

September IRB Update:

eIRB Update Project: Important Dates and Submission Restrictions

In order to migrate study data from the current eIRB system to the upgraded one, there needs to be a **strategic submission slowdown**, currently planned for January 2020. This slowdown will allow our vendor to efficiently conduct the data migration process and will shorten the overall time to complete the upgrade. The current proposed dates for the slowdown are **January 7-January 31**. These dates are subject to change depending on technical issues discovered along the way. Rest assured we will keep you well-informed of any changes! **Please note that the IRB will not process or accept the submission of any continuing reviews during the slowdown period.** Please read on to learn how the slowdown may affect your studies.

New Studies

During the submission slowdown, the IRB will generally **only accept new study submissions for interventional studies (i.e. treatment studies) that meet the following criteria:**

- Competitive enrollment or contractual obligation for quick start-up (eg. NCI grant), **and**
- IRB review is the limiting factor in study start-up (i.e. you should not submit if a contract, etc. is not close to being ready)

All other types of studies should be held until the new system go-live date. If you have special concerns, please consult with [IRB staff leadership](http://www.irb.emory.edu/about/staff.html) at <http://www.irb.emory.edu/about/staff.html>.

Also: *Any new studies submitted during the slowdown that are not approved within **90 days** of the upgraded system going live (i.e. when the second wave of data will be migrated), will be **withdrawn**.* You will have to submit again in the upgraded system because the study cannot be migrated. Please consider the likelihood of all pending issues being addressed (e.g. ancillary reviews, IND issues) in the required time frame before submitting during the slowdown.

Continuing Reviews

The IRB will not process or accept the submission of any continuing review submissions during the slowdown period. Due to the possibility that the slowdown period may shift, the IRB is requiring that **all studies scheduled to expire between January 1, 2020 and February 21, 2020 submit a continuing review in November 2019 to avoid a lapse in approval.** Please review your portfolio of active studies to determine whether your studies may need to submit continuing review early, and contact irb@emory.edu if you have any questions.

Amendments

Amendment submissions will only be accepted and processed if they consist of changes **required to protect research subjects' safety and welfare** or immediate changes **required by the study Sponsor.**

Reportable Events

No changes. All reportable events should be submitted in the current eIRB system as normal until the go-live date for the new system.

WIRB and other External-IRB-reviewed studies

Another workflow will be available outside of eIRB. Please stay tuned for more information.

[Help Us Test the eIRB System Upgrade: An Opportunity for Input \(and Food\)!](#)

This is an invitation for those interested in helping us test the new system. Help us prevent hiccups later by giving input now! You'll also get acquainted with the new system in advance. We welcome all volunteers, but need at least a couple people **who rarely or never use eIRB** and can really test the new system's user-friendliness. We have room for the first 20 respondents to join in the fun! A warm thank you to those who have already signed up- we have your information and are looking forward to your assistance. We will be reaching out to all system testers at the end of September with more information about the testing schedule in October. **Food will be provided!** Please [send us an email](mailto:irb@emory.edu) at irb@emory.edu to confirm your interest.

[New Protocol Templates Required for Upgraded System](#)

We have updated our protocol templates to coordinate with the new system's **streamlined smartforms**. The use of the new protocol templates is **required for all new study submissions in the new system** on the go-live date, but we encourage you to **start using them now!** You can review the new protocol templates on our website: http://www.irb.emory.edu/eirb_project_huron_saas/New_Templates.html.

We will also require a [supplement to a sponsor protocol template](http://www.irb.emory.edu/eirb_project_huron_saas/New_Templates.html) (http://www.irb.emory.edu/eirb_project_huron_saas/New_Templates.html) to capture the Emory-site-specific information (e.g. local recruitment methods, data storage plans, etc.) no longer captured in smartform pages.