RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

WORKSHEET: Communications & Responsibilities		
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The purpose of this worksheet is to provide support for the Reliance Coordinator, HSPP staff or an Investigator when developing a communication plan and identifying roles and responsibilities of the IRB of Record, Relying sites and/or the Overall PI or Lead Study Team.

1 Organizational Responsibilities

Activity	Responsible Party
Education and Training: Providing education to researchers and research staff.	Reviewing IRB Relying IRB Other: _____
Conducting Scientific Review.	Reviewing IRB Relying IRB Other: _____
Ensuring concordance between any applicable grant and the IRB application.	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits.	Reviewing IRB Relying IRB Other: _____
Organization responsible for deciding whether allegations of non-compliance has basis in fact.	Reviewing IRB Relying IRB Other: _____
Organization responsible for deciding whether each incident of non-compliance is serious or continuing.	☐ Reviewing IRB ☐ Relying IRB ☐ Other: _____
Obtaining management plans for researcher and research staff conflicts of interest. **NOTE:** If the relying organization maintains responsibility for this issue, the management plan must be provided.	Reviewing IRB Relying IRB Other: _____
Managing organizational conflicts of interest.	☐ Reviewing IRB ☐ Relying IRB ☐ Other: _____
Ensuring continued oversight of active studies until closure or a mutually agreed upon transfer of the studies should early termination of the reliance agreement occur.	☐ Reviewing IRB ☐ Relying IRB ☐ Other: _____
Notes:	

2 Study-Specific Responsibilities

Training & Qualifications: Providing the IRB of record with confirmation that study teams at relying sites have completed relevant trainings and are qualified to conduct the proposed research.	Reviewing IRB Relying IRB Contact Lead Study Team Relying Study Team Other: _____
Local Context Information: Providing local context information (e.g., consent language, local laws, institutional requirements) to the reviewing IRB.	Reviewing IRB Relying IRB Contact Lead Study Team Relying Study Team Other: _____
Ensuring organizational compliance with the requirements of other parts of the local HRPP and communicating to the external IRB. This includes obtaining approval from other internal review committees prior to IRB or EC approval.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:

IRB Application Materials: Preparing and submitting the study materials for initial or continuing review or submitting modifications to the sIRB.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study Team ☐ Other: _____
Site-specific Materials: Preparing and submitting site-specific materials to the sIRB.	Reviewing IRB Relying IRB Contact Lead Study Team Relying Study Team Other: _____
IRB Determinations and IRB-Approved Documents: Providing sIRB determinations and approved study materials to participating sites.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study Team ☐ Other: _____
Templates: Providing study document templates (e.g., consent forms, recruitment materials) to participating sites.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study Team ☐ Other: _____
Policies of the sIRB: Providing the lead study team with all relevant sIRB policies.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study Team ☐ Other: _____
pSite Continuing Review Information: Obtaining and collating CR information from all participating sites.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study Team ☐ Other: _____
Reportable New Information: Reporting RNI information to the sIRB for participating sites.	Reviewing IRB Relying IRB Contact Lead Study Team Relying Study Team Other: _____
Closing a Study: Reporting study closures to the sIRB.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study Team ☐ Other: _____
Obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team
NIH Genomic Data Sharing (GDS) Studies: Submission of Institutional Certification (Consult with Genomic Program Administrator from the funding NIH Institute or Center to discuss the appropriate certification)	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team
Notes:	