

Submitting a Continuing Review Progress Report for Multi-site Studies

PURPOSE

This guidance outlines **how the Emory study team should submit a CR progress report to obtain IRB studywide continuing review approval where Emory IRB is serving as the Reviewing IRB for multiple sites.**

RESPONSIBILITIES

- Emory/Lead Study Team: submitting overall eIRB submission to Emory IRB using the eIRB smartform for continuing review. Providing each participating site study team with the CR Site Update Form to fill out and uploading each site's form as part of the submission.
- Relying Site Study Team: providing the Emory/Lead Study Team with the completed CR Site Update Form.

PROCEDURE

- The Emory study team must provide each participating site relying on Emory IRB with the CR Site Update Form (on the website) and gather the form once completed from each participating site.
- The Emory study team must fill out the online CR smartform for Emory as a site and upload the the forms to Question 6.0 of "Continuing Review IRB Study Status" section of the eIRB smartform.

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Continuing Review

6.0 * Is there any other information that was not previously reported before, not fitting the above-described criteria that needs to be reported at continuing review? (Prior to July 2015, eIRB here asked for copies of any changes to protocol-related documents in the past year, these should instead be submitted via amendments only.)

Yes No Clear

If yes, please upload:

Name	Modified	Version
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- Once the CR is approved, the Emory study team is responsible for sending approval letters and documents to their contact for each participating site's study team.

FAQs

What does "significant new findings" mean?

As set forth in Emory IRB Policies and Procedures, a CR report must contain a statement of any finding (that's taken place since the last approval date) which has developed during the course of the research which may relate to a human subject's willingness to participate or to continue participation in the study. These significant new findings must be reflected in the most current consent document and communicated to all subjects (both prospective new subjects and those already enrolled in the study).

For questions that refer to "enrolling" or "enrollment," what constitutes enrollment?

As defined by the Emory IRB Policies and Procedures, a subject is considered to be enrolled in a study when he/she gives informed consent to participate. Accessing the identifiable information of an individual similarly counts as enrolling a subject.

Any individual who has gone through the consent process has "enrolled" even if they did not complete any other research activities. Those who were "recruited" but did not follow through with the consent process are NOT considered "enrolled."