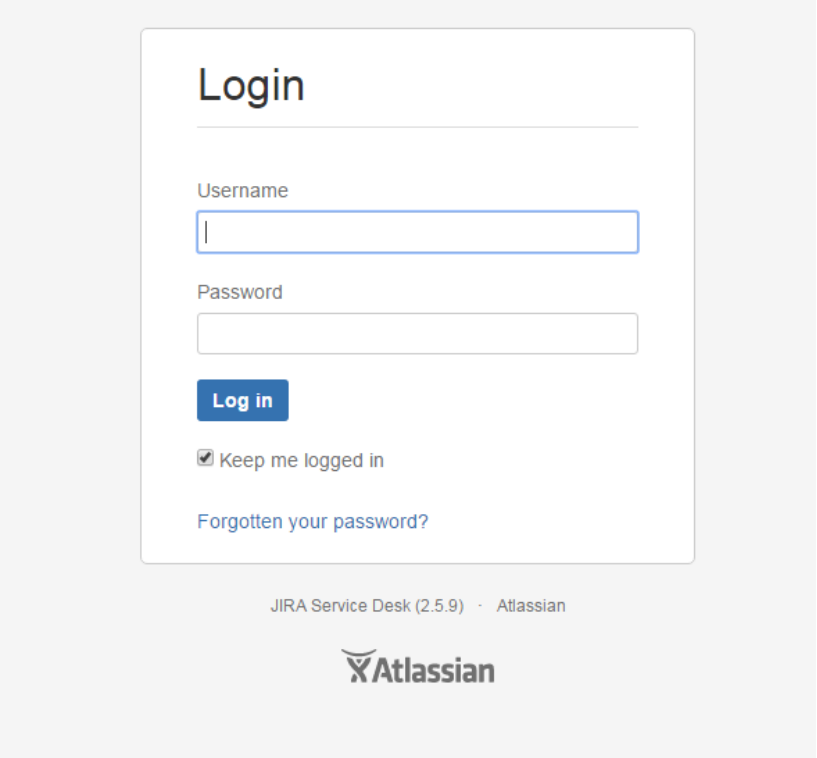
Training—Submitting a Ticket for Update

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.

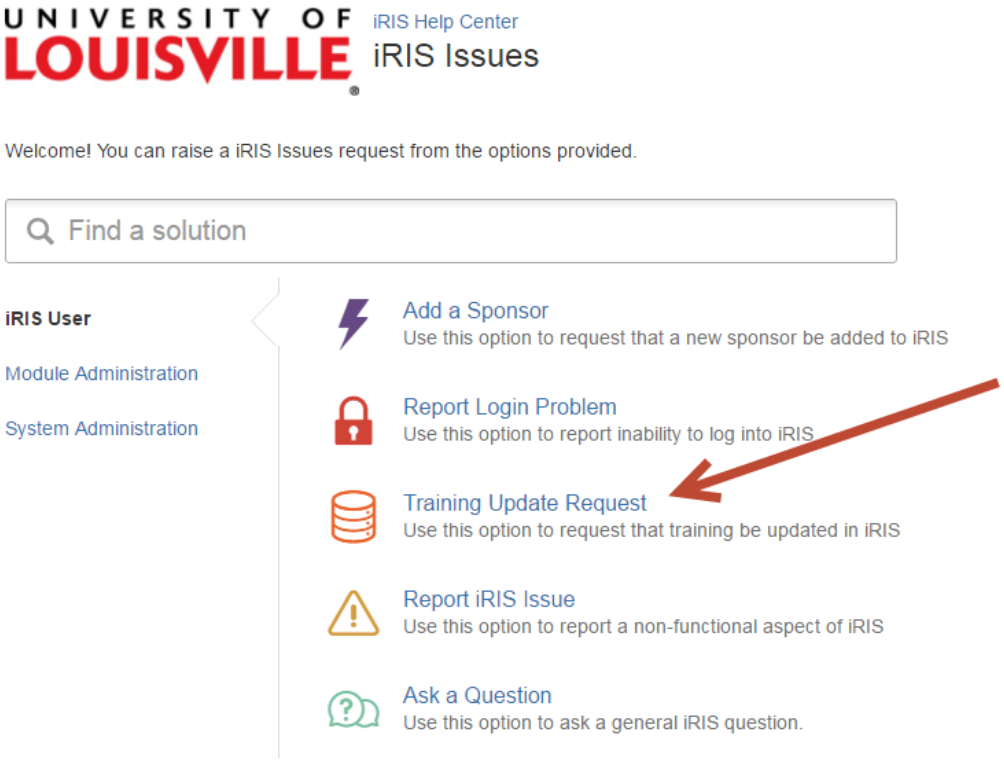
1. Click on either the “Help” button or My Assistant—Custom Links—Submit iRIS Issue



