Communication Plan Table

Emory PI:
Other Site PI:
Protocol Title:
Institution Relying on Emory for IRB Review (Name, FWA#):

RESPONSIBILITY	RESPONSIBLE PARTY	NOTES
FWA/Oversight: Maintaining an OHRP-approved FWA and notifying all participating sites promptly in writing of any suspension, restriction, termination, or expiration of said FWA; or of any failure to maintain registration of its IRB; or any loss of/change to its HRPP accreditation status	☑ Reviewing IRB ☑ Relying IRB	
IRB Membership: Maintaining IRB membership in line with Federal Policy and other applicable regulations and policies	☑ Reviewing IRB ☐ Relying IRB	
SOPs and P&Ps: Which IRB's Standard Operating Procedures and Policies and Procedures will be used and followed for this study?	☑ Reviewing IRB ☐ Relying IRB	
Providing Procedures and Policies: Providing said SOPs and P&Ps to the relying site study team when applicable and upon request	☑ Reviewing IRB ☑ Reviewing Site Study Team ☐ Relying Site Study Team ☐ Relying IRB	The Reviewing IRB has made the P&Ps available on Emory IRB's website. The Reviewing Site Study Team is responsible for telling the Relying Site when relevant updates to the P&Ps are made
COI: Providing conflict of interest determinations and management plans for the relying site study teams to the Reviewing IRB so that Reviewing IRB may incorporate them into its review	☐ Reviewing IRB ☐ Reviewing Site Study Team ☑ Relying Site Study Team ☐ Relying IRB	

Study Team Training/Qualifications: Checking and providing confirmation to Reviewing IRB that relying site study team has completed relevant training and is qualified to conduct the study	☐ Reviewing IRB ☐ Reviewing Site Study Team ☐ Relying Site Study Team ☑ Relying IRB	The Relying IRB must sign off on the Local Context Worksheet that investigator training is completed and up-to-date.
Congruence with Federal Grant Apps/Contract Proposals: Reviewing the congruence of grant application or contract proposal with the protocol submitted when required by law or regulations	☑ Reviewing IRB ☐ Reviewing Site Study Team ☐ Relying Site Study Team ☐ Relying IRB	
Local Context Information: Providing local context/site submission information to Reviewing IRB with state and local law and institutional policies which are relevant to the study	☐ Reviewing Site Study Team ☑ Relying Site Study Team ☑ Relying IRB	The Relying Site Study Team must fill out the Local Context Worksheet and send to the Relying IRB for review. Representatives from both the study team and the IRB must sign.
Institutional Authorization Signoff: Maintaining a system of checking training/qualifications, informed consent and HIPAA authorization documents, and local context form responses prior to signing the Reviewing IRB's Local Context/Site Submission Form(s)	○ Relying Site Study Team ◉ Relying IRB	The person who signs as the Local Context Representative SHALL be the IRB STAFF MEMBER designated to complete that task by the Relying Institution.
Compliance: Ensuring that **relying site study team** understands and complies with the determinations of the Reviewing IRB, application law and regulations, governing P&Ps and SOPs, and the reliance agreement	○ Reviewing Site Study Team ○ Relying Site Study Team ◉ Relying IRB	
Studywide Application: Preparing and submitting the studywide application for initial review and amendments to Reviewing IRB	☑ Reviewing Site Study Team ☐ Relying Site Study Team	
Site-Specific Application: Preparing and submitting site-specific application for site onboarding (e.g. site ICF language, HIPAA language, subject identification and recruitment, etc.)	☐ Reviewing Site Study Team ☑ Relying Site Study Team	Relying Site Study Team must provide customized consent and HIPAA authorization documents and any other necessary information to the Reviewing Site Study Team for site onboarding.

IRB Determinations: Making and promptly notifying the relying IRB and relying site study team of IRB determinations and providing any necessary supporting documents (to be accepted by the Relying IRB)	☐ Reviewing IRB ☑ Reviewing Site Study Team ☑ Relying Site Study Team	Reviewing Site Study Team shall provide documentation of IRB determinations to Relying Site Study Team. Relying Site Study Team shall thereafter provide to the Relying IRB.
Reviewing Site IRB-Approved Documents: Providing copies of the IRB-approved materials to the reviewing site study team	Reviewing IRB	
Relying Site IRB-Approved Documents: Providing copies of the most current versions of IRB-approved materials to relying site study team in timely manner	○ Reviewing IRB ◉ Reviewing Site Study Team ○ Relying Site Study Team ○ Relying IRB	Reviewing Site Study Team shall provide materials to Relying Site Study Team. Relying Site Study Team shall thereafter provide to the Relying IRB.
HIPAA: Serving as HIPAA Privacy Board for the relying site study team	◉ Reviewing IRB ○ Relying IRB ○ Other: _____	
Confidentiality: Treating confidential information provided by other participating sites in accordance with the same standards and lawful protections for confidentiality and security as it would normally apply	☑ Reviewing IRB ☐ Reviewing Site Study Team	
Consent Form Template: Providing approved/model consent form template to relying site study team	○ Reviewing IRB ◉ Reviewing Site Study Team	
Consent Form Language: Incorporating site-specific language into ICFs (after vetting by the Relying IRB) and providing customized ICFs to Reviewing IRB	☐ Reviewing Site Study Team ☑ Relying Site Study Team ☐ Relying IRB	Then providing the customized documents to the Reviewing Site Study Team. The Reviewing Site Study Team thereafter submits the customized documents during site onboarding.

