TO: University of Massachusetts Medical School Faculty and Staff

FROM: Katherine Luzuriaga, MD, Vice Provost for Clinical and Translational Research
Allison Blodgett, PhD, CIP, Director of IRB Operations

DATE: August 26, 2021

RE: eIRB Upgrade – Data Migration and Timeline for Access to Legacy eIRB

As noted in earlier communications, eIRB is being upgraded to a cloud-based environment. The **anticipated go-live date is October 12, 2021**. For a period of time, the UMMS IRB will need to freeze receipt of new studies, modifications, and continuing reviews to ensure data integrity across the two systems. We will do our best to keep the period as short as possible and to minimize the impact this may have on researchers. *From now through December, we encourage researchers to plan to submit time sensitive submissions (e.g., NIH JIT awards) well in advance of their due dates.*

We would also like to communicate important information regarding data migration and access to study records in Legacy eIRB. We will share continued communications, including information on key dates and times, as we progress along the project timeline.

Which studies will migrate from Legacy eIRB to the new eIRB?

The only studies that will migrate from Legacy eIRB to the new system are non-exempt approved studies. Non-exempt approved studies are studies that have a future expiration date at the time of data migration.

All other entries – including exempt studies (which have no expiration date), lapsed studies, dockets deemed to be not human subjects research, and submissions that are not yet approved – will be locked to editing and archived in Legacy eIRB. These entries will not migrate to the new eIRB.

Which personnel will migrate from Legacy eIRB to the new eIRB for non-exempt approved studies?

The PI and all individuals who are listed as active study staff in Legacy eIRB at the time of data migration will be linked to the study in the new eIRB.

No additional contacts from Legacy IRB will migrate. Study staff will be able to add a primary contact to migrated studies in the new eIRB after the system goes live.

What documents will migrate from Legacy eIRB to the new eIRB for non-exempt approved studies?

Non-exempt approved studies will appear in the new eIRB with their existing eIRB docket number, current expiration date, and the top-most current approved investigator study plan.

Prior follow-on submissions, all documents other than the study plan, and all prior versions of documents will not migrate.

How will documents other than the study plan be entered into new eIRB for non-exempt approved studies?

Study teams will be able to start fresh and to enter just their current approved documents (with any requested revisions) into the new eIRB at the first regularly scheduled Modification or Continuing Review with Modification.

This allows study teams to make use of new document categories, to discard outdated files, and to control where documents appear in the new eIRB.

Once the first Modification or Continuing Review with Modification is approved in the new eIRB, the new eIRB will house all current approved documents for a given study. Up until this point, all current approved documents remain current and approved in Legacy eIRB.

When will Legacy eIRB undergo database lock?

Legacy eIRB will be locked and archived once data migration begins. Locking the database closes Legacy eIRB to all changes. The date for data migration and database lock is TBD but will be announced well in advance.

Will study teams be able to access the Legacy eIRB archive?

Study teams will have read-only access to their studies and will be able to download and print from the Legacy eIRB archive when the following criteria are met:

- Individuals were listed as PI, active study staff, or additional contact on a given study at the time of database lock.
- Individuals access the archive via their UMassMed Single Sign-On credentials and the UMassMed network (i.e., on campus or via VPN or Pulse Secure).

How long will study teams have access to the Legacy eIRB archive?

Study teams will have access to the Legacy eIRB archive until 5pm, Friday, February 4, 2022. We encourage you to plan ahead and prepare for this deadline as outlined below.

How can study teams prepare for the February 4, 2022, 5pm deadline?

We have prepared a checklist to assist study teams in preparing for the deadline. Study teams are expected to download copies of the materials for which they are likely to need ongoing access. These include:

- Copies of IRB approval letters for the parent and each follow-on submission
- Copies of the SmartForms for the parent and each follow-on submission
- Copies of the approved study documents at the parent study and any corresponding Word versions used by eIRB to generate a stamped PDF of consents, HIPAA forms, and flyers
- A snapshot or download of the Project Personnel tab
- A snapshot of the Follow-On Submissions tab

What if a study team needs study records from the Legacy eIRB archive after 5pm on February 4, 2022?

Study teams are expected to prepare ahead and to download copies of the materials for which they are likely to need ongoing access. **After 5pm, Friday, February 4, 2022,** all direct access by the study team to the Legacy eIRB archive ends.

The Legacy eIRB archive will be maintained in compliance with regulatory requirements. In truly exceptional cases, such as an FDA audit, study teams should contact the UMMS IRB Office, which will work with UMMS Information Technology to facilitate document retrieval.

What can researchers do to help ensure a smooth transition?

