Handling Changes to the Study for Single/Central IRB Multi-site Studies

PURPOSE

This guidance will detail how to handle needed changes to a study when Emory is the IRB of Record and when Emory has ceded review to an External IRB.

RESPONSIBILITIES

- Reliance Specialist – identifying and making a record of the notification of approval sent by external IRBs and/or Study Teams.

PROCEDURE

When Emory is the Reviewing IRB for other sites:

- The Emory study team will need to submit an amendment.
    - If Emory specifically is making a change that will not affect the other sites (such as a change in study staff), the Emory study team should submit an amendment as normal through eIRB. The IRB analyst assigned to the study will process and approve the amendment as normal.
    - If a substantive change is being made that will affect all sites (such as a change in the protocol), the Emory study team should submit an amendment as normal through eIRB. The IRB analyst assigned to the study will process and approve the amendment as normal. The Emory study team will be responsible for collecting any information needed for the amendment from the relying sites and for sending any approval documents post-processing to the relying sites.
    - If a change needs to be made specifically for a site which will not affect the other sites (such as a change in their study staff), the Emory study team is responsible for collecting the necessary information and documentation from the relying site in order to submit the amendment. The IRB analyst assigned to the study will process and approve the amendment. The Emory study team is then responsible for sending any approval documents post-processing to the relying sites.

When Emory is Relying on Another IRB:

- An amendment will need to be submitted to the external IRB for any change to the overall study or Emory as a site. An amendment does NOT need to be submitted to Emory. The Emory study team should follow the external IRB's procedure for submitting an amendment. The Emory IRB only needs the final approval documents (letter, consent and HIPAA authorization documents, any recruitment materials or brochures, etc.). You should upload those into a logged comment in the XIRB submission.
    - NOTE: If the change is one that triggers a new ancillary review at Emory, requires changes to Emory's site language in the consent forms, or requires Emory to "sign-off" on new recruitment materials or investigator brochures, log a comment prior to the amendment being sent for review and Emory will review and provide you a new institutional signoff.
- If the change is one to Emory's PI or co-investigators, log a comment with the changes, and the reliance specialist will administratively make the change in the XIRB shell. If the change is one to the Emory study staff, you should use the Study Staff Change tool as you normally would.