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 AND ANY REVISED CONSENT FORMS, HIPAA AUTHORIZATIONS FORMS, AND STUDY MATERIALS) FOR THE AMENDMENT SENT TO THE RELIANCE SPECIALIST VIA EMAIL AT HANNAH.ALLEN@EMORY.EDU.
- The reliance specialist will log a comment in eIRB (uploading the approval documents) that states the following:
- If the change is one to Emory’s PI or study staff, the reliance specialist will administratively make the change in the XIRB shell to reflect that by using the “Admin View” button on the top left side of the screen.