Purpose of the form: This form should be used to document key communication roles/responsibilities for specific studies. Reviewing IRB/HRPPs may use this form to document general expectations of study teams and relying site IRB/HRPPs, or less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team. The SMART IRB recommends this form be kept up to date with all key information throughout the life of a study.

Communication Plan Template

Definitions:

+ **REVIEWING IRB – Point of Contact (POC):** Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
+ **LEAD STUDY TEAM – Representative:** Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
+ **RELYING SITE – POC:** Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
+ **RELYING SITE STUDY TEAM – Representative:** Main person responsible for communication with the Lead Study Team regarding the ceded study

ROLE	NAME, TITLE, INSTITUTION	CONTACT INFORMATION
Reviewing IRB POC		
Lead Study Team Representative		
Relying Site POC		
Relying Site Study Team Representative		
Study Name		
Overall PI (Lead PI)		
Site Investigator (Local PI)		

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AREA OF COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY (*TYPICAL PARTY IDENTIFIED)	NOTES
Conflict of Interest: Providing applicable Relying Site Conflict of Interest management plans to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Study Team Training & Qualifications: Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Local Considerations: Collecting local information related to Relying Institution's local and state laws; federalwide assurance applicability (e.g. "checking the box"); institutional requirements; unique cultural, language, geography, or socioeconomic factors; or standard of care	☐ Relying Site Study Team* ☐ Relying Site POC* ☐ Lead Study Team ☐ Other, specify:	
Local Considerations: Providing completed local context information to the Reviewing IRB throughout the study	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
IRB Application – Studywide: Preparing and submitting the initial studywide application and studywide amendments to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
IRB Application – Site-Specific: Preparing and submitting the site-specific applications to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	

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AREA OF COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY (*TYPICAL PARTY IDENTIFIED)	NOTES
IRB Determinations: Providing documentation of IRB determinations to relying site study teams	☐ Reviewing IRB POC ☐ Lead Study Team* ☐ Relying Site POC ☐ Other, specify:	
IRB-Approved Documents: Providing copies of IRB-approved materials to the lead study team	☐ Reviewing IRB POC* ☐ Relying Site POC ☐ Relying Site Study Team ☐ Other, specify:	
IRB-Approved Documents – Relying Sites: Providing copies of the most current versions of IRB-approved materials to relying site study teams	☐ Reviewing IRB POC ☐ Lead Study Team* ☐ Relying Site POC ☐ Other, specify:	
Consent Form Template: Providing the consent form template to relying site study teams	☐ Reviewing IRB POC ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Consent Form Language: Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Reviewing IRB Policies (Lead Study Team): Providing relevant Reviewing IRB policies to the Lead Study Team	☐ Reviewing IRB POC* ☐ Relying Site POC ☐ Relying Site Study Team ☐ Other, specify:	

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AREA OF COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY (*TYPICAL PARTY IDENTIFIED)	NOTES
Reviewing IRB Policies (Relying Sites): Providing relevant Reviewing IRB policies to Relying Site study teams	☐ Reviewing IRB POC ☐ Lead Study Team* ☐ Relying Site POC ☐ Other, specify:	
Continuing Review Information: Obtaining and collating studywide information for continuing review to the Reviewing IRB	☐ Relying Site Study Team* ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Continuing Review Submission: Submitting continuing review progress report to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Reportable Events: Providing reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, significant subject complaints)	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Closure Reports: Providing the Reviewing IRB with required information when all research activities are completed at a Relying Site	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	