

Duties of the Lead PI (Overall PI at the Institution that is Prime Awardee)

1. The Lead PI is responsible for carrying out the research in compliance and having appropriate procedures in place the same as if it were a single site study as well as any additional requirements imposed specifically for multi-site studies.
2. The Lead PI is responsible for all of the ordinary recordkeeping duties required under applicable law and regulations when conducting research.
3. The Lead PI is responsible for drafting the protocol document and consent/HIPAA documents and for drafting any study-wide changes to those documents (to be reviewed via amendment by the IRB) throughout the life of the study.
4. The Lead PI is responsible for going through the Reviewing IRB's reliance request process (at Emory, filling out the Reliance Request Form).
5. The Lead PI is responsible for promptly responding to questions or requests for information from study teams and HRPP personnel at the Relying Institutions and participate in calls and meetings as necessary.
6. The Lead PI is responsible for providing to the Site PI the Local Context Worksheet and any other documents the Reviewing IRB requires the Site PI to fill out.
7. The Lead PI is responsible for providing the Site PI the grant/award to provide the appropriate offices at the Relying Institution.
8. The Lead PI is responsible for collecting any documents necessary to onboard the Relying Site with the Reviewing IRB (the fully-executed reliance agreement, the completed local context worksheet, the site-specific consent/HIPAA documents, etc.).
9. The Lead PI is responsible for preparing and submitting the study-wide application for initial IRB review, continuing IRB review, and study-wide amendments to the Reviewing IRB.
10. The Lead PI is responsible for onboarding the Relying Site with the Reviewing IRB via amendment and uploading the reliance agreement, local context worksheet, and site-specific documents to the study in the electronic system.
11. The Lead PI is responsible for collecting any information or documents necessary for a Relying Site's site-specific amendment (changes in Relying Site study staff, changes in Relying Site consent/HIPAA documents, etc.) and submitting the amendment with the Reviewing IRB.
12. The Lead PI is responsible for providing the Reviewing IRB's studywide approval letters and approved study documents (protocol, consent, HIPAA, recruitment materials etc.) at the initial review, amendment, and continuing review stages, as well as any approval letters specific to the Relying Site (amendment to onboard the site, any other amendment specific to the Relying Site).
13. The Lead PI is responsible for collecting site-specific information for the continuing review progress report from the Site PI.
14. The Lead PI is responsible for providing access, upon request, to study records for audit by the Reviewing IRB, the Relying Institution, or other regulatory or monitoring entities.
15. The Lead PI is responsible for obtaining and collating studywide information for continuing review and submitting the continuing review progress report to the Reviewing IRB.
16. The Lead PI is responsible for forwarding any notifications received from the Reviewing IRB about updates to the Reviewing IRB's Policies and Procedures to the Site PI.
17. The Lead PI is responsible for notifying the appropriate offices of changes in PI, changes in conflict of interest, changes that would impact procedures that have a billable code, changes which would require further ancillary review.
18. The Lead PI is responsible for providing required information to the Designated IRB when the study is closed.

Duties of the Site PI (Designated Co-Investigator at the Relying Institution)

1. The Site PI is responsible for going through the Relying IRB's reliance request process (at Emory, filling out the Reliance Request Form once receiving the submission materials initially approved by the Reviewing IRB from the Lead PI).
2. The Site PI is responsible for filling out the Reviewing IRB's local context worksheet, as well as any other worksheets required by the Reviewing IRB for reliance, to the best of his/her ability and providing the filled-out worksheet to the Relying IRB so that the Relying IRB can review and make additions or changes to the worksheet and provide an IRB signature.
3. The Site PI (and other relying investigators) are responsible for going through their local conflict of interest review and providing conflict of interest determinations and management plans to the Reviewing IRB.
4. The Site PI (and other relying investigators) are responsible for completing the training requirements of the Relying Institution and providing confirmation of that training to the Relying IRB for institutional signoff.
5. The Site PI is responsible for ensuring that the study goes through departmental review, ancillary reviews (Radiation Safety, Biosafety, Office of Quality Manager, etc.), and routing through the research administration offices (Office of Clinical Research, Office of Sponsored Programs, etc.) prior to the institutional signoff from the Relying IRB.
6. The Site PI is responsible for providing the Relying IRB with confirmation that contract and budget negotiations have been completed and that the correct cost and injury options have been provided by the offices in charge of that language (At Emory, providing written confirmation from OCR and OSP).
7. The Site PI will be responsible for creating the site-specific consent and HIPAA authorization document(s) by incorporating site-specific provisions, determined by the Designated IRB, into the Designated IRB's approved consent and HIPAA authorization document(s) and will then be responsible for providing the documents to the Lead PI for the Designated IRB's review.
8. The Site PI is responsible for completing the local "XIRB" submission in the Relying IRB's electronic system (attaching the protocol, grant/award, and consent/HIPAA documents) and awaiting institutional signoff from the Relying IRB.
9. The Site PI will be responsible for providing all other site-specific documents and information necessary for IRB submission (at the initial review, amendment, and continuing review stages) to the Lead PI.
10. The Site PI is responsible for providing any approval letters or approved study documents received from the Lead PI to the appropriate offices at the Relying Institution (IRB, OSP, etc.) at the initial review, amendment, and continuing review stages.
11. The Site PI is responsible for maintaining the relying investigators' CVs, licenses, and training records on site.
12. The Site PI is responsible for only implementing changes of protocol, including local variations, after the Reviewing IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.
13. The Site PI is responsible for reporting any of the site's reportable events to the Reviewing IRB.
14. The Site PI is responsible for sending any reportable event report made to the external IRB to the appropriate individuals at the Relying IRB.
15. The Site PI is responsible for reporting any of the following changes to the appropriate Relying Institution offices: changes in PI, changes in conflict of interest, changes that would impact procedures that have a billable code, changes which would require further ancillary review.
16. The Site PI will be responsible for providing to the Lead PI any site-specific information necessary for the closure report to the Designated IRB.
17. The Site PI is responsible for providing access, upon request, to study records for audit by the Reviewing IRB, the Relying Institution, or other regulatory or monitoring entities.