iRIS Training and Quick Tips

August 13, 2018

Please refer back to this page often since it will be updated continuously over time as we have more tips and/or training to provide.

1. iRIS Training

1. For iRIS Training Material and tip sheets in general, please Click Here
2. For the training "Introduction to Submitting an IRB Application in iRIS, please Click Here.
   - This course will outline the basic process for IRB application submission using the iRIS system.
   - The module will describe the workflow between the two main research workflow systems iRIS and OnCore and will introduce users to the iRIS system, basic navigation and initial protocol submission.
3. For the training "Post Approval Submission Forms in iRIS, please Click Here.
   - This course is designed to outline the basic functions of post approval submission forms using the iRIS system including:
     - DUHS IRB Amendment Forms
     - DUHS IRB Migration Amendment Forms
     - DUHS IRB SAE/AE Forms
     - DUHS IRB Continuing Review Forms
     - DUHS IRB Study Closure Forms
     - DUHS IRB KSP Forms

2. General Tips

1. iRIS supports all browsers, but functionality differs between browsers.
   - Internet Explorer (Most Compatible)
   - FireFox
   - Chrome
   - Safari (Least Compatible)
2. If you are having trouble printing, check to ensure your browser’s pop-up blocker is disabled or allows pop-ups from iRIS.
3. If you cannot find someone when adding KSP, have the user log in to the system. For users that were not migrated in on studies from the old eIRB system, iRIS accounts are automatically created when they first log in, and they will then appear in the look-up.

4. Where to Find Approved Consent Forms
   - If you have an approval in iRIS for a continuing review or an amendment affecting the consent form, please check in iRIS for the latest approved consent form(s).
   - If you have had no amendment changes or a continuing review in iRIS since the system went live on May 21, look in the Legacy eIRB for your approved consent form(s).
   - Once document migration is complete, all consent forms will be in iRIS. Until that process is finalized, you will potentially need to check both systems. Please be sure you are always downloading and using the most current approved consent form.

5. Responding to Email Correspondence within the iRIS System
   - When you receive an email correspondence that comes out of the new iRIS system there are a few important things to remember when replying in order for the correspondence to be logged in the iRIS System:
     - Do not change the Subject Line.
     - Use *only* Reply All. Do not use Reply.
     - Do not use Forward.
   - If you change the subject line or forward the email, the response will not be captured in the iRIS system and will not become a part of the record for that study.

6. Uploading Revised Documents in iRIS
   - The IRB requests that study teams upload only a tracked version of an amended document (such as consent forms, phone scripts and advertisements) in iRIS. In general, clean versions should not be uploaded. The exception to this is sponsor-generated items like sponsor protocols and IBs, when red-lined versions are sent, still need clean copies provided.
   - Amended documents should replace the original document that was approved. To do this, create a revision of the approved document, check it out, track the changes that you are making with the amendment, and check back in the tracked document. Remember to save changes.
   - The Tip Sheet for How to Revise an Existing Study Document can be found on the DOCR web site.

7. iRIS: Error Message 500 ? Internal Server Error
   - If you are getting the message ?Error Message 500 ? Internal Server Error? in iRIS when trying to open a document, check the filename of the document. Filenames of all documents have a character limit of 250 characters and if a filename is too long, the error will be caused. Shortening the length of the filename seems to resolve the issue.

8. iRIS: Consent Forms
   - All consent forms in iRIS should use the Microsoft extension .doc. The extension .docx is not compatible for watermarking in iRIS, so please change consent form files to .doc before submitting to the IRB. Note that when you change the file from .docx to .doc,
some formatting changes may result.

- Use the consent form templates available on the IRB web site when you have to create new consent forms for your study. See DUHS Sample Consent: https://irb.duhs.duke.edu/forms/duhs-sample-consent

9. iRIS: Continuing Reviews and Amendments

- Please do not submit Amendments in iRIS during the time a Continuing Review is in process. This will cause versioning issues and may lead to a delay in processing both the amendment and renewal. If you have an urgent Amendment during this time, please contact your IRB Specialist for assistance: https://irb.duhs.duke.edu/about-us/staff-and-chairs

3. Migration Tips

1. Please do not enter a migration amendment unless you have an upcoming regular amendment or continuing review that you need processed. Please wait to submit the Migration Amendment if you do not have a Continuing Review or Amendment that you need to otherwise submit now.

2. Migration amendments should ONLY contain information that was previously approved by the IRB. Since the submission form was updated, please fill it out to the best of your ability. You may use N/A and provide an explanation if something does not apply.

3. Safety Events: migration amendment is not required

4. Exempt: migration amendment not required. The submission can be updated via a regular amendment if you otherwise need to submit an amendment

5. If you have a closed study and need to re-open it just for data analysis, you do not need to do a migration amendment. If you have to re-open the study for any other purpose, then a migration amendment is required.

6. You can change Key Personnel without submitting the migration amendment
   - Except in the case you are adding an external KP or changing a PI/Co-PI which requires a regular amendment

4. Application Tips

1. When completing an iRIS Application please type ?N/A? in any fields that appear but are not required for your application.

2. When entering the Blood Draw amount on the Protocol Application, please round up to the nearest whole mL.

3. Copying and pasting the Research Summary from eIRB into iRIS caused a problem with footnotes and endnotes. You may paste the endnotes into the last section. We are working on a solution to this problem.

5. Amendment Tips

1. When submitting an amendment please be sure to attach an ?iRIS Application?. This action can be completed in question 1.8 ?Revise the application to reflect the proposed changes?. Even if no changes are necessary, please associate the current approved version of the application with the amendment form.