September IRB Update

eIRB Update Project: Important Dates and Submission Restrictions
To migrate study data to the upgraded eIRB system, we need to have a strategic submission slowdown, to take place from January 7 to January 31. These dates are subject to change. We will keep you well-informed of any changes! Please read on to learn how the slowdown may affect your studies.

New Studies: During the submission slowdown, the IRB will 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 (e.g. 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.

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approved within 90 days of the upgraded system going live (i.e. when the second wave of data will be migrated), will be withdrawn.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. All studies scheduled to expire between January 1, 2020, and February 21, 2020, submit a continuing review by November 1st for Full Board and by November 15, 2019, for expedited studies to avoid a lapse in approval. Review this list to see if your study is affected. Contact the IRB 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.

WIRB and other External-IRB-reviewed studies: Another workflow will be available outside of eIRB. Please stay tuned for more information.

New Protocol Templates Required for Upgraded System
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. For sponsor created protocols, we will also require a supplement to a sponsor protocol template to capture the Emory-site-specific information (e.g. local recruitment methods, data storage plans, etc.) no longer captured in smartform pages.