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	Author:	T. Graham
	Approved by:	S. Little
SOP TITLE: STUDY TEAM ROLES AND RESPONSIBILITIES		

1 PURPOSE

1.1 This SOP defines Principal Investigator (PI) and clinical research study team member roles, responsibilities, and expectations to ensure compliance with institutional, federal, and sponsor requirements aimed at safeguarding participant safety, data integrity, and ethical research practices.

1.2 The process begins when an investigator- or sponsor-initiated clinical study is being developed or is under review by the principal investigator.

1.3 The process ends when an investigator- or sponsor-initiated clinical research study is no longer under consideration or has been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 N/A

3 REQUIREMENTS

3.1 This SOP applies to all clinical research studies conducted at UC San Diego Health, including but not limited to, clinical trials, observational studies, and federally or privately funded research and to all personnel involved in study conduct, including the PI, co-investigators, research coordinators, data managers, and other study team members under the PI's direction.

3.2 The PI is the individual responsible for the overall conduct of the study, including participant safety, data integrity, regulatory compliance, and financial management.

3.3 Other responsible study team members include co-investigators, research coordinators, clinical research staff, data managers, and others who are delegated, by the PI, the authority to perform study tasks.

3.4 All study team members must complete applicable human subjects' protection training as required by the Office of IRB Administration (OIA). For research involving certain patient populations or conditions and drugs, devices, or agents, it is also suggested that you complete optional training, such as the Collaborative Institutional Training Initiative (CITI) Good Clinical Practice (GCP) Course, that may satisfy training expectations of a study sponsor.

4 RESPONSIBILITIES

4.1 The PI assumes overall responsibility for all aspects of a clinical research study. These responsibilities include securing and maintaining all institutional approvals (e.g., contracting, coverage analysis, IRB, radiation safety), prior to and during the study; and adhering to the IRB approved protocol, investigator brochure, relevant federal regulations, and GCP guidelines.

4.2 The PI may delegate authority to conduct study tasks to sub-investigators, coordinators, and other qualified study personnel; however, the PI remains ultimately responsible for overall study conduct.

5 PROCEDURE

5.1 The PI will directly perform or supervise performance of the following study responsibilities:

5.1.1 Develop or evaluate the study protocol to ensure the study design is scientifically sound and that the protocol clearly outlines study objectives, procedures, and participant safety measures.

5.1.2 Obtain all institutional approvals before initiating any research involving human participants and maintain approvals in accordance with university policies.

5.1.3 Appropriately interact with study sponsor in a timely manner to ensure that the protocol is followed according to the funding terms or study agreement.

5.1.4 Manage all phases of the study conduct:

- 5.1.4.1 Oversee all start-up activities, including site initiation, budget sign-off, and study staff training.
- 5.1.4.2 Oversee study conduct by regularly reviewing the study activities to ensure that study procedures are carried out as required by the IRB-approved protocol.
- 5.1.4.3 Ensure all team members receive protocol-specific training before study initiation, and any new team members who join the study mid-course receive relevant training before performing any study activities.
- 5.1.4.4 Ensure that data integrity is maintained through accurate and timely data collection and that data is adherent to GCP guidelines.
- 5.1.4.5 Oversee study close-out by verifying final data collection has occurred; required reports, including IRB closure reports, have been filed; and study documents are completed and archived in a compliant manner.
- 5.1.4.6 Provide regular updates to the study sponsor, the IRB and the study team regarding study status, safety monitoring outcomes, protocol amendments, or any other changes to the study.

5.1.5 Oversee participant safety:

- 5.1.5.1 Obtain informed consent from participants by ensuring all participants are fully informed about the study and their consent is obtained following ethical and regulatory requirements and practices.
- 5.1.5.2 Monitor and report adverse events by monitoring participants' health and well-being throughout the study and making necessary adjustments as required to ensure continued safety, and promptly reporting any adverse events or unanticipated problems involving risks to participants to the IRB and sponsor, as required.
- 5.1.5.3 Promptly inform study participants if new information becomes available that may affect their willingness to continue participating in the study.
- 5.1.5.4 Provide DSMB reports to the IRB at continuing review, or sooner as required by the DSMB, IRB or sponsor.

5.1.6 Comply with regulatory requirements, to include all applicable federal regulations and institutional policies.

5.1.7 Maintain accurate and complete study records, including participant source documents, study data, and regulatory files, for the duration of the study and applicable retention period.

5.1.8 Conduct periodic internal audits to verify compliance with the study protocol, institutional policies, and regulatory requirements.

5.1.8.1 Report non-compliance in accordance with IRB requirements.

5.1.8.2 Implement corrective actions promptly if any deficiencies are identified in study conduct, documentation, or reporting.

5.1.9 Personally supervise personnel to whom study tasks have been delegated.

5.1.9.1 Maintain a record of any study tasks delegated or assigned to others (i.e., delegation of authority log), using an appropriate paper or electronic record.

5.1.9.2 Ensure that study personnel have received appropriate training and/or are appropriately qualified through licensure or experience to conduct delegated tasks.

5.1.9.3 Ensure an effective mechanism exists for communication between the PI and the study team via meetings or other means.

5.2 Study team members may perform tasks as delegated by the PI.

5.2.1 Study coordinators and other research staff, if delegated by the PI, and in compliance with the study protocol and relevant policies and regulations, may:

5.2.1.1 Recruit and manage research participants, including screening and enrollment activities described in the study protocol.

5.2.1.2 Collect and enter study data into databases, data collection tools, and/or the participants' medical records, ensuring data integrity and confidentiality.

5.2.1.2.1 Medical record access is limited to authorized study personnel in compliance with institutional HIPAA policies and privacy regulations and IRB approvals.

5.2.1.3 Monitor data by performing ongoing data quality checks and identifying and resolving data discrepancies in collaboration with other study team members, as appropriate.

5.2.1.4 Manage research database(s), if applicable, by overseeing the design, maintenance, and security of databases used in the study.

5.2.1.5 Perform other protocol-specific tasks if qualified, trained, and delegated to do so by the PI.

6 MATERIALS

6.1 OCR-107 Sample delegation of authority log

7 REFERENCES

7.1 FDA Regulations: 21 CFR Part 312 Subpart D – Responsibilities of Sponsors and Investigators
7.2 FDA Regulations: 21 CFR Part 812 Subpart C – Responsibilities of Sponsors
7.3 FDA Regulations: 21 CFR Part 812 Subpart E – Responsibilities of Investigators
7.4 Integrated Addendum to ICH E6(R1): Guidelines for Good Clinical Practice E6(R2)