



USC Overall Principal Investigator’s Communication Plan

Purpose of the form: To identify and document how the USC Study Team will communicate with Relying Site Study Teams for a multi-site study when USC is the Reviewing IRB. A good communication plan involves initial study start-up discussions and regularly scheduled meetings, calls, presentations, etc. to discuss oversight of the conduct of the study. Sufficient administrative resources are required to implement this process. **This form must be completed and submitted to the USC IRB for review and approval. Once approved by the USC IRB, this document should be shared with all Relying Site Study Teams.**

Study Title:	
Overall Study PI:	
USC IRB No.:	
Completed by:	
Date Form Completed:	
USC Study Team Responsibilities – Please review the responsibilities below and indicate the USC Study Team’s agreement to comply with the following requirements by placing a check in the box next to “USC Study Team Acceptance” for each item.	
IRB Responsibilities – submissions to the USC IRB	
Initial Application and Amendments to the USC IRB:	Preparing and submitting the study-wide application for initial USC IRB review and any study-wide amendments to the USC IRB via iStar. USC Study Team Acceptance: <input type="checkbox"/>
Adding Relying Sites to the Study:	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 USC Study Team Acceptance: <input type="checkbox"/>
Continuing Review Information and Submission to the USC IRB:	Obtaining and collating study-wide enrollment totals and study progress information from all Relying Site Study Teams for continuing review application submission to USC IRB via iStar. USC Study Team Acceptance: <input type="checkbox"/>
New Information that Requires Prompt Reporting to the USC IRB:	Reporting new information that requires prompt reporting to the USC IRB (e.g., new or increased risks, unexpected harm to subjects or others, or new safety information; unanticipated problems, subject complaints, noncompliance with the protocol, federal regulations or the determinations of the USC IRB). USC Study Team Acceptance: <input type="checkbox"/>



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Closure Reports to the USC IRB:	<p>Providing the USC IRB with required information from all Relying Site Study Teams when the study is closed (or when a Relying Site is closed).</p> <p>USC Study Team Acceptance: <input type="checkbox"/></p>
Relying Site Responsibilities – collection and dissemination of information to Relying Site(s)	
Consent/Assent Templates and Recruitment Templates:	<p>Providing the USC IRB approved master consent/assent form templates and any approved master recruitment material templates to the Relying Site Study Teams.</p> <p>USC Study Team Acceptance: <input type="checkbox"/></p> <p>Ensuring that the Relying Site Study Teams properly incorporate site-specific language into the templates and send them to the USC Study Team for submission to the USC IRB via iStar.</p> <p>USC Study Team Acceptance: <input type="checkbox"/></p>
USC IRB Determinations and USC IRB-Approved Documents	<p>Providing documentation of all USC IRB determinations and copies of the most current versions of USC IRB-approved study materials to Relying Site Study Teams in a timely manner.</p> <p>USC Study Team Acceptance: <input type="checkbox"/></p>
Local Context Information from Relying Sites:	<p>Providing local context information to the USC IRB regarding state laws and institutional requirements that pertain to the review of Relying Sites.</p> <p>USC Study Team Acceptance: <input type="checkbox"/></p>
Training & Qualifications Documentation:	<p>Providing confirmation to the USC IRB that the Relying Site Study Teams have completed relevant training and are qualified to conduct the proposed research.</p> <p>USC Study Team Acceptance: <input type="checkbox"/></p>
Financial Conflicts of Interest Management:	<p>Providing and ensuring implementation of required financial conflict of interest management plans required for the Relying Site Study Team members to the USC IRB.</p> <p>USC Study Team Acceptance: <input type="checkbox"/></p>
<p>USC IRB Review and Oversight: Describe the <u>plan</u> for communicating with Relying Site Study Teams about USC IRB review requirements, policies, procedures, and guidance.</p>	
<p>Dissemination of USC IRB Approved Study Documents: Describe the <u>plan</u> for providing documentation of USC IRB determinations and the most current approved versions of USC IRB-approved materials to Relying Site Study Teams in a timely manner.</p>	



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USC Prompt Reporting Requirements: Describe the plan for ensuring Relying Site Study Teams understand USC IRB requirements for prompt reporting of new information to the USC Study Team.

Continuing Review Information: Describe the plan for ensuring Relying Site Study Teams provide site enrollment and study progress information to the USC study team.

Closure Report Information: Describe the plan for ensuring Relying Site study teams provide the USC study team with the required information when a study is closed (or if a site is closed prior to study closure).