Purpose of the form: *This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.*

Template Communication Plan for SMART IRB

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 - POC: 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 POC: Main person responsible for communication with the Lead Study Team regarding the ceded study

Role	Name(s)	Contact Information
REVIEWING IRB – POC		
LEAD STUDY TEAM – POC		

Communication Plan

Communication Responsibility	Responsible Party	Notes
COI: Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
STUDY TEAM TRAINING / QUALIFICATIONS / RESOURCES: Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research … and have adequate resources to conduct the study	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
LOCAL CONTEXT INFORMATION: Providing local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s)	

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Communication Responsibility	Responsible Party	Notes
	☐ Other, specify:	
IRB APPLICATION – STUDYWIDE: Preparing and submitting the studywide application for initial IRB review and studywide amendments to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
IRB APPLICATION – SITE-SPECIFIC: Preparing and submitting the site-specific applications and site-specific amendments to the Reviewing IRB that address site variations in study conduct, informed consent language, HIPAA Privacy Rule requirements, subject identification and recruitment processes (including recruitment materials), and any other applicable components of the research	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
IRB DETERMINATIONS: Providing documentation of IRB determinations to relying site study teams. For OHRP reliance agreements, Reviewing IRB will obtain any additional approvals from DHHS for prisoners, children, pregnant women, and/or neonates as necessary.	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
IRB-APPROVED DOCUMENTS: Providing copies of IRB-approved materials to the lead study team	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team ☐ Relying Site POC ☐ Other, specify:	

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Communication Responsibility	Responsible Party	Notes
IRB-APPROVED DOCUMENTS – RELYING SITES: Providing copies of the most current versions of IRB-approved materials to relying site study teams in a timely manner	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
CONSENT FORM TEMPLATE: Providing the consent form template to relying site study teams	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
CONSENT FORM LANGUAGE: Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
REVIEWING IRB POLICIES: Providing relevant Reviewing IRB policies to the lead study team	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
CONTINUING REVIEW INFORMATION: Obtaining and collating studywide information for continuing review to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s)	

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Communication Responsibility	Responsible Party	Notes
	☐ Other, specify:	
CONTINUING REVIEW SUBMISSION: Submitting continuing review progress report to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
REPORTABLE EVENTS: Reporting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints)	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
CLOSURE REPORTS: Providing the Reviewing IRB with required information when a study is closed.	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	

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