UCLA Research Administration
Human Research Protection Program

May 28, 2021

Reviewing Investigator Responsibilities Checklist

For UCLA Investigators Serving as Lead PI where UCLA IRB is Reviewing for Another Institution

This checklist outlines UCLA investigators' responsibilities when a study is under the oversight of the UCLA IRB and includes review for collaborating institutions and/or investigators that are external to UCLA. These responsibilities apply to EACH study where UCLA is reviewing for external institutions/investigators.

Once you have agreed to collaborate with an investigator at another institution and intend to use the UCLA IRB for oversight of the study, please review this checklist to identify your ongoing responsibilities for communicating with the UCLA IRB/OHRPP, the external institutions, and the external (Relying) research team(s).

If you have any questions related to the reliance process, please contact us at irbreliance@research.ucla.edu or (310) 825-5344.

NOTE: For the purpose of this checklist, all mentions of "UCLA IRB" reflect "Reviewing IRB" responsibilities.

ADDITIONAL UCLA PRINCIPAL INVESTIGATOR RESPONSIBILITIES As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by a single IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role.	
☐	CONTACT the UCLA Office of the Human Research Protection Program (OHRPP) to discuss whether the UCLA IRB can act as the single IRB for all or some institutions participating in this study, or whether another external IRB would be appropriate. ➢ In order to provide information about the proposed research collaboration, and to describe UCLA's role, EMAIL a completed Application for UCLA to Serve as IRB of Record to irbreliance@research.ucla.edu
☐	Identify who will act in the role of the Lead Study Team (e.g., your own study team, a coordinating center, or both). The Lead Study Team assumes additional responsibilities when single IRB review will be used.
☐	Provide the Lead Study Team with details about the study, including the study-wide protocol and template consent document(s), which will help facilitate the discussion with your local IRB/HRPP.
☐	Identify all sites that will be engaged in human subjects research and thus need IRB coverage.

LEAD STUDY TEAM RESPONSIBILITIES **If UCLA Agrees to Serve as Single IRB,** **The UCLA PI Will Need to Ensure That the Lead Study Team …**	
☐	Provides a reliance request to the Overall PI's home institution using the process required by that institution. Documentation of this reliance request will be required by UCLA.
☐	Works in collaboration with the UCLA IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
☐	Promptly responds to questions or requests for information from study teams and IRB/Human Research Protection Program personal at institutions who are relying on the UCLA IRB.

☐	Participates in conference calls regarding a study as requested.
☐	Provides the Site Investigators with the IRB policies of the UCLA IRB. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.
☐	Provides the participating Relying Site Study Teams with the minutes, IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials), and other records that document the IRB's determinations to the relying sites.
☐	Prepares and submits IRB applications on behalf of all sites, including initial reviews, local amendments, personnel updates, local reportable events, and study-wide information for continuing review. As part of preparing the IRB application, the Lead Study Team (or designee) must:
☐	Have a mechanism in place to obtain and collect information from Relying Site Study Teams and/or Relying Site IRB offices, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
☐	Have a mechanism in place to obtain and collect information from Relying Site study team regarding events/incidents occurring at the relying sites that meet the UCLA IRB threshold for reporting via Post Approval Reports and to submit those applicable events/incidents as "internal" events within the required time frames.
☐	Assist Relying Site Study Teams and/or Relying Site IRB offices, in ensuring consent documents follow the UCLA IRB's template form and include applicable site-specific required language from each Relying Institution.
☐	Notifies Site Investigators of all UCLA IRB determinations and communications, including those for initial review, continuing review, amendments, reportable events, suspension, and termination.
☐	When agreed upon in coordination with the UCLA IRB, promptly reports to the Site Investigator (or designee on the Relying Site Study Team) any unanticipated problems involving risks to subjects or others, research related injuries, or significant subject complaints that are related to or may affect subjects participating in the research at the Relying Institution.
☐	If a Relying Site Study Team does not provide the UCLA Study Team (or designee) with the required information before the continuing review application is submitted to the UCLA IRB, reports the absence of this information as part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.
☐	Providing access, upon request, to study records for audit by the Relying Institution, the UCLA IRB, and other regulatory or monitoring entities.
☐	Follow all requirements of the Relying Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.

UCLA IRB Review – For Each Relying Site	
☐	Submit a webIRB application for review. Relying sites may be added with the initial research application or added as an amendment to previously approved research. The relying collaborators' involvement should be outlined as follows:
☐	Section 1.1a should list the Lead investigator for each relying site
☐	Section 1.5 List each collaborating site, describe their role, and indicate whether they are asking to rely on the UCLA IRB or will complete their own review

☐	Upload site-specific consent documents if required by relying sites
☐	Upload the completed site-specific local context form for each relying site
☐	For sites relying on UCLA, we prefer to use the SMART IRB Master Authorization Agreement to document reliance. If an institution has not signed onto the SMART IRB Agreement, then the relying site will be required to sign UCLA's IRB Authorization Agreement (IAA). The relying site will sign the agreement first and then the UCLA IRB will finalize the IAA. The UCLA PI is responsible for providing the relying site with a copy of the fully signed IAA.
☐	When serving as sIRB, UCLA follows the processes recommended by the SMART IRB Harmonization Committee, for all reliance's including those that are not formalized via SMART IRB. When UCLA is the reviewing IRB, UCLA expects Relying Institutions and investigators assume the primary responsibility to assess study personnel training and qualifications both initially and throughout the course of the study. See SMART IRB Responsibilities Associated with the Review of Study Personnel.

UCLA – OTHER REQUIRED REVIEWS & PROCESSES		
☐	Ensure that all local reviews and sign offs are in place before a study is activated. The following may be applicable	
	☐	Finalize contract or grant
	☐	Ancillary committee reviews - Radiation Safety - Institutional Biosafety - Research Pharmacy - Conflict of Interest in Research (CIRC) - Nursing Practice Research Council (NPRC) - Any other required committee reviews
	☐	Data use agreements
	☐	Coverage analysis
	☐	Material transfer agreements