1 PURPOSE

1.1 This procedure establishes the process for Office of IRB Administration (OIA) staff to conduct the review of a reliance request for cooperative research, multi-site research, or multi-center non-exempt human subjects research.

1.2 The process begins when the OIA receives notice, either through a submission, telephone call or other business communication, that an external investigator or independent investigator intends to rely on the UCSD IRB.

1.3 The process ends when the study 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 None

3 REQUIREMENTS

3.1 Circumstances arise in which an individual who is not a university/affiliate investigator may wish to use the UCSD IRB for review and oversight of their non-exempt human subjects research or to rely on the UCSD IRB for oversight of non-exempt human subjects research.

3.2 The UCSD IRB will generally only review studies for an external or independent investigator when that investigator is involved in non-exempt human subjects research being conducted by a collaborating UCSD investigator.

3.2.1 Exceptions may be made upon consultation with the OIA director/medical director, and/or institutional official.

3.3 Human subjects research may not commence at the independent investigator's/external investigator's site until the conditions and responsibilities specified herein are met.

3.4 In accordance with *OIA-085 SOP: Reliance Agreement*, the UCSD OIA reviews reliance requests and determines whether it is appropriate to execute a reliance agreement for the UCSD IRB to serve as the single IRB (sIRB) or IRB of record for an external or independent investigator.

4 RESPONSIBILITIES

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

4.2 The executed reliance agreement delineates the roles and responsibilities of the external institution and participating site principal investigator, including adhering to the participating site's required institutional approvals, notifications and other reporting requirements.

5 PROCEDURES FOR RELIANCE

5.1 When UCSD is serving as the IRB of record for an independent investigator:

5.1.1 OIA receives notice that an independent investigator plans to rely on the UCSD IRB.

5.1.1.1 Check to see whether a reliance agreement already exists and use applicable, existing agreements whenever feasible.

5.1.1.2 Follow the steps at 5.1.7 for collection of study documents and distribution of approval notifications and documents.

5.1.2 If no reliance agreement exists, OIA staff members provide, either directly to the independent investigator or via the UCSD investigator/designee, a copy of the individual investigator agreement (IIA) and *OIA-509 – TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire* (LCQ).

5.1.3 Upon UCSD OIA receipt of the IIA and LCQ, OIA staff will administratively review for completeness.

5.1.4 When complete documents are received, OIA staff will forward the agreement to the OIA director/medical director.

5.1.5 The OIA director/medical director will review the agreement and notify OIA staff if any issues are identified. Once the agreement is acceptable to the OIA director/medical director, they will forward to the institutional official to sign.

5.1.6 The OIA staff member may return the fully executed agreement to the UCSD investigator and/or may also send a copy directly to the independent investigator.

5.1.7 A copy of the signed agreement should be retained in the study file within the OIA's electronic submission system.

5.1.8 OIA staff informs the UCSD investigator that the independent investigator site must be added to the study by amendment in the electronic submission system. A description of the activities to be performed by the independent investigator must be provided. The fully signed reliance agreement, completed LCQ, and any other site-specific study documents must be uploaded for review.

5.1.9 Inform the analyst responsible for the study to review the amendment to add an independent investigator as a participating site, using *OIA-021 SOP: Pre-Review* (Section 3.1).

5.1.10 Upon UCSD IRB approval of the independent investigator's addition to the study, the UCSD investigator will forward letters, notices and approval documents to the independent investigator.

5.2 When UCSD is serving as the IRB of record for an external investigator:

5.2.1 OIA receives notice of a request to use UCSD as the sIRB for a multi-site project.

5.2.1.1 Check to see whether an IRB reliance agreement already exists and use applicable, existing agreements whenever feasible.

5.2.1.2 Follow the steps at 5.2.7 for collection of study documents and distribution of approval notifications and documents.

5.2.2 If no reliance agreement exists, OIA staff members provide, either directly to the external investigator and relying IRB, or via the UCSD investigator/designee, the UCSD IRB authorization agreement (IAA) template and the LCQ. The external investigator must complete *OIA-509 – TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire* (LCQ) with the help of a relying IRB representative.

5.2.3 Upon UCSD OIA receipt of the IAA and LCQ, OIA staff will administratively review for completeness.

5.2.4 When complete documents are received, OIA staff will forward the agreement to the OIA director/medical director.

5.2.5 The OIA director/medical director will review the agreement and notify OIA staff if any issues are identified. Once the agreement is acceptable to the OIA director/medical director, they will forward to the institutional official to sign.

5.2.6 The OIA staff member may return the fully executed agreement to the UCSD investigator and/or may also send a copy directly to the external investigator.

5.2.7 A copy of the signed agreement should be retained in the study file within the OIA's electronic submission system.

5.2.8 OIA staff informs the UCSD investigator that the external investigator site must be added to the study by amendment in the electronic submission system. A description of the activities to be performed by the external investigator must be provided. The fully signed reliance agreement, completed LCQ, and any other site-specific study documents must be uploaded for review.

5.2.9 Inform the analyst responsible for this study to review the amendment to add an external investigator as a participating site, using *OIA-021 SOP: Pre-Review* (Section 3.1).

5.2.10 Upon UCSD IRB approval of the external investigator's addition to the study, the UCSD investigator will forward letters, notices and approval documents to the external investigator.

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*

6.2 *OIA-021 SOP: Pre-Review*

6.3 *OIA-085 SOP: Establishing Reliance Agreements*

6.4 *OIA-509 TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire*

7 REFERENCES

7.1 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)