UC San Diego Senior Associate Vice Chancellor in Health Sciences Office of Clinical Research	SOP Number	OCR:003 Page 1 of 2
	Date:	04/02/2025
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SOP TITLE: PROTOCOL DEVELOPMENT AND REVIEW		

1 PURPOSE

1.1 This procedure establishes the process to develop an investigator-initiated research protocol and obtain protocol review and approval to ensure that research protocols adhere to institutional policy, regulatory requirements and ethical standards while promoting participant safety and scientific integrity.

2 REVISIONS FROM PREVIOUS VERSION

2.1 N/A

3 REQUIREMENTS

3.1 All human subjects research studies, including clinical trials, observational studies, and biomedical research must have an appropriately formulated study protocol that has undergone the required review process.

3.2 The study protocol is a detailed research plan outlining the study objectives, design, methods, and safety measures necessary for conducting the research.

3.3 Document protocol revisions using a version number, a version date, or some other method.

3.3.1 Track changes in each protocol version.

3.3.2 Maintain copies of each protocol version in the study regulatory file.

4 RESPONSIBILITIES

4.1 Principal Investigators (PI) and their designees are responsible for carrying out these procedures.

4.1.1 The PI may delegate authority for developing the protocol but is responsible for ensuring that it meets regulatory requirements, accurately describes the research activity, and reflects the study's objectives, methods, and safety measures required to protect human subjects.

4.1.2 The PI may delegate authority for submitting the protocol for scientific, regulatory, and ancillary reviews, but is responsible for ensuring that all required approvals are obtained before commencing research activities.

5 PROCEDURE

5.1 Develop the study protocol.

5.1.1 If UC San Diego is the IRB of record:

5.1.1.1 Consult the Office of IRB Administration (OIA) web page for protocol development guidance[1] and the appropriate protocol template[2] for the study.

5.1.1.1.1 Write the protocol according to the UC San Diego protocol template instructions.

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[1] OIA-103 IRB Handbook "How do I write an investigator protocol"?

[2] Forms, Templates & Instructions: Protocol Templates

5.1.1.1.2 Consult with the OIA, as needed, to confirm protocol requirements are met for the type of research being conducted.

5.1.2 If UC San Diego is relying on another IRB as IRB of record:

5.1.2.1 Consult with the office of the IRB of record, as required, to ensure the protocol requirements for the type of research being conducted are met.

5.1.2.2 Human subjects research can rely on a single IRB (sIRB) review for multi-site research under certain circumstances.

5.1.2.3 Submit the protocol for scientific and ancillary review, as required.

5.1.3 Determine other internal reviews[3] that may be required for protection of human subjects.

5.1.4 Submit the protocol to applicable scientific and ancillary committees.

5.1.5 Maintain copies of all submitted documents, committee correspondence, and approvals in the study regulatory file.

6 MATERIALS

6.1 UC San Diego IRB Biomedical Interventional Protocol Template

6.2 UC San Diego IRB Biomedical Non-Interventional Protocol Template

6.3 UC San Diego IRB Social/Behavioral/Educational Research Template

7 REFERENCES

7.1 OIA-103 IRB Handbook

[3] OIA-103 IRB Handbook: "What other internal reviews are also involved in the protection of human subjects"?