Duration of Oversight Authority: Which IRB will review amendments and CRs for the relying site study team?	☑ Reviewing IRB ☐ Relying IRB	
Continuing Review Information: Obtaining and collating studywide information for CR to said IRB	☑ Reviewing Site Study Team ☐ Relying Site Study Team	
Continuing Review Submission: Submitting CR progress report to said IRB	☑ Reviewing Site Study Team ☐ Relying Site Study Team	
Site-Specific CR Information: Obtaining and collating site-specific information for CR and submitting the information	☐ Reviewing Site Study Team ☑ Relying Site Study Team	Relying Site Study Team fills out the appropriate form (provided by the Reviewing Site Study Team) and gives the filled out form to the Reviewing Site Study Team for the overall CR submission
Ongoing Approval: Promptly providing the Relying IRB with any and all initial, AM, or CR approval letters when they become available.	☐ Reviewing IRB ☑ Reviewing Site Study Team ☑ Relying Site Study Team	Reviewing Site Study Team shall provide documentation to Relying Site Study Team. Relying Site Study Team shall thereafter provide to the Relying IRB.
AM and CR Local Context Review: Providing the Relying IRB with any and all updated Local Context/Site Submission Forms required to be submitted for AM or CR approval so that Relying IRB POC can sign off on them prior to submission	☐ Reviewing IRB ☑ Reviewing Site Study Team ☑ Relying Site Study Team	Reviewing Site Study Team shall provide documentation to Relying Site Study Team. Relying Site Study Team shall thereafter provide to the Relying IRB.
QA/QI: Maintaining, implementing, or having access to a human subjects research quality assurance/quality improvement process or other monitoring program to accept subject complaints, conduct for-cause and not-for-cause audits, and report results to the relying site study team and other IRB	☑ Reviewing IRB ☑ Relying IRB	

Review of REs: Reviewing unanticipated problems and potential noncompliance of the relying site and providing details of the determinations (including suspension, termination, or remediation) to relying site study team and other IRB	☑ Reviewing IRB ☐ Reviewing Site Study Team	Reviewing IRB is responsible for notifying the Relying IRB of any communications regarding UPs, suspension, termination, SNC or CNC determinations.
Initial Report of REs: Initially reporting relying site REs to above-chosen IRB and providing CAPA plan as necessary	☐ Reviewing IRB ☐ Reviewing Site Study Team ☑ Relying Site Study Team ☐ Relying IRB	Relying Site Study Team is responsible for providing applicable information to the Reviewing Site Study Team.
Notification of Serious/Continuing Noncompliance: Notifying necessary IOs and regulatory bodies regarding any determination of SNC or CNC from relying site study team	○ Reviewing IRB ◉ Relying IRB	
Cooperation with Audits: Providing cooperation with any audit or investigation of any matter	☐ Reviewing IRB ☑ Relying IRB	
Liabilities/Claims: Notifying the IRB(s) and study team(s) and any other participating sites of any legal request (e.g. subpoena, open records request) connected to the study and reasonably assisting with investigation and response to such requests as mutually determined to be lawful and appropriate	☑ Reviewing IRB ☑ Reviewing Site Study Team ☑ Relying Site Study Team ☑ Relying IRB	
Recordkeeping: Maintaining records of IRB membership, review activities and determinations, ICFs, HIPAA authorizations, and other records as required by law, regulations, and governing P&Ps and SOPs; making such records accessible to designated officials at the other participating sites upon reasonable request and according to the law	☑ Reviewing IRB ☑ Reviewing Site Study Team ☐ Relying Site Study Team ☐ Relying IRB	

Closure Reports: Providing the Reviewing IRB with required site-specific information when a study is closed	☐ Reviewing IRB ☑ Reviewing Site Study Team ☑ Relying Site Study Team	Relying Site Study Team is responsible for providing applicable information to the Reviewing Site Study Team.