UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

OIA-442 CHECKLIST: External IRB Review Clearance

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The purpose of this checklist is to provide support for Office of IRB Administration (OIA) staff conducting pre-review to issue clearance for a study to be reviewed by an external IRB. This checklist, or equivalent, is to be used. It does not need to be completed or retained.

IRB Number:	
Protocol Name:	
Investigator:	
Funding	
Reviewing IRB:	

Pre-Review

☐ The human subjects research is minimal risk

Or

☐ The human subjects research is greater than minimal risk and reviewing IRB is accredited by Association for the Accreditation of Human Research Protection Programs (AAHRPP), Consortium for Applied Research Ethics-Quality (CARE-Q), or equivalent body

Or

☐ The human subjects research is greater than minimal risk and reviewing IRB has an internal quality review process to ensure compliance with ethical principles, applicable law and guidance, and OIA director/medical director or institutional official has agreed to cede review

☐ The UCSD Investigator(s) has completed required training. Not required for clearance, but required for acceptance

☐ The external reliance administrative review application includes the following items:

- Master protocol/research protocol
- Overall study approval from the reviewing institution/IRB
- Investigator brochure(s)/package insert/instructions for use (as applicable to the research)
- Recruitment material template(s) from sponsor or reviewing institution/IRB, as applicable (for non-commercial IRBs only)
- Informed consent template(s) from sponsor or reviewing institution/IRB (for commercial IRBs only)
- Informed consent template with UCSD required institutional language added and tracked (for non-commercial IRBs only)
- The reliance agreement (when necessary)

Initial Administrative Review

☐ The protocol is complete and understandable.

☐ UCSD local context has been taken into consideration in the application and consent form(s).

☐ N/A, commercial IRB or National Cancer Institute Central IRB with master reliance agreement

☐ Ancillary reviews have been triggered (when applicable).

☐ If the study is a Phase I clinical trial, the OIA director/medical director has provided sign-off to be reviewed by an external IRB.

☐ The research is acceptable; there is no apparent error or omission in the approval of the reviewing IRB based on regulatory criteria for approval of human subjects research.

☐ Clearance sent to investigator (include clearance statement in a 'revisions required' action). Investigator to send approval documentation from the reviewing IRB for the addition of UCSD as a relying site, before final reliance acceptance letter is issued.

OR

☐ Any deficiency in documentation or other item is conveyed to the investigator for reconciliation with criteria for clearance.