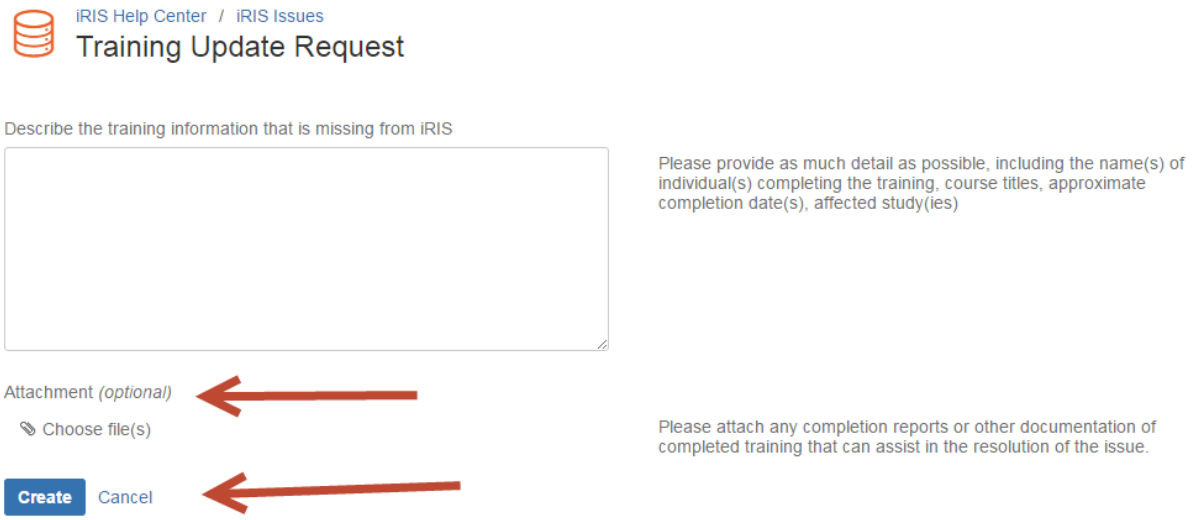
2. This will route to the following page.
    a. You must log in with your UofL userid and password. Just like you would log into iRIS.



3. Click on “Training Update Request”



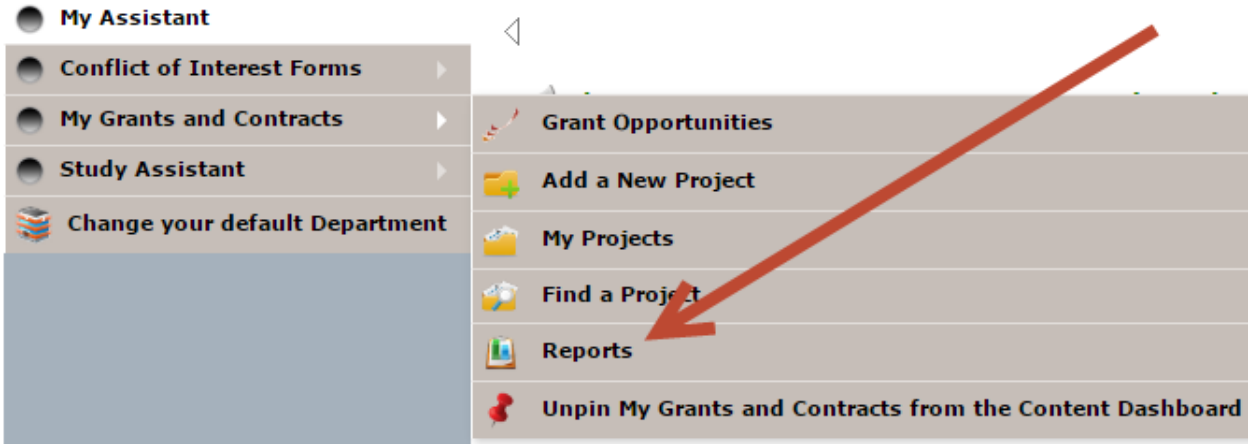
4. Describe what you are requesting in the box. If you have completed your CITI training, attach your completion report in the "Attachment" section.
5. Click "Create"
6. You will receive a response to your UofL email address



