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Board**

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ADULT EMERGENCY





GOING LIVE!
TIME FOR THE eIRB TRANSITION

February 6, 2020



TOPICS TO COVER

Important Reminders

Reportable Events

Continuing Reviews

Modifications-including Staff Changes

New Studies

Protocol Templates

Consent Forms

Plan for studies not approved by initial migration

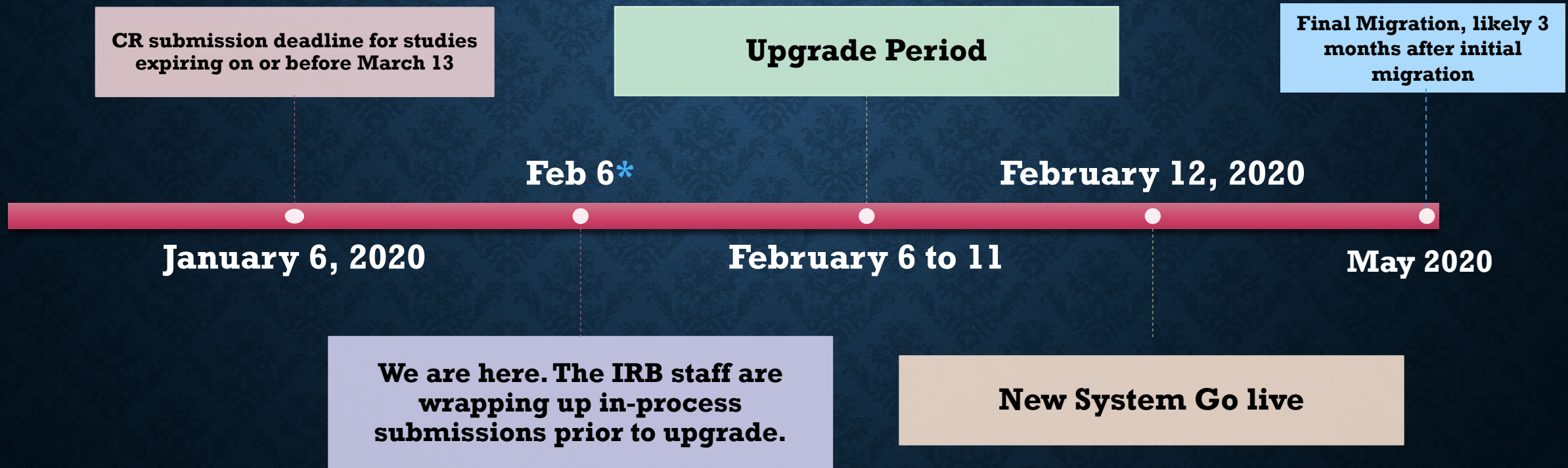
Your questions!



IMPORTANT REMINDERS



STRATEGIC SLOWDOWN



Studies with open submissions (not yet approved or open AM/CRs/REs) **cannot** be migrated on 2/6/2020. This now includes Reportable Events

Studies that do not migrate on 2/6/2020 to the new system will have to wait until second (or third) migration

If not fully approved with no open follow-on submissions by last migration, will need to do outside system and recreate in new system

All submissions we received this week (starting on 2/3) were withdrawn and we instructed teams to submit in the new eIRB on 2/12

IMPORTANT REMINDERS



EXAMPLE!

Study had an open submission (not approved)-did not migrate

Study needs to submit a Amendment

- The amendment can be submitted in the old system, since it will likely be wrapped up before next wave of migration
- If this were much later, may need alternative process.

February 15

May 2020

February 6

February 17, 2020

Submission gets approved in old system! Waiting for next migration...

Last chance to migrate studies!



REPORTABLE EVENTS



REPORTABLE EVENTS (RE'S)

New Reportable Events (Soon to be “Reportable New Information”):

If you became aware of a reportable event *after* 1/30/2020, please wait and submit it in the new system on 2/12/2020. You still will be in compliance.

The new RNI smartform screenshot is posted under our eIRB upgrade page so you can start preparing your submission

In-Process Reportable Events: Since open RE submissions will delay study migration, the Q team analysts are working diligently to wrap up open submissions.

If an event will not be acknowledged in the system by 2/6/2020, the Q team will manually re-create in the new system on your behalf. You will be contacted if any action is required on your part.

For studies that do not migrate that need to submit a reportable event (or “RNI” in the new system), this can be done in the old system. The review will need to be complete prior to the final wave of migration.



