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	Date:	10/07/2025
	Author:	B. Cale
	Approved by:	L. Johnson

SOP TITLE: RESEARCH TEAM ROLES AND RESPONSIBILITIES

1 PURPOSE

1.1 This procedure identifies roles of, and outlines responsibilities for, research team members, including, but not limited to, principal investigators (PI); additional (sub- or co-) investigators; study coordinators/clinical research coordinators (CRC); and Center for Clinical Research (CCR) personnel, to include medical personnel, nurses, nurse practitioners, coordinators, or ancillary personnel; in conducting and overseeing clinical trials within the CCR, and may be applied to the conduct of other types of clinical research to promote quality and to meet Good Clinical Practice (GCP) guidelines.

1.2 This procedure applies to all studies in which any portion of the research procedures are conducted within the CCR clinics.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 GUIDANCE

3.1 The UC San Diego Policy and Procedure Manual (PPM) 100-5 defines activities that UC San Diego considers to be "human subjects research" and defines responsibilities of institutional entities who conduct research.

3.2 Office of IRB Administration (OIA) OIA-103 IRB Handbook describes the PI's ultimate responsibility for the conduct of a study and details requirements for submission and post-approval activities for the PI.

3.3 The PI is responsible for adherence to all University of California and UC San Diego policies related to human subjects research as well as all relevant federal and state regulations, including, for clinical trials, responsibilities and obligations for the conduct and oversight of the trial detailed in the Code of Federal Regulations (CFR) and in the Good Clinical Practice (GCP) guidelines, to ensure protection of the rights, safety and welfare of study participants, and to ensure the integrity of the study results.

4 RESPONSIBILITIES

4.1 The CCR director and CCR assistant clinical director are responsible for providing the study PI with a copy of this procedure.

4.2 The study PI is responsible for ensuring compliance with these procedures.

5 PROCEDURE

5.1 Principal Investigator Responsibilities

5.1.1 In conducting clinical trials in compliance with federal regulations and GCP, the PI commits to personally conduct or supervise the trial, including, but not limited to:

5.1.1.1 Ensuring the clinical trial is conducted according to the signed investigational plan (protocol), applicable regulations, and ICH guidelines on GCP.

5.1.1.2 Protecting the rights, safety, and welfare of subjects under the investigator's care through obtaining informed consent and ensuring initial and ongoing IRB review and approval of the study.

5.1.1.3 Providing or ensuring adequate medical care for subjects during and following their participation in the trial.

5.1.1.4 Controlling, maintaining, and accounting for drugs, biologics, or devices under investigation.

5.1.1.5 Maintaining adequate and accurate study records, and reporting study data, including safety data, to the sponsor and/or regulatory agency in a timely manner.

5.1.2 The study is required to have and maintain a PI or Sub-I with clinical privileges at UCSD in order to write clinical orders to be carried out by clinical staff (e.g., RN's, LVN's, lab technicians, ultrasound technicians and radiology technicians).

5.1.3 When study tasks or duties are delegated by the PI, the PI is responsible for providing adequate training and supervision to all delegates (see CCR 006 SOP): Delegation of Authority), and for ensuring that the delegated tasks are appropriate to the education, training and experience of the delegate.

5.1.4 When study tasks or duties are delegated to nursing personnel within the CCR, the PI or delegate is responsible for providing clear and specific written orders for these activities.

5.1.5 The PI will receive appropriate instruction and training prior to conducting or being involved in clinical research.

5.1.5.1 The PI may receive training in the conduct of clinical research through mentoring, professional courses, sponsor-provided training, UC San Diego training, or other means.

5.1.6 The PI will develop a plan for the supervision and oversight of the study, to include training of study personnel, and ensuring compliance to the study protocol, SOPs, and study-specific processes.

