IRB Reliances

IRB Reliance	IRB Partners & Affiliates	UCI's Role	Research Eligibility Criteria
CMU	Children's Hospital of Orange County (CHOC) & MemorialCare Health System (MHS)	Reviewing IRB **OR** Relying IRB	1. Collaborative or multi-site effort involving two more locations, **or** A UC investigator conducts research solely at CHOC or MHS. 2. When the research does not include subject interaction, the research involves obtaining individually identifiable data from two or more locations, on which one or more locations will conduct analyses, **or** Involves obtaining biospecimens from two or more locations for research subject to FDA regulations. 3. *UCI exception: Phase I and early Phase II clinical trials are not eligible.*
NCI CIRB	National Cancer Institute Central IRB (CIRB) The NCI CIRB reviews all Phase 3 Cooperative Group trials, as well as any other studies opened in the Cancer Trials Support Unit (CTSU). The NCI CIRB is accredited by AAHRPP.	Relying IRB	1. Phase III Cooperative Group Trial (ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC, NSABP, RTOG, and SWOG). 2. A Waiver (partial or full) of HIPAA Research Authorization is not required. NCI CIRB is not a Privacy Board. 3. If a subject becomes incarcerated, s/he will not remain on the study. NCI CIRB is not constituted to review prisoner research.
Single Protocol	Protocol Specific – Other academic and independent IRBs or non-UCI investigators	Reviewing IRB **OR** Relying IRB	When UCI is the Reviewing IRB: 1. The scope of human research activities conducted at the non-UCI site are considered minimal risk and discussed in the UCI IRB Application. 2. An IRB Authorization Agreement, **or** an Individual Investigator Agreement is established for federally funded non-exempt research. When UCI is the Relying IRB: 1. The non-UCI investigator is the prime recipient of the funding award, **or** The PI of the study is affiliated with the Reviewing IRB's institution, **or** The research will primarily take place at the Reviewing IRB's institution, **or** The other institution's reviewing IRB is more properly constituted to review a certain scope or topic of work, or may have knowledge of the local research context. 2. The UCI investigators will conduct human research activities that involve no more than minimal risk to subjects.

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			3. No UCI research team member has a disclosable financial interest that would require review by the UCI Conflict of Interest Oversight Committee (COIOC). 4. An IRB Authorization Agreement is established is established for federally funded non-exempt research. *UCI IRB reserves the right to make additional exceptions and has final say on whether UCI IRB review is required.*
UC	All UC campuses and Lawrence Berkeley National Laboratory	Reviewing IRB **OR** Relying IRB	4. Collaborative or multi-site effort involving two more UC locations. 5. When the research does not include subject interaction, the research involves obtaining individually identifiable data from two or more UC campuses, on which one or more other UC campuses will conduct analyses, **or** Involves obtaining biospecimens for research subject to FDA regulations. Additional criteria for when UCI will serve as the Relying IRB: 6. Another UC location is the prime recipient of the funding award, **or** UCI acts solely as the funding recipient of an award however no research activities will be taking place at UCI, **or** The Principal Investigator (PI) of the study is affiliated with another UC location. 7. No UCI research team member has a disclosable financial interest that would require review by the UCI Conflict of Interest Oversight Committee (COIOC). 8. *UCI exception: Phase I and early Phase II clinical trials are not eligible.*
UC BRAID	All UC campuses and Lawrence Berkeley National Laboratory The UC Biomedical Research Acceleration, Integration, and Development (UC BRAID) consortium provides a Reliance Service to UC investigators conducting clinical trials at more than one UC campus.	Reviewing IRB **OR** Relying IRB	1. Clinical trial with a multi-site effort involving two or more UC locations. 2. Industry authored and industry funded. 3. *UCI exception for when UCI will serve as the Relying IRB: Phase I and early Phase II clinical trials are not eligible.*
WIRB	Western IRB	Relying IRB	1. Phase III or Phase IV clinical trials.

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	Western Institutional Review Board (WIRB) is an independent IRB located in Olympia, Washington that provides services for academic and non-academic institutions. WIRB is accredited by AAHRPP.		2. Industry authored and industry funded. 3. Sponsor/CRO has contracted with WIRB or with an affiliated IRB (i.e., Copernicus Group IRB, Aspire IRB, MidLands IRB and New England IRB) to provide IRB services for the study (documentation required). Research involving the following procedures or populations do not qualify for WIRB review: • Surgical techniques or procedures • Transplant techniques, procedures or other interventions • Stem cell therapies • Gene therapy or gene transfer • Investigational radiologic procedures or investigational radiological agents • Neonates *UCI IRB reserves the right to make additional exceptions and has final say on whether UCI IRB review is required.*