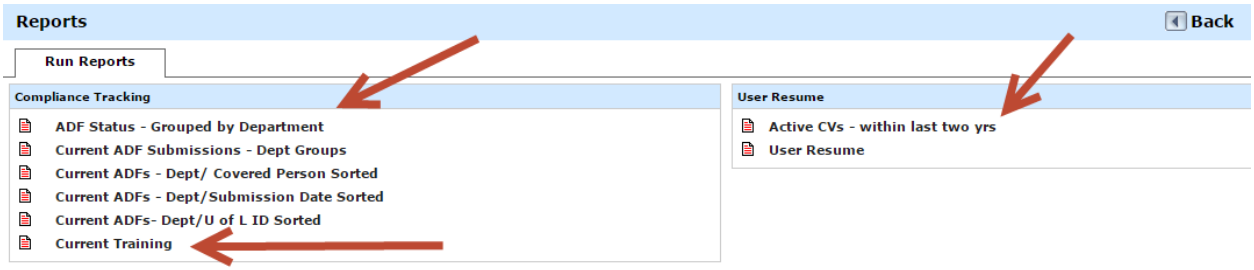
Training—iRIS Report for Personnel Training/CV/ADF

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.

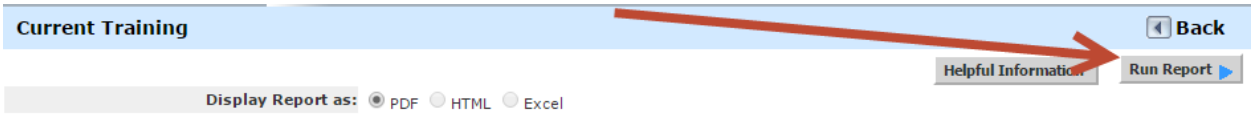
1. Log into iRIS
2. Click on "My Grants and Contracts"
3. Click on "Reports"



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



5. Click "Run Report"

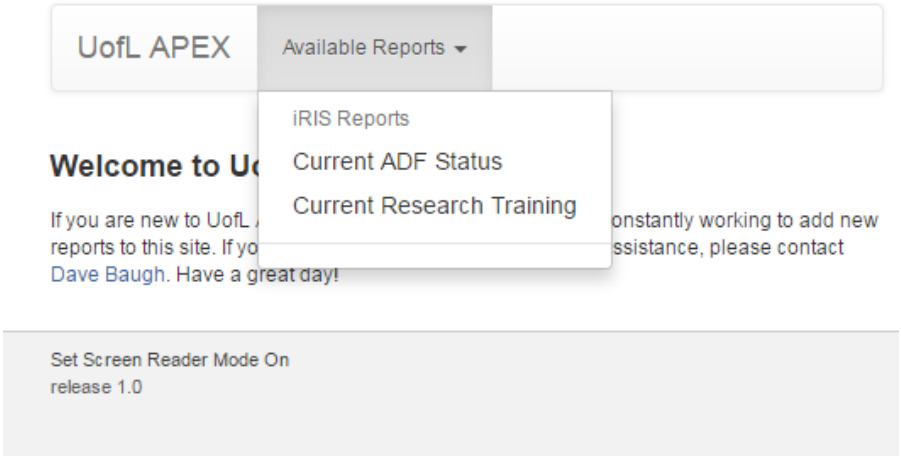


6. The PDF will pop up in a separate screen. Scroll through or click Ctrl+F (Mac Command+F) to look up the individual.

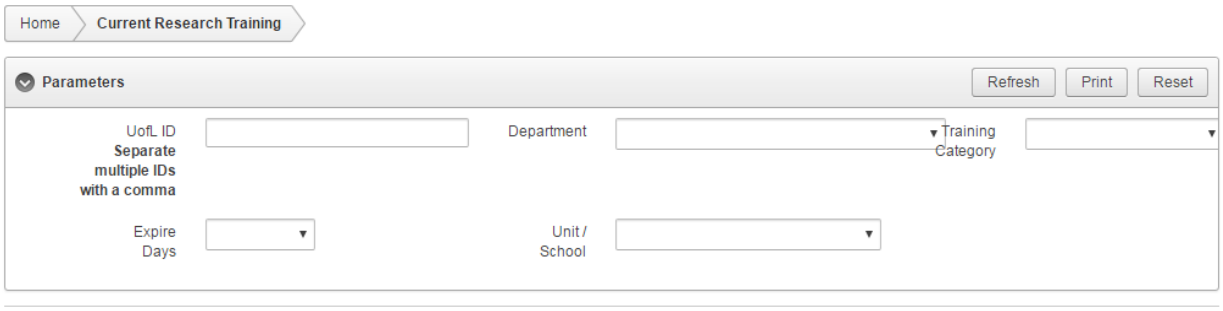
Training—Apex Reports

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



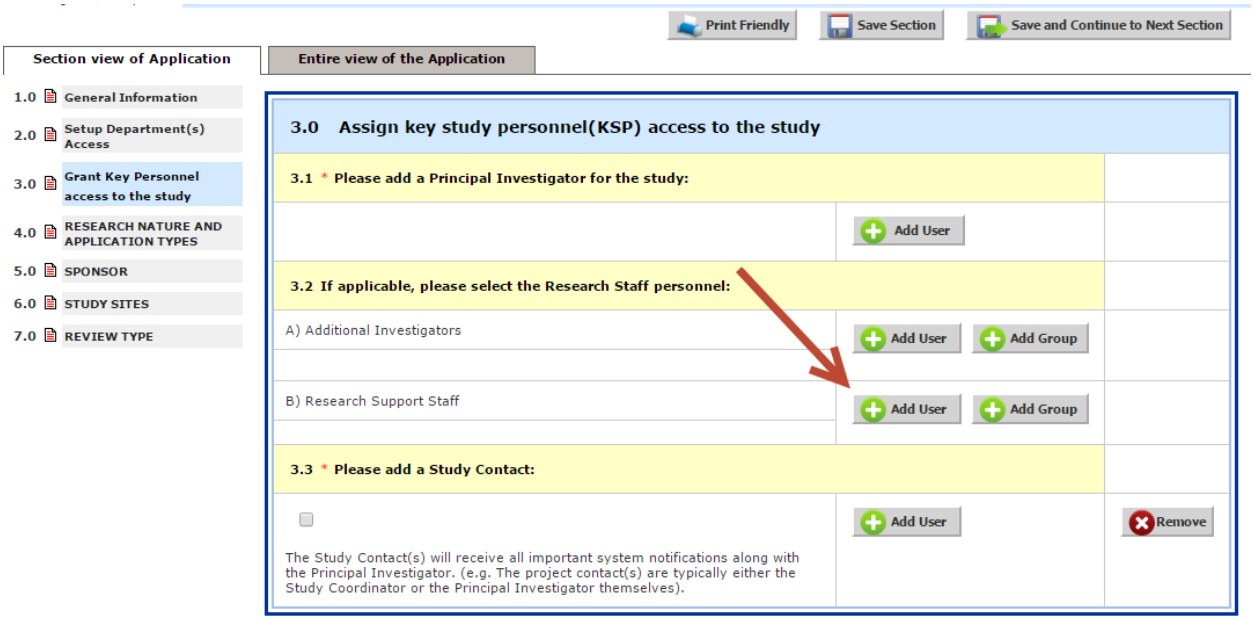
4. Select a report. Enter in the search criteria you wish to use and click refresh.



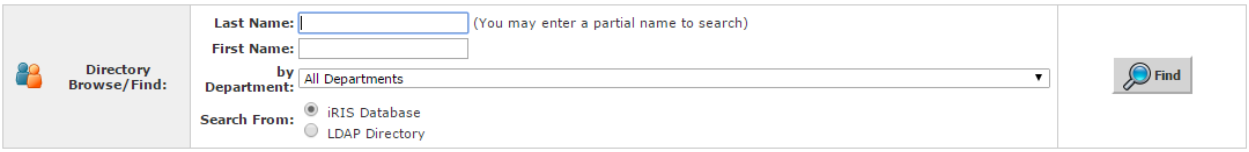
Training—Adding Personnel to a Study

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.