5.1.6.1 The PI will ensure that all personnel participating in the conduct of the study, including any personnel added to the study, have adequate training, ensuring that study personnel/delegates are:

5.1.6.1.1 Familiar with the objectives of the study and have an adequate understanding of the details of the protocol and attributes of the investigational product to perform their assigned tasks.

5.1.6.1.2 Knowledgeable of GCP and applicable regulatory requirements.

5.1.6.1.3 Competent to perform or have been trained to perform the tasks they are delegated.

5.1.6.1.4 Informed of any pertinent changes during the conduct of the trial and receive additional training as appropriate.

5.1.6.2 The PI will ensure that regular updates with study personnel occur as needed during the clinical trial to review the study status and progress, including review of:

5.1.6.2.1 Enrollment status and progress and condition of current study participants.

5.1.6.2.2 Performance of delegated duties, including reassignment of duties in the event of personnel turnover.

5.1.6.2.3 Informed consent process and documentation.
5.1.6.2.4 IRB approval status.
5.1.6.2.5 Protocol compliance.
5.1.6.2.6 Appropriate use, storage and accountability of investigational product(s).
5.1.6.2.6.1 For studies requiring high risk, complex medication or infusion administration (e.g., cell therapy, gene therapy, or administration of any therapeutic to a pediatric participant) in the CCR, the PI or appropriately delegated sub-investigator must be present **in the clinic** for the first dose administration.
5.1.6.2.6.2 For studies requiring any medication administration in the CCR; the PI must be in the ACTRI building and available within 15 minutes for the first dose administration.
5.1.6.2.7 Source data, to ensure the data are complete and accurate, that data captured in the study database or case reports are consistent, and that data security and participant privacy are maintained in accordance with regulatory requirements.
5.1.6.2.8 Safety data, including adverse events, external safety reports, if applicable, and protocol deviations, to develop appropriate corrective and preventative action when indicated.

5.1.6.3 PI Availability and Coverage
5.1.6.3.1 The PI will remain accessible to study personnel and available for participant-related or study-related inquiries at all times during active study conduct. The PI will respond promptly to any issues that may impact participant safety, protocol compliance, or data integrity.
5.1.6.3.2 The PI will ensure that research personnel have current contact information and clear instructions for reaching the PI or designated coverage during normal clinic hours and, when applicable, after hours.
5.1.6.3.3 When the PI is unavailable (e.g., during travel, scheduled leave, or off-site commitments), the PI will designate a qualified sub-investigator to assume oversight responsibilities during the absence. The coverage plan will be documented on the study Delegation of Authority Log and communicated to study personnel, CCR staff, and the sponsor, as appropriate.
5.1.6.3.4 The PI retains overall responsibility for the conduct of the study and will review and acknowledge any significant study-

related events, safety concerns, or decisions that occur during a period of delegated coverage.

5.2 Sub-Investigator/Co-Investigator Responsibilities

5.2.1 The PI may delegate study tasks or duties to qualified co- or sub-investigators (see CCR-006 SOP: Delegation of Authority). Delegated tasks or duties typically include:

5.2.1.1 Obtaining informed consent.

5.2.1.2 Screening evaluations, assessment, confirmation of eligibility criteria, and randomization of participants.

5.2.1.3 Physical examinations and vital signs.

5.2.1.4 Evaluation of adverse events.

5.2.1.5 Prescribing study treatment, or making medical determinations for treatment adjustments.

5.2.1.6 Review and interpretation of lab results and other study assessments.

5.2.1.7 Assessments of primary and secondary study endpoints.

5.2.1.8 Investigational product maintenance, dispensing, and accountability.

5.2.1.9 Assuring compliance with study protocol, GCP, applicable regulations, institutional policies and SOPs.

5.3 Clinical Research Coordinator

5.3.1 The PI may delegate study tasks or duties to the CRC, who assists the PI in managing delegated aspects of the clinical trial. Delegated tasks or duties typically include:

5.3.1.1 Facilitating protocol compliance through a thorough