

## Reliance Process When Relying on An External IRB

1. Submit reliance request to IRB Reliance Listserv.
2. Receive determination from Emory IRB staff member about willingness to cede review.
3. If yes, Emory IRB staff member reaches out to proposed Reviewing IRB to negotiate reliance agreement (including division of responsibilities, proof of insurance provision, indemnification provision if applicable, and process for notification about falsification/fabrication of data).
4. Emory IRB staff member receives proposed Reviewing IRB template with negotiated provisions and drafts memo to institutional official.
5. Emory IRB staff member sends agreement and memo to IO for signature.
6. Emory IRB staff member emails partially executed reliance agreement to Reviewing IRB and relying study team.
7. Emory IRB staff member creates XIRB submission shell in eIRB and sends to Emory study team.
8. Emory study team completes and submits in the XIRB shell, uploading 1) protocol, 2) grant/award document, 3) model consent/assent documents and model HIPAA authorization forms, 3) site-specific consent/assent documents and site-specific HIPAA authorization forms and XIRB Consent Checklist, 4) site-specific recruitment materials and/or investigator brochures (See XIRB Smartform Guidance Document uploaded into the shell).
9. Emory IRB staff member checks local submission- including investigator training, COI, departmental and ancillary review completion, budget and contract completion, model/approved consent template with Emory-specific language plugged in, and XIRB Consent Checklist.
10. Emory study team fills out local context worksheet to the best of its ability and sends to reliance specialist for review and signature.
11. Once local submission is complete (including all ancillary reviews), Emory IRB staff member logs a comment in electronic system giving Emory study team institutional signoff to submit to the Reviewing IRB and attaches local context worksheet to the comment.
12. Emory study team sends local context worksheet, local ICF/HIPAA form, and any other site-specific information needed to Lead Study Team for submission to the external IRB.
13. Once Emory study team receives site-specific approval letter and documents from the external IRB, Emory study team sends the documents to the Emory IRB staff member as well as any other necessary ORA staff member.