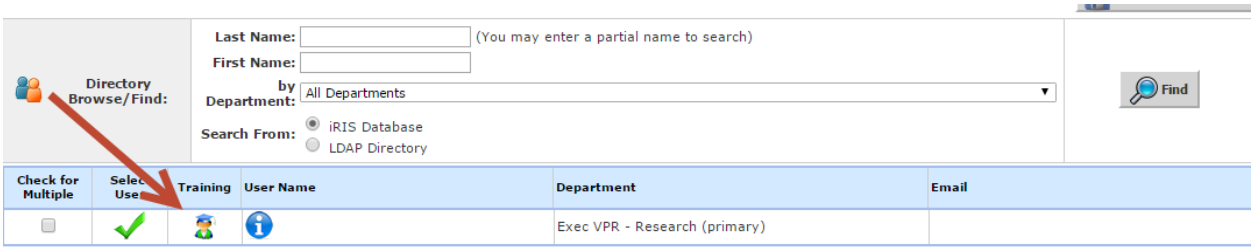
1. In the "Assign key study personnel (KSP) access to the study" section (this is located in both the initial application and the amendment form), click on the "Add User" button.



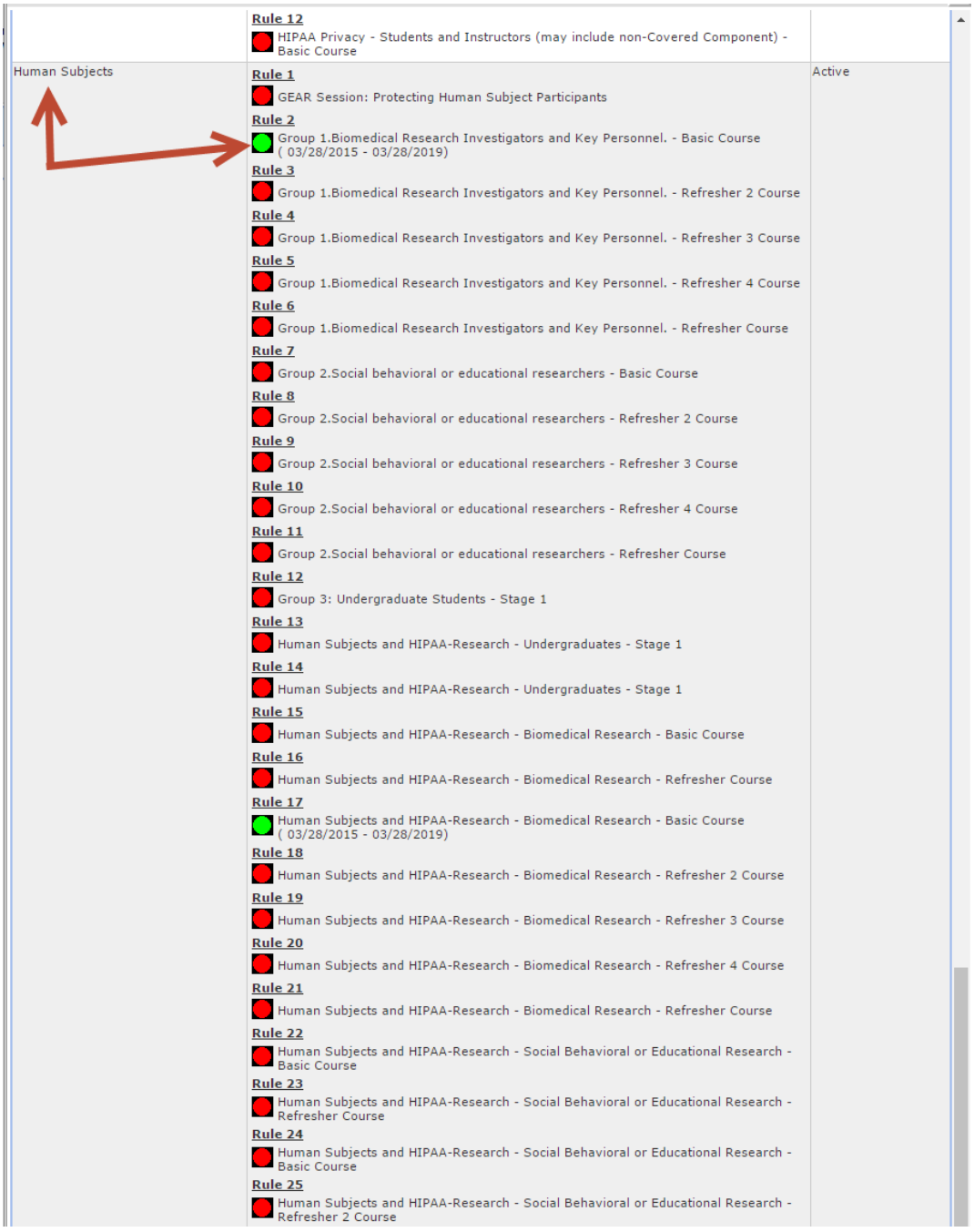
2. Search for the individual.



