

	OIA-334 WORKSHEET: Reliance Agreement		
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The purpose of this worksheet is to provide support for Office of IRB Administration (OIA) staff conducting pre-review. The worksheet, or equivalent, is to be used. It does not need to be completed or retained.

IRB Number:	
Protocol Name:	
Investigator:	
Reviewing IRB:	

Eligibility for Relying on an External IRB using its own Template IRB Authorization Agreement (IAA) (if applicable). (At least one must be checked)

- The research is minimal risk. The OIA staff member may agree to an external review subject to a signed IRB reliance agreement.
- The research is greater than minimal risk and the reviewing institution is accredited by Association for the Accreditation of Human Research Protection Programs (AAHRPP), Consortium for Applied Research Ethics-Quality (CARE-Q), or similar organization. The OIA staff member may agree to an external review subject to a signed IRB reliance agreement.
- The research is greater than minimal risk and the reviewing institution is not accredited by AAHRPP, CARE-Q, or similar organization and the OIA director or medical director has agreed to the external review subject to a signed IRB reliance agreement.

Reliance Agreement includes the following (all items must be checked)

- Statement naming and containing contact information for the reviewing and relying institutions and indicating that UCSD will rely on the external IRB for review and oversight of the proposed human subjects research. Contact information may be provided in a separate document.
- Statement that reviewing IRB will follow written procedures.
- If federally funded or supported, federalwide assurance (FWA) numbers for reviewing and relying IRBs are included on the agreement. (N/A if individual investigator agreement).
- The review conducted by the external IRB will comply with the requirements of UCSD's FWA.
- The reviewing IRB will follow written procedures for making notifications to the investigator, appropriate individuals at the relying institution, and regulatory authorities.
- The reviewing IRB will notify appropriate individuals at UCSD of an intention to report (1) an unanticipated problem involving risks to subjects or others/unanticipated problem report (UPR); (2) serious or continuing non-compliance; or (3) suspensions and/or terminations of IRB approval of research activities. The notification will include a copy of the report and UCSD will be afforded adequate time and opportunity to suggest edits to the report.
- The agreement will remain effective as long as the proposed research will be subject to IRB oversight.
- The agreement allows UCSD to review minutes of full IRB decisions involving this research.
- UCSD remains responsible for compliance with the reviewing IRB's determinations and the terms of UCSD's Office for Human Research Protections (OHRP)-approved FWA.

Reliance Agreement Does not Include the Following (All items must be checked)

- Requirement for insurance coverage.
- Indemnification unless the indemnification is mutual.

Agreement Specified Requirements of UCSD

- Yes** **No** UCSD must ensure that investigator meets UCSD requirements for principal investigator (PI) *OIA-103 IRB Handbook*.
- Yes** **No** UCSD must notify the reviewing IRB of any findings related to the investigator. Enter specific findings here, if any:
- Yes** **No** The PI/UCSD must notify the reviewing IRB of related financial interests of the UCSD investigator and/or UCSD research staff in the research and provide the management plan.
- Yes** **No** Other:
- Yes** **No** Other:

Comments: