



USC Amendment to Add Relying Site

PURPOSE

This guidance outlines the process for **how the USC study team will submit an amendment to obtain IRB approval for relying sites to begin multi-site research** post-USC IRB approval of the main protocol, consent form, and other study documents.

SCOPE

This guidance applies to any study that is engaged in multi-site research human subjects research where USC is serving as IRB of record. It applies to new multi-site studies as well as USC studies that were previously approved as single-site studies and are now onboarding new relying sites, and USC has agreed to be the IRB of record.

NOTE: These amendments should ONLY be used to add relying sites. Any substantive changes to the overall study, or for USC as a site, will require a separate amendment submission.

RESPONSIBILITIES

(For other responsibilities, reference the *USC Overall Principal Investigator's Communication Plan*)

- USC/Lead Study Team: Submits a separate iStar amendment to USC IRB for each relying site and will upload all documents including study-specific consent and HIPAA authorization documents, reliance agreements, and completed and signed Local Context Form; shares approval letters and appropriate documents with the Relying Site study team.
- Relying Site Study Team: Will provide the USC/Lead Study Team with the SMART IRB Acknowledgement letter (if not using the SMART IRB platform) and completed Local Context Form and/or Implementation Checklist signed by the Relying PI and/or IRB, provide the USC/Lead Study Team with a clean WORD version of the Site Specific Information Consent, provide USC/Lead Study Team with recruitment material by revising the USC IRB approved recruitment documents using tracked changes to add Relying Site information.
- Relying IRB: Will provide the Relying Site Study Team the completed and signed SMART IRB Acknowledgement letter (if not using the SMART IRB platform) and Local Context Form and/or Implementation Checklist; review the Relying Site consent documents for accuracy before giving institutional sign off, be responsible for ensuring that the Relying Site's requirements are completed (current training and qualifications, conflict of interest, ancillary review, and any applicable local institution approvals).

PROCEDURE

1. Amendment Request: *(the amendment shall include only one site)*
 - a. The USC Study Team will submit an amendment in iStar specific to adding a Relying Site.
 - b. The USC/Lead Study Team will provide amendment approval and approved documents to the Relying Site team so they may begin study activities.
2. Naming site documents:

Document Name_Version Date (MM/DD/YYYY)_Site Name
(ABC Protocol_MM/DD/YYYY/UCLA)

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