UCLA Research Administration
Human Research Protection Program

February 4, 2022

Relying Investigator Responsibilities Checklist

For UCLA Investigators Relying on IRB review from another Institution

This checklist outlines UCLA investigators' responsibilities when a study is under the oversight of an IRB external to UCLA. These responsibilities apply to EACH study where UCLA is relying on an external IRB. Once you have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of the study, please review this checklist to identify your ongoing responsibilities for communicating with the UCLA OHRPP, the external IRB, and the external (Lead) research team. More information can be found in OHRPPs Guidance and Procedure: Reliance.

UCLA OHRPP REGISTRATION OF RELIANCE	
☐	REGISTER the study at UCLA by submitting an IRB Reliance Registration using the UCLA IRB electronic submission system. Reliance registration is the mechanism for the UCLA researcher to provide the OHRPP with the following:
☐	Names and roles of all UCLA key personnel
☐	Management plans for potential conflicts of interest (COI) relevant to the study, including any new or altered management plans put in place throughout the lifespan of the study
☐	Upload the protocol and other relevant documents reviewed by the reviewing IRB
☐	Management of required local ancillary reviews, such as MRSC review
☐	Verify that consent documents include any required local language . See UCLA Consent Form Checklist for Reliance on External IRBs for the required UCLA consent form language.
☐	Ensure a fully signed reliance agreement has been established between the institutions
☐	EXTERNAL REVIEW ACCEPTED (ERA) – Notice is issued by UCLA OHRPP when UCLA OHRPP administrative review is complete. **This may not be the only UCLA approval required to commence the research.** Research may not begin at UCLA until the ERA notice has been issued and any other required approvals have been issued.
☐	MODIFICATIONS are not routinely reviewed by UCLA OHRPP. Amendments will be required for the following only: ➢ Change in Principal Investigator and other study personnel ➢ New or additional ancillary review required ➢ New or changes in HIPAA determinations (made by UCLA) ➢ New or changes in Conflict of Interest (COI) ➢ New or change in funding
☐	POST APPROVAL REPORTS are not routinely reviewed by the UCLA OHRPP. Limited exceptions are noted in Guidance and Procedure: Post-Approval Reporting (PAR) or UCLA Relying PAR Decision Tree. Additionally, review the terms of the reliance agreement which may specify reporting requirements

COMMUNICATIONS WITH THE LEAD PI/STUDY TEAM & REVIEWING IRB	
☐	Promptly respond to questions or requests for information from the Lead Study Team (or their designee) as well as from the Reviewing IRB
☐	Participate, as required, in conference calls regarding study as requested by the Lead Study Team, Reviewing IRB, or the UCLA OHRPP
☐	Work with the Lead Study team and the UCLA OHRPP to incorporate locally required language into the consent template to be used by the UCLA study team. ➢ UCLA ICF Checklist for Relying on Another IRB

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 - Conflict of Interest Review Committee (CIRC)Any other required ancillary committee reviews
	☐	Data use agreements
	☐	Coverage Analysis
	☐	Material transfer agreements

REGULATORY COMPLIANCE	
☐	Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required.
☐	Notify the lead PI of: • Any reportable events that occur locally, according to regulations and the Reviewing IRB's policy. • Any changes (including those related to funding and personnel) in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions. • Any management plans, including any updates to these plans, as relevant to the study. • Any applicable information for continuing review progress reports in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.
☐	Follow all determinations of the Reviewing IRB.
☐	Only implement changes of protocol, including local variations, after the Reviewing IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.
☐	Provide, upon request, access to study records for audit by the local institution, the Reviewing IRB's institution, and other regulatory or monitoring entities.