

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-085 SOP: Establishing Reliance Agreements				
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1 PURPOSE

- 1.1 This procedure establishes the process to execute a reliance agreement between the UCSD IRB and other institutions/organizations, sites, or investigators.
- 1.2 The process begins when a reliance review request has been identified by the UCSD IRB and the use of a reliance agreement is required.
- 1.3 The process ends when the reliance agreement is fully executed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS

- 3.1 Federally-funded studies initially approved on or after January 20, 2020, which meet the definition of cooperative research must rely upon approval through a single IRB (sIRB) review except as described at [45 CFR 46.114\(b\)\(2\)](#).
- 3.2 Reliance arrangements will not be entered into for studies which are exempt from the requirements for IRB review or are deemed to be not human subjects research (NHSR).
 - 3.2.1 Exceptions may be granted on a case by case basis when it is determined by the UCSD IRB that entering into a reliance agreement will not be more administratively burdensome than conducting the review at each institution separately.
- 3.3 The institutional official, or designee, is authorized to sign reliance agreements. Depending on whether the reliance agreement is for an external investigator or an independent investigator, the reliance agreement will be in the form of an IRB authorization agreement (IAA) or an individual investigator agreement (IIA), respectively.
- 3.4 The institutional official/signatory, Office of IRB Administration (OIA) director, OIA assistant director, and OIA reliance supervisor are authorized to sign cede letters [e.g., Western IRB-Copernicus Group (WCG), Advarra IRB, UC Reliance Registry, etc.] and SMART IRB acknowledgments.¹


4 RESPONSIBILITIES

- 4.1 An OIA reliance staff member carries out these procedures. The institutional official, or designee, authorizes reliance agreements.

5 PROCEDURES

- 5.1 Upon receiving a request to execute a reliance agreement with an external institution/organization/site, external investigator, or independent investigator, the OIA reliance staff member will review the request to determine if it is appropriate.
 - 5.1.1 If appropriate and a valid reliance agreement is already in place, this process is complete.
 - 5.1.2 If appropriate and no reliance agreement is in place, and one is required, proceed with the steps below.
 - 5.1.3 If not appropriate to execute a reliance agreement, the OIA reliance staff member will communicate the determination to the UCSD investigator, and work with all parties to resolve the issues, as appropriate.
- 5.2 OIA reliance staff member may use *OIA-334 WORKSHEET: Reliance Agreement*, or equivalent, to verify all relevant criteria have been met.
- 5.3 Upon determining that the request for a reliance agreement is appropriate, complete the following:
 - 5.3.1 If the external institution/organization/site/investigator participates in SMART IRB and requests the use of the SMART IRB agreement, then determine whether to use the SMART IRB letter of acknowledgment (LOA) or online reliance system (ORS) to document the use of the SMART IRB agreement.
 - 5.3.2 Document in the agreement the terms and conditions under which:
 - 5.3.2.1 UCSD's IRB will serve as the IRB of record for that institution/organization, site or investigator, using the standard IAA or IIA template, or

¹ Cede letters and SMART IRB acknowledgments are not reliance agreements as they only specify that a study is following the terms of a previously executed reliance agreement that has been put in place.

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- 5.3.2.2 The external IRB will serve as the IRB of record for UCSD using the standard IAA template.
- 5.3.3 Negotiate the terms of the agreement, if different from the standard template. Any non-standard language may require additional review and approval by:
 - 5.3.3.1 The director/medical director of OIA;
 - 5.3.3.2 The institutional official; and/or
 - 5.3.3.3 The office of chief campus counsel
- 5.3.4 The agreement is typically first forwarded to the relying institution/organization, site or investigator to collect a signature from the institutional official/signatory before it is fully executed by the reviewing institution/organization. Ensure all parties have signed the agreement and relevant parties have received the final executed copy.

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-334 WORKSHEET: Reliance Agreement*

7 REFERENCES

- 7.1 [21 CFR 56.104](#)
- 7.2 [45 CFR 46.101\(b\)](#) (pre-2018 Common Rule)
- 7.3 [45 CFR 46.104](#) (2018 Common Rule)
- 7.4 [45 CFR 46.114](#)
- 7.5 NIH Single IRB Policy and related announcements ([NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#))