RE/RNI GUIDANCE

- We have posted [new guidance](#) on our website.
- Please plan to use the new “[Summary at CR](#)” form to report events at the time of renewal.
- You can find [videos](#) and screen shots of the [RNI smartform](#) on our website.

CONTINUING REVIEWS



CONTINUING REVIEW

As of 1/10/2020, studies expiring *after* March 13 were asked not to submit a CR. Those that submitted were asked to withdraw and submit in the new system.

A copy of the CR submission form from the new system is available on the website. Take a look so you can start preparing for your submission if needed.



MODIFICATIONS

Includes Staff Changes



MODIFICATIONS

- If your study is migrated: No modifications will be accepted until go-live in the new system.
 - Don't stress! If you have a reporting requirement, our P&Ps allow up to 10 business days for the report with few exceptions.
 - Check our website for screen shots of the Modification form in the new system. This will allow for a head-start on preparing the submission for go-live
- If your study was not migrated in the first data migration wave, modifications can be submitted in the old system. Every effort will be made to process quickly in order to allow for migration in the next wave.
- Good News! Track-changes versions of revised docs will not be required in the new system, due to advanced functionality with document comparison if using a word document (does not work with PDF).



STAFF CHANGE MODIFICATIONS

- The current online tool for staff changes was available until 2/4/2020, 5 pm. We will cease processing these requests until go-live on 2/12/2020.
- After go-live, studies that were migrated will need to submit a Modification for staff updates.
- Studies that are not migrated initially can still use the online tool, until migrated
- In order to facilitate our review, please make sure all staff have training that is up to date!
- New system has special modification type for staff changes – allows another modification to be in process at same time. Will be handled by dedicated IRB team members.



NEW STUDIES

Associated Updates to
Protocol and Consent
Templates



NEW STUDIES

NO new studies will be accepted during the upgrade period (2/3 til go-live).

Review our [current protocol templates](#) when preparing for your new study submission. These templates will be **required** for study submission moving forward.

If your study can wait, it's worth it! This will prevent you waiting for future migrations for your study to be available in the new system.

Review the upgraded [smartform document](#) to prepare your submission for the new system.



- We have posted all current protocol templates on our website. There is also a short video to walk you through the document.
- Keep as a Word document. Otherwise, it won't keep track of your changes in the system.
- You will be able to add information but not delete or rearrange the section headers.
This is critical to ensure we are not missing important information
- We have a site-specific addendum for studies with protocols issued by a sponsor or central site.



WIRB & CIRB STUDIES

- We have released new guidance, including how to complete the SmartForm for [WIRB](#) and [CIRB](#) studies.
- As a reminder, the “[Form A](#)” for WIRB studies is now an online form.
- Also, you won’t have to wait for a shell creation. Study teams will create the submission themselves in the new system (same for XIRB studies).

WIRB Form A

Complete this form to learn if your study is eligible to be submitted to Western IRB (WIRB). For more information about WIRB, please go to <http://www.irb.emory.edu/forms/external-irbs/wirb.html>. Please attach this form with your IRB submission under the "Study-Related Documents" section, question 3.

Hi Shara, when you submit this form, the owner will be able to see your name and email address.

* Required

1. Title of study: *

2. Local Principal Investigator Name *

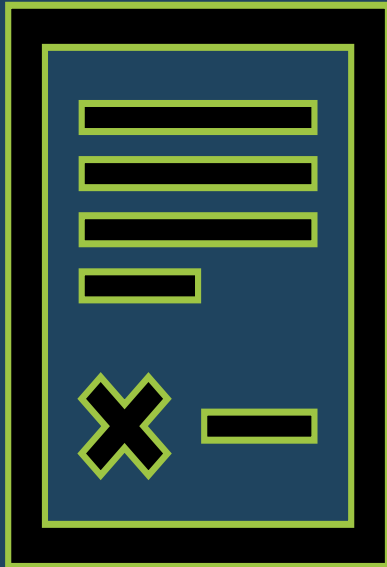
3. Are you required to submit to WIRB as you are participating in a single-site, federally funded study? *

- Yes-- submit to the Emory IRB.
- No

Send me an email receipt of my responses

Submit

CONSENT FORMS



- SaaS Biomedical Consent/HIPAA Template (v. 01-24-20)
 - Emory Biomedical Consent/HIPAA Template (v. 12-14-2018)
- SaaS Emory Biomedical Consent Template - HIPAA does not apply (v. 01-24-20)
 - Emory Biomedical Consent Template-HIPAA does not apply (v. 12-14-2018)

- We have published [new versions of all our consent form templates](#) to be used for studies submitted after go-live (labelled “SaaS...”)
- You are not required to immediately update your consents if already approved by the IRB.
- After go-live, any time your consents need to be re-stamped (modification or renewal) you will be required to remove the consent header.



