1 PURPOSE

1.1 This procedure establishes the process for relying on an external IRB for review of non-exempt human subjects research in which UCSD is engaged.

1.2 The process begins when the Office of IRB Administration (OIA) receives notice, through a submission, telephone call, email message or other business communication, that UCSD is being asked to rely on an external IRB.

1.3 The procedure ends when the research subject to IRB review is completed and/or closed, or the written agreement establishing the relationship of reliance is otherwise terminated under its terms and conditions.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Added Section 3.7

3 GUIDANCE AND REQUIREMENTS

3.1 Circumstances arise in which an investigator at UCSD may rely on an external IRB for review and oversight of non-exempt human subjects research in which UCSD is engaged.

3.2 The use of an external IRB may be warranted when one or more of the following are applicable:

3.2.1 UCSD is a sub-contracted site and IRB approval for the overall study has been provided by the external institution/organization.

3.2.2 The request is mandated by the funding agency per single IRB (sIRB) review or cooperative research requirements.

3.2.3 The request is mandated by the study sponsor or funding agency in order for the UCSD site to participate in the research.

3.2.4 The UCSD site is collaborating with the lead site for the study and is engaged in human subjects research.

3.2.5 The study is a clinical trial that is industry-authored and financially sponsored, unless the principal investigator or sponsor requests the UCSD IRB conduct review.

3.3 UCSD may generally only cede IRB review for greater than minimal risk studies to IRB's that are accredited by a recognized accrediting organization or that otherwise have a quality assurance process for ensuring compliance with ethical principles, applicable law, and guidance.

3.4 The UCSD OIA must receive and administratively review the protocol, consent document(s) and approval documents in order to accept the approval of an external IRB, and before UCSD faculty, employees and students can engage in human subjects research under external IRB oversight.

3.5 The UCSD IRB must accept the reliance and sign a reliance agreement before UCSD faculty, employees or students can engage in human subjects research under the oversight of an external IRB.

3.6 For purposes of this SOP, a "commercial IRB" is a for-profit IRB with which the UCSD IRB has a standing master reliance agreement.

3.7 In the event that the UCSD OIA and all UCSD IRB committees were to close or be unable to perform their regulatory duties for any reason, any current active protocols would be transferred (using a reliance agreement mechanism) to a suitable IRB. This includes, but is not limited to, a commercial IRB or another UC IRB.

4 RESPONSIBILITIES

4.1 UCSD OIA staff members and principal investigators carry out these procedures.

5 PROCEDURES

5.1 OIA staff members will review inquiries for reliance on external IRBs for review of non-exempt human subjects research:

5.1.1 If the non-exempt human subjects research is minimal risk, the OIA staff member may agree to external review subject to a signed IRB reliance agreement.

5.1.2 If the non-exempt human subjects research is greater than minimal risk and the 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, the OIA staff member may agree to external review subject to a signed IRB reliance agreement.

5.1.3 If the non-exempt human subjects research is greater than minimal risk and the reviewing IRB is not accredited by AAHRPP, CARE-Q, or equivalent body, the OIA director/medical director or institutional official may agree to external review subject to a signed IRB reliance agreement from the external IRB and existence of a quality assurance process for ensuring ethical and compliant review.

5.2 OIA staff members will review the IRB reliance agreement provided by the external IRB.

5.2.1 UCSD and the reviewing IRB will take maximum advantage of other existing reliance agreements. If the non-exempt human subjects research is subject to an existing agreement (e.g., the National Cancer Institute-Central IRB), go to Section 5.3.

5.2.2 If the reviewing IRB provides its own template agreement, the OIA staff member may review the document using *OIA-334 WORKSHEET: Reliance Agreement*, or equivalent. The OIA staff member will work with the external IRB to create an acceptable agreement. Once the document is acceptable, OIA staff will forward the worksheet, or equivalent, and agreement to the OIA director/medical director.

5.2.3 The OIA director/medical director will review the agreement and notify staff if any issues are identified. Once the agreement is acceptable to the OIA director/medical director, they will forward to the institutional official/signatory to sign, and a signed copy will be returned to the OIA staff.

5.2.4 The OIA staff member will return the partially executed reliance agreement to the external IRB with a copy to the UCSD investigator and will include the following contingency in the correspondence:

> "UCSD must administratively review an external reliance application submitted via the electronic submission system before UCSD faculty, staff and students are engaged in human subjects research reviewed by an external IRB. Documents to be provided for review include: master protocol/research protocol; overall study approval from the reviewing institution/IRB; investigator brochure(s) (IB)/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(s) with UCSD required institutional language added and tracked (for non-commercial IRBs only)."

5.2.5 A copy of the signed agreement should be retained in the study file within the OIA's electronic submission system (initial external reliance submission).

5.3 OIA staff will review the external reliance submission using *OIA-442 CHECKLIST: External IRB Review Clearance*, or equivalent. If the submission is complete and an external reliance is appropriate, OIA staff will provide clearance using *OIA-442 CHECKLIST: External IRB Review Clearance*, or equivalent.

5.4 The UCSD investigator provides to the reviewing IRB UCSD information and documents for consideration and approval.

5.5 Upon approval of the addition of UCSD as a relying site by the reviewing IRB, the UCSD investigator will then provide copies of the reviewing IRB approval letter and approved UCSD-specific study documents (stamped), as applicable, to the OIA through the electronic submission system.

5.6 OIA staff will review the approval documentation from the reviewing IRB. If everything is acceptable, using *OIA-443 CHECKLIST: External IRB Review Acceptance*, or equivalent, the OIA staff will finalize the review process by issuing *OIA-527 TEMPLATE LETTER: Acceptance of Reliance on External IRB*.

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*

6.2 *OIA-334 WORKSHEET: Reliance Agreement*

6.3 *OIA-442 CHECKLIST: External IRB Review Clearance*

6.4 *OIA-443 CHECKLIST: External IRB Review Acceptance*

6.5 *OIA-527 TEMPLATE LETTER: Acceptance of Reliance on External IRB*

7 REFERENCES

7.1 45 CFR 46.114

7.2 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)