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



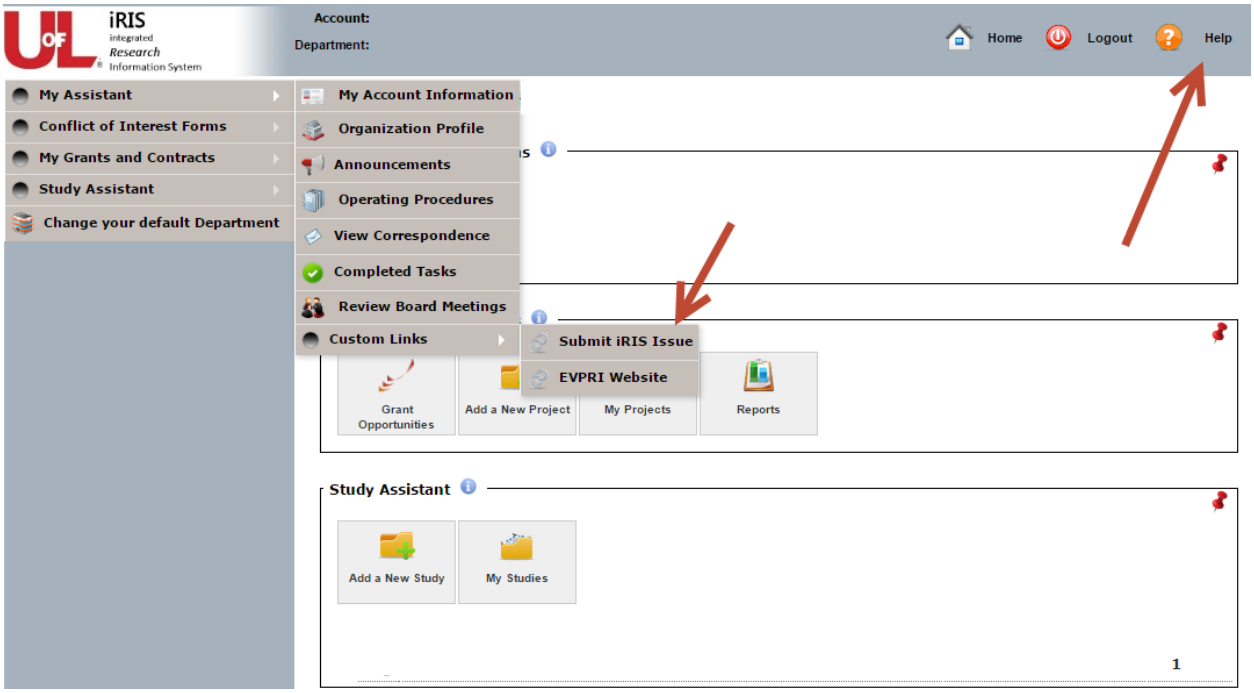
4. Look for the sections that say Human Subjects. If there is a green dot, which means that training is current. You can see the approval and expiration date under the title.



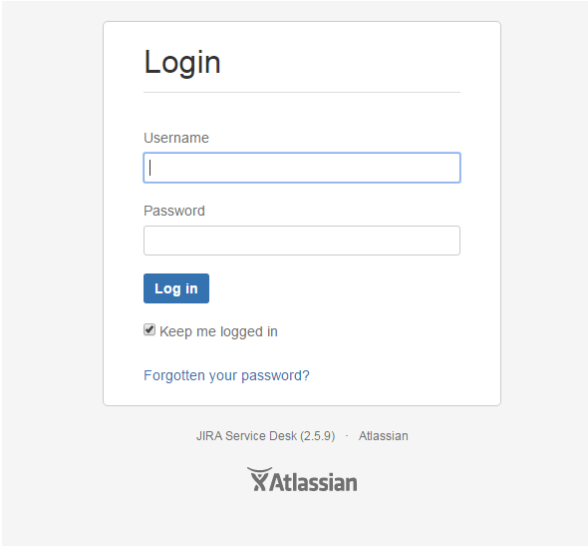
Adding a Sponsor to iRIS

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.