STUDIES NOT REVIEWED BEFORE GO-LIVE

- Beginning today (Feb 6th): If your **new study**, **amendment**, or **continuing review** is in “Changes Required by IRB Staff” without action for over a couple of weeks, IRB staff will withdraw so that it does not interfere with study migration. (**Note:** if any ancillary approvals were already received, the IRB staff will ensure that is reflected in the new system after submission.)
- Any items that were in Pre-Submission state as of Feb 5th were withdrawn and teams will need to re-submit in the new system.
- As long as you respond to the analyst in a timely fashion with the information requested, the submission will keep moving along.



IMPORTANT TIPS FOR AFTER MIGRATION

- Funding sources: use wildcard (%) to search for your funder. All the NIH agencies are under "NIH National Institute..." (So searching "National" wouldn't work, nor would "NIAID," for example, unless you start with the wildcard)
- For local study team members, upload non-CITI training records in the "Local Site Documents" section under "Other attachments"
- You will see that migrated studies retain their IRB number. For newly submitted studies, there will be a different numbering convention.
- IRB staff will not be able to make edits on the study team's behalf



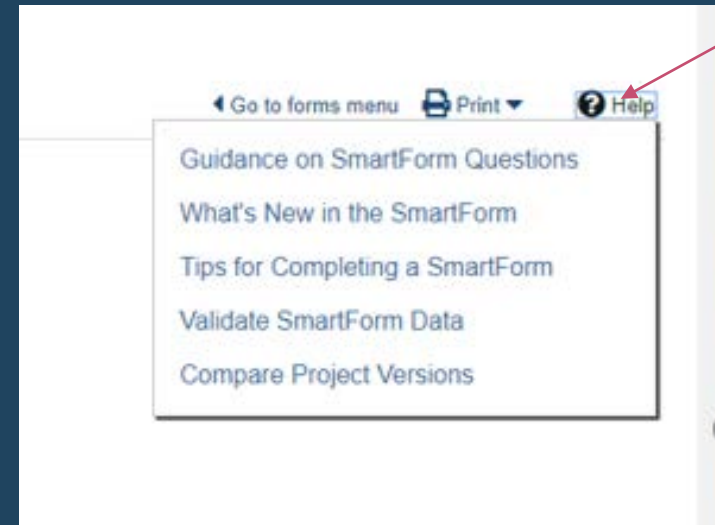
IMPORTANT TIPS FOR AFTER MIGRATION

- There will be **required** fields that weren't populated during migration. When you do amendments, you will get errors saying certain things aren't filled out, and it may not be obvious. Use the system messages to go to the relevant section, then look for error messages, and questions with asterisks that are blank.
- “Snapshots” of the latest (and prior) versions of study smartforms and documents, along with snapshots of past AM, RE, and CR submission forms, will be available in the *Documents* tab of the new system. In the smartform snapshots, the links to documents will work. Links to pop-up windows will not work; instead, scroll down to the bottom of the snapshot to see the contents of all pop-up windows (e.g. Drugs, Devices...)



IMPORTANT: HOW TO ACCESS SMARTFORM HELP

- There is page-level help on our website to guide you through every section and question of the new SmartForms.
- Select “Guidance on SmartForm Questions”
- [Also, find it here!](#)





- Additional training will be offered via Zoom after go-live. We will post available dates on the website by February 3, 2020
- [Instructional videos](#) have been posted on our website. Please review them and let us know if your group needs additional training or if you have any questions.
- The videos require you to login with an Emory NetID and password.



- Be sure to **save copies of your study documents** in the regulatory file. This is always a good idea, since you can't always depend on an electronic system!
- See the [policy on record retention](#) for more details on requirements specific to your project.



QUESTIONS?

IRB@emory.edu

Call or email your study analyst directly,
for specific study question.

Call any of our staff for general questions.

To schedule training for a group, contact
Shara Karlebach at 404-712-0727 or via
email at shara.karlebach@emory.edu

For any other questions, reach out to our QA
and Education team