- Complete the action items on the *eIRB Upgrade Checklist for PI's and Study Staff*.

- Download copies of the materials from Legacy eIRB for which they are likely to need ongoing access, following the model in *H00000000_piName_Legacy_eIRB_Download_Checklist.xls*.

- Monitor email for updates related to the new eIRB implementation.

- Complete new eIRB training as it is offered.

- Review the additional Q & A related to data migration and the Legacy eIRB Archive below.

We look forward to continuing to serve the UMMS research community with an improved eIRB system.

Please contact Allison Blodgett, Director of IRB Operations (Allison.Blodgett@umassmed.edu), with any questions or concerns.

ADDITIONAL Q & A RELATED TO DATA MIGRATION AND THE LEGACY EIRB ARCHIVE

What if my study is lapsed at the time of database lock?

A lapsed study does not have IRB approval. A study that is lapsed at time of database lock requires a new submission in the new eIRB and prior IRB review and approval.

What if my study, continuing review, modification, or reportable new information is not yet in an approved state at the time of database lock?

Only non-exempt approved studies will migrate to the new eIRB.

Study teams will need to re-create and submit in the new eIRB all other pending submissions that still require IRB review and approval. This includes new studies and all follow-on submissions.

Is it possible to change who has access to studies in Legacy eIRB?

Before database lock, it is possible to Edit Research Staff in Legacy eIRB. Once data migration and database lock begin, no changes are possible.

What if a new staff person needs access to studies in Legacy eIRB after database lock?

Once data migration and database lock begin, no changes to study staff can be made in Legacy eIRB. Principal Investigators are expected to prepare ahead and to ensure that study team members are listed as Active Study Staff or an Additional Contact prior to database lock.

When should study teams submit their first Modification or Continuing Review with Modification in the new eIRB?

Study teams are encouraged to complete their initial submission before Friday, February 4, 2022, to ensure access to current approved documents through Legacy eIRB.

8/26/2021

Messages through Legacy eIRB permit only a single attachment. For this reason, this document contains the following embedded files:

- 20210826_eIRBUpgradeChecklistForPIsAndStudyStaff
- eIRB Job Aid – Critical Deadlines and Steps for Downloading Files from Legacy eIRB ver. 8-26-2021
- H00000000_piName_Legacy_eIRB_Download_Checklist ver 8-18-2021.xls

To access an embedded file within a PDF, click on the link in the Attachments section of the header. If that does not work, open the PDF with Adobe Reader and access the navigation pane. Select Attachments to access the embedded files.
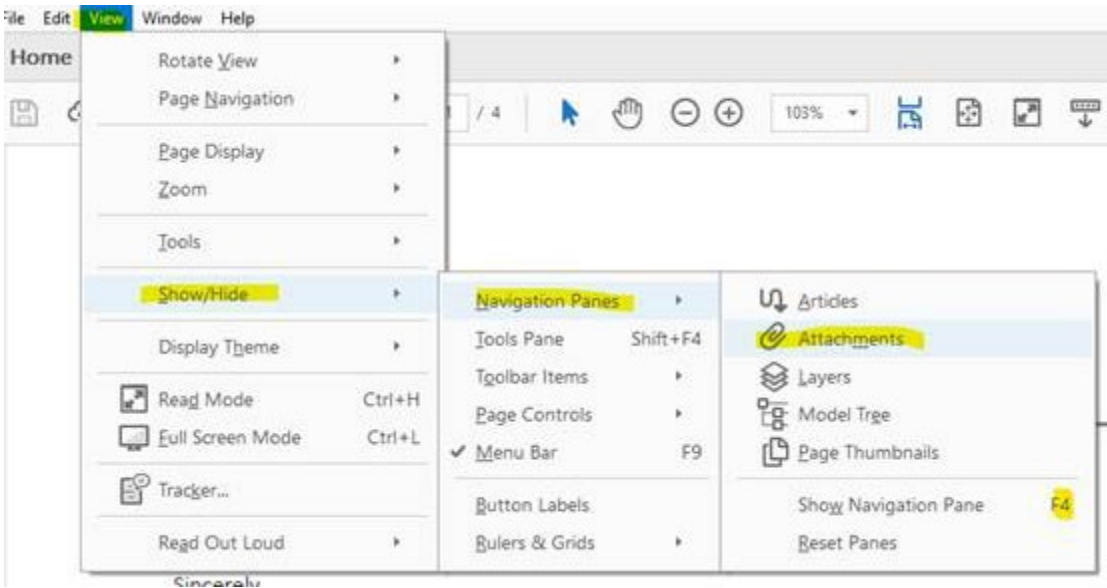
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