Submitting an Amendment to Onboard a Participating Site

PURPOSE

This guidance outlines how the Emory study team should submit an amendment to obtain IRB approval for participating sites to begin multi-site research post-Emory IRB approval of the main protocol, consent form, and other study documents.

SCOPE

This guidance applies to any study which has multiple sites engaged in human subjects research, where Emory is serving as IRB of record. It applies to new multi-site studies being handled by the IRB Reliance Specialist as well as Emory studies which were previously approved as single-site studies but are now onboarding new sites, and Emory has agreed to be the IRB of record. (Note: generally the latter only occurs when the added sites have limited involvement, e.g. data analysis). This should not happen until a reliance agreement has been fully executed per the Setting up an IRB Authorization Agreement or Individual Investigator Agreement SOP or the Reliance Specialist Process for New Multisite Study sIRB Requests SOP.

NOTE: These amendments should ONLY be used to add participating sites. Any substantive changes to the overall study or for Emory as a site will have to submitted in a separate amendment for the Analyst to process.

RESPONSIBILITIES (For other responsibilities, reference your study’s Division of Responsibilities Table)

- Emory/Lead Study Team: submitting amendment to Emory IRB for each participating site and uploading all documents including study-specific consent and HIPAA authorization documents, reliance agreements, and completed and signed Local Context Worksheets.; sharing approval letters and documents with the Relying Site study team.
- Relying Site Study Team: providing the Emory/Lead Study Team with the completed and signed Local Context Worksheet from the Relying IRB; providing the Emory/Lead Study Team with a redlined version and a clean version of all site-specific consent documents (by taking the Emory model consent and plugging in site-specific language for costs, in case of injury, HIPAA authorization, site name, and PI contact information as applicable); providing Emory/Lead Study Team with a staff listing.
- Relying IRB: signing and providing to the Relying Site Study Team the completed Local Context Worksheet; checking the Relying Site consent documents for accuracy before giving institutional signoff; checking that Relying Site Study Team’s site requirements (training and qualifications, conflict of interest, ancillary review, etc.) have been completed at the Relying Institution.

PROCEDURE

1. Amendment Request:
   a. The Emory Study Team submits amendment specific to onboarding new site (see NOTE above) by clicking “New Amendment” at the bottom left of the eIRB submission workspace. For guidance on how to do this in eIRB, go here: http://www.irb.emory.edu/eirb/how-to.html#faq5.
   b. For Question 1.0, the Emory study team checks “Changes to Study Team Members” and “Changes to Study Sites.”
i. If the Relying Site study team is enrolling its own subjects: also checks “Change to Consent Form(s)” and “Change to Study Enrollment” (if the original study submission does not already reflect the correct “Number of Total Enrollment.”)

ii. If the Relying Site study team using its own recruitment materials: checks “Changes to Advertisements.”

c. For Question 2.0, study team describes the makeup of the Relying Site study team (e.g. one graduate student receiving academic credit, a group of 14 physicians, etc.) and the Relying Site’s involvement in the study including whether the Site 1) is prime awardee or receiving a subcontract from Emory, 2) is enrolling subjects and how many, 3) will access identifiable information or biospecimens (and if so, which kind?), 4) will administer study interventions (including surveys or questionnaires), 5) will participate in data analysis. If Relying Site isn’t conducting the full protocol but coming to Emory to assist at our site, study team states this and describes how the researchers will be assisting. If the researchers are students, study team includes whether they are receiving payment or academic/internship credit from the Relying Institution for their participation.

d. For Question 3.0, study team clicks “Yes” if subjects have already been enrolled at Emory.

e. For Question 6.0, study team checks all current Emory sites and includes Relying Sites under the correct “Other” option (e.g. If Georgia State University is the participating site, it would be appropriate to check “Other – In Atlanta metropolitan area”).

f. Study team then clicks “Continue” in the bottom right corner and fills out each page until they arrive at “Instructions for Updating the Study.” See guidance as applicable:

   i. For all Relying Sites: Go to Study Team Changes and click “No” for questions 1.0 through 4.0. Click “Yes” for Question 5.0.

   ii. If Relying Sites enrolling subjects: Go to Consent/Assent Form Changes and fill out description to reflect that new site-specific forms are being added for the Relying Site. Go to Enrollment Changes and change Number of total enrollment to reflect the total number of subjects that will be enrolled total.

   iii. If Relying Sites using their own recruitment materials: Go to Advertisement/Recruitment Material Changes and fill out description to reflect that new site-specific materials are being added for the Relying Site.

g. Upon arriving at “Instructions for Updating the Study”, study team clicks “Go to the forms for the Study being amended” as pictured below and is taken to the main study submission to make changes described in the amendment.

Instructions for Updating the Study

- To make changes or update information for this study, click on the link below
- This link will take you to a copy of the application form (the online form originally filled out and submitted to the IRB office to request Study approval)
- Once changes are made to the form, follow the on screen instructions to submit the Amendment and all changes to the IRB office

i. For all Relying Sites: add names of Relying Site Study Team staff to Study Identification Information Question 9.0. In pop-up window, fill out questions. Type Relying Institution name as the “Affiliation.” Add the Relying Sites to Study Sites Question 2.0 by clicking “Add” and filling out all questions in pop-up window. For “Has the site granted permission for the research to be conducted?” respond “Yes” and upload the fully-executed reliance agreement.
by clicking the “Add” button. Include Emory IRB as “IRB of Record for Site” and check “the site wishes to rely on the Emory IRB.” Under Miscellaneous Documents, upload Relying Site’s Local Context Worksheet and sub-contract agreements, if applicable.

1. **NOTE:** Study Team does NOT have to include CITI certificates for the Relying Site Study Team, as the Relying IRB is in charge of checking their training and qualifications.

   ii. If Relying Site enrolling subjects: Change Questions 2.0 and 3.0 of the Informed Consent Process section to reflect the site-specific documents. Add redlined clean versions of each site-specific consent document (and specify in document name whether clean or redlined and which Relying Site).

   iii. If Relying Site using site-specific recruitment materials: Upload materials to Recruitment and Payment Question 4.0 (and specify which Relying Site in document name).

h. Once completed, study team clicks Save and Exit at the top center and goes back to the “Instructions for Updating the Study” page then clicks “continue” at the bottom right corner and the Finish button.

i. Any changes needed will be requested by the Analyst/Reliance Specialist through the “Changes Requested by IRB Staff” state. Study team should make those changes as requested.

j. Once approval documents are sent, Emory’s study team must provide those to the Relying Site Study Team so they can begin study activities.