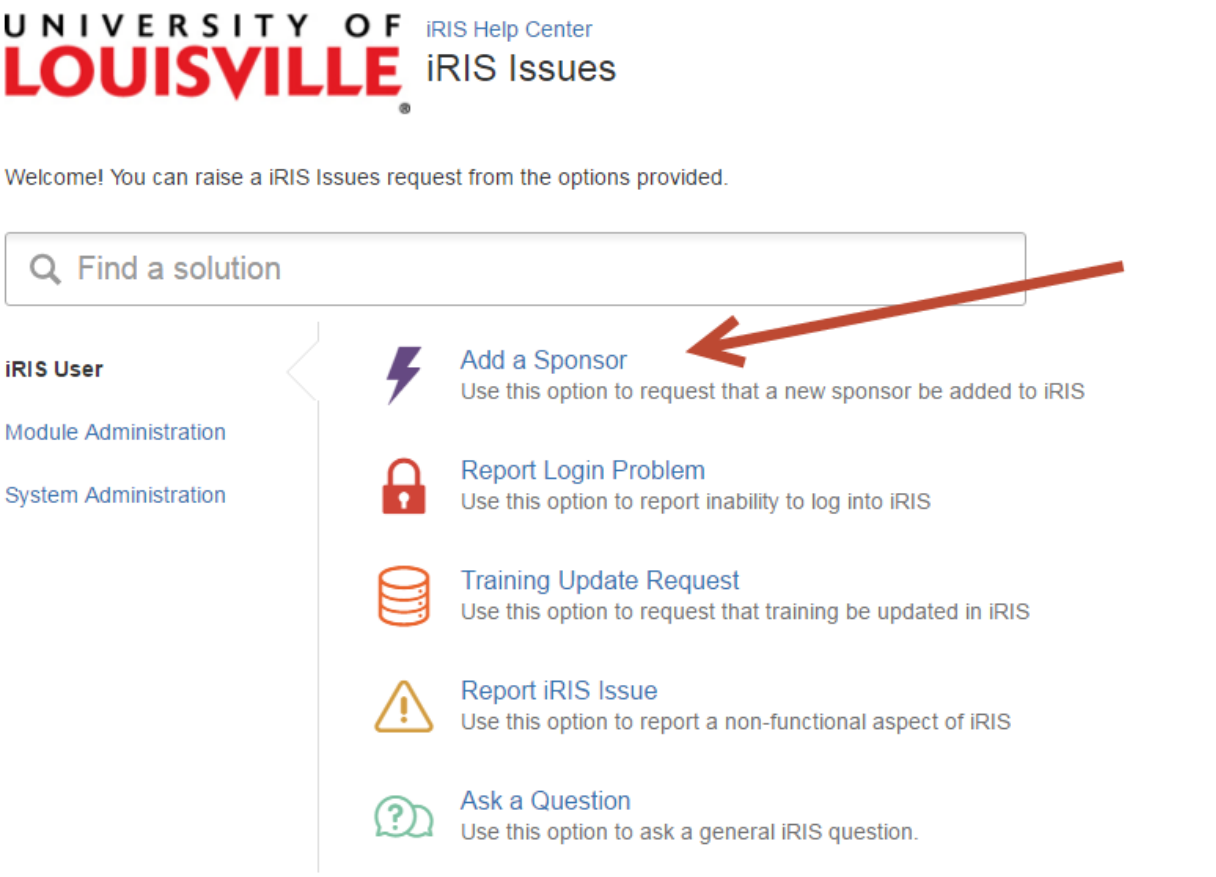
1. Click on the "Help" button or My Assistant—Custom Links—Submit iRIS Issue



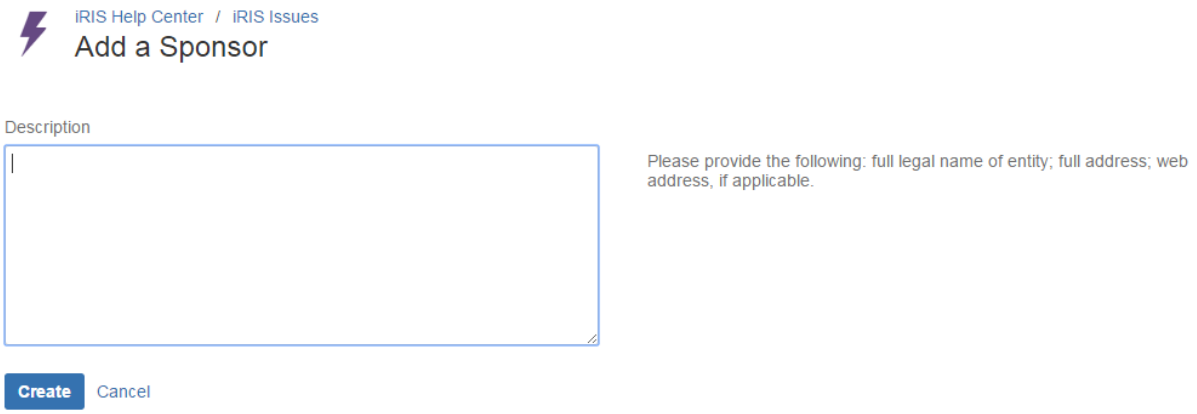
2. This route will take you to the following page.
    a. You must log in with your UofL userid and password. Just like you would in iRIS.



