FAQs

Data Migration from *eIRB* to *iRIS*

Updated 4/19/18

What is iRIS?

iRIS stands for Integrated Research Information Software. It is the application that is replacing *eIRB* for research protocol approvals at Duke.

What studies will be migrated from *eIRB* to iRIS?

- All active studies will be migrated
- All studies closed on or after January 1st 2013 will also be migrated
- All studies in pre-submission that were last updated on or after July 1st 2017 will be migrated

How and when will migration occur?

Migration will occur in 2 phases. Migration of study shells *(Title, PI, co-PI, Short Title, full study team, submission history)* will begin after 5pm on Friday, May 18, and is expected to conclude by 8 am on Monday, May 21. No attached study documents will migrate during that time. Migration of study documents will begin immediately after shell migration is complete, and is expected to be complete by June 30.

Will I have access to either *eIRB* or *iRIS* during the migration?

No, study teams will not have access to either system from May 18th at 5pm until May 21st at 8am. On May 18th at 5pm, *eIRB* will be brought offline for migration. On May 21st, after shell migration is complete, study teams will be able to do two things only in *eIRB*: (i) view the complete study record; and (ii) download attached documents. *eIRB* will be accessible to study teams at least through mid-2019.

When will it be mandatory to use *iRIS* and stop using *eIRB*?

No submissions can be made in either system from 5 pm on Friday, May 18 until 8 am Monday, May 21. Study teams must make all submissions in *iRIS* beginning Monday, May 21.

Emergency safety events or emergency amendments during that weekend can be submitted via email to Jody Power at jody.power@duke.edu.

How do I view studies that do not migrate to *iRIS*?

Studies that were closed prior to January 1st 2013 will continue to be accessible in *eIRB* in a read-only state. *eIRB* will be accessible to study teams at least through mid-2019.

How will migration of study documents work?

Study documents will be prioritized for migration according to study status as follows:

1. In-Progress Submissions that have reached the DUHS IRB (New, CR, Amendment, etc)
2. All Study Documents for Active Studies, with the nearest CR Date going first
3. All Documents for Closed Studies from January 1st 2013

Documents will migrate over in the format (.pdf, .doc, etc.) in which they existed in *eIRB*.

What will I see in *iRIS* on Monday, May 21?
Beginning May 21, study teams will see the study shell. Study documents will begin to appear through the end of May and throughout June in the order described above. Studies will retain the original Pro#s that were assigned in *eIRB*.

When migration is complete, how will the study history appear in *iRIS*?
Past study submissions will be seen in *iRIS* as .pdf files. Study teams will be able to see the submission form, past documents, requested changes, and IRB approval notices.

When can I submit new studies, amendments, safety events, and CRs in *iRIS*?
Study teams can begin submissions as soon as 8 am on Monday, May 21.

What should I do if I need to submit my first amendment, safety event, or continuing review (CR) in *iRIS*?
Regardless of whether or not all study documents have been migrated, two submissions must be made. The first submission will be a "Migration Amendment" to complete the *iRIS* study submission form. Please do not upload study documents in this amendment; all approved documents will be migrated over prior to June 30. This amendment will be clearly labeled in *iRIS* as a "Migration Amendment" and will bypass all institutional reviews, including CRU review. When the PI hits the submit button, the Migration Amendment will come directly to the IRB. Once that amendment is approved by the IRB, the second submission will be the amendment, safety event, or CR and the most recently approved study documents relevant to the submission. For example, if an amendment is revising the protocol and consent form, study teams only need to upload the red-lined protocol and consent. All other most recently approved study documents will migrate over throughout May and June.

Because of volume, the IRB requests study teams not immediately file Migration Amendments unless a regular amendment, safety event, or CR needs to be submitted.

<u>No revisions to IRB- approved documents can be made via the Migration Amendment.</u>

What will happen to my studies in *eIRB* that have not been approved by 5pm on Friday, May 18?

- New studies that are not in IRB ownership by 5pm on Friday, May 18 will migrate back to 'Pre-Submission' (Draft) status in *iRIS*, maintaining the Study Shell, Pro#, etc, but requiring the Study team to fill out the *iRIS* submission form, attach all study documents, and submit to the standard workflow
- Studies that are in 'Pre-Submission' status in *eIRB*, that have been updated since July 1st, 2017, will migrate to 'Pre-Submission' (Draft) status in *iRIS*, requiring the Study Team to fill

out the *iRIS* submission form, attach all study documents, and submit to the standard workflow

- Submissions that have been routed to the IRB queue in *eIRB* by May 18th at 5pm, but have not yet received IRB approval will follow the sequence below:
  A. Post migration, IRB will return the submission for modification, requesting that the study team fill out the *iRIS* submission form
  B. Study team will only need to complete the *iRIS* submission form (no documents need to be attached), then return to IRB for processing;

What if I have an emergency amendment or safety event immediately after migration?
If a study team has an emergency amendment or emergency safety event during the first few days after Monday, May 21, the normal sequence of Migration Amendment, followed by a second submission (CR, amendment, safety event) does not need to be followed. The emergency amendment or safety event can be submitted first and reviewed by the IRB. A Migration Amendment can be submitted later at the study team's convenience.

What should I do to prepare for migration?
Before the end of the day on Friday, May 18, study teams that anticipate consenting subjects over the weekend should download the approved consent form and any supporting documents, such as the protocol/research summary, to a desktop for use. Please remember that neither *eIRB* nor *iRIS* will be accessible during the May 18-21 weekend. Otherwise, study teams will have the ability to view study documents and download approved consent forms from *eIRB* no later than 8am on Monday, May 21.

Study teams should make every effort to complete outstanding modifications and return to the IRB before 5pm on Friday, May 18. Even if modifications have not been completed, study teams must return the submission to the IRB with a note to hold for migration as that deadline approaches. The IRB specialist will hold the uncompleted submission in his/her workspace until shell migration is complete on May 21. He/She will then return the submission to the study team for completion of the modifications and completion of the *iRIS* submission form.

Remember that anything that is in the IRB's possession at 5pm on Friday, May 18, will not have to be re-submitted by the study team. However, all active studies will require a Migration Amendment to complete the iRIS submission form prior to any amendments, safety events, or CRs. Study teams with in-progress submissions will be asked by the IRB to complete the *iRIS* submission form prior to approval.

Can I start my study immediately after I receive IRB approval from *iRIS*?
No. A major difference in workflows between *eIRB* and *iRIS* is that IRB approval will be issued from *iRIS,* but institutional approval will be issued from *OnCore*. Once IRB approval is issued, study teams may initiate interim study activities as described in the IRB policy, but cannot recruit or consent subjects until institutional approval has been issued.

Are there any other significant differences between *eIRB* and *iRIS*?
Yes, the submission form in *iRIS* will be a smart form. In other words, your responses to questions will determine the next fields you will see. This is why it is important for you to

go stepwise through the submission instead of jumping between sections throughout the form.

In addition, the research summary, waivers, and several other forms are now embedded forms, not separate attached documents. IRB, CRU and Specialty Committee checklists will now also be embedded.

Finally, conversations between reviewers and the study team will be captured within *iRIS.*

Where and when can I get training on *iRIS*?
On-line videos and accompanying documentation specifically for study teams will be made available before the end of April. Additional training opportunities will be communicated as they are scheduled. Please also keep checking the IRB website at irb.duhs.duke.edu, *eIRB, and the DOCR Newsletter* for notice of their availability.

In addition, your IRB specialist, IRB management, and DOCR can help with your questions.