3. Click on "Add a Sponsor"

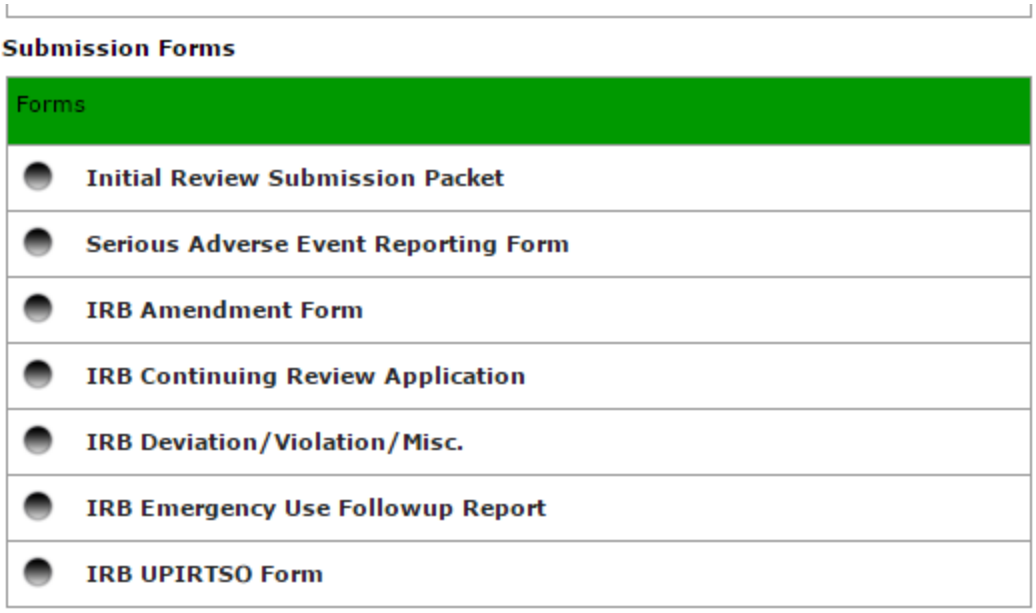


4. Include the name of the entity, full address, and web address, if applicable.
5. Click “Create”
6. You will be notified by the System Administration team via UL email once this task has been completed.



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.



5. Click “Add a New Form”

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
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

5. Click “Add a New Form”

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
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

5. Click "Add a New Form"

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

#002 Additional Protections for Minors- OHRP

#003 Additional Protections for Pregnant Women, Fetuses, and Neonates

#004 Additional Protections for Research Involving Prisoners

#005 Definitions

#006 Approved Sources of Public Use Data

#007 Common Terms and Acronyms

#008 Conflicting Interests of IRB Members

#009 Emergency Use of a Test Article

#010 Exempt Review Categories

#011 Expedited Review Categories

#012 FDA- Special Considerations for the Oversight of Research of FDA-Regulated Drugs or Devices

#013 FDA-IND Application Guidance

#014 Federal Agencies- Additional Reporting Requirements

#015 Federal Grants and IRB Review

#016 HIPAA and PHI

#017 Informed Consent- Dos and Don'ts

#018 Informed Consent- Minors

#019 Informed Consent- Required Criteria

#020 Informed Consent- Waiver of Consent

#021 Informed Consent- Optional Consent within Main Consent

#022 IRB- Approval Criteria

#023 IRB- Events that Require Prompt Reporting to the IRB

#024 IRB- Review Fees

#025 Is My Project Research?

#026 What Qualifies as Human Subjects Research?

#027 Quality Assurance - Quality Improvement

#028 Significant and Non-Significant Devices

#029 Recruitment Tools

#030 Paying Human Subjects

#031 Utilizing the NCI CIRB-Guidance for Investigators

#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, Eligility Checklist, Drug Dispensing Log, etc.)-- http://louisville.edu/research/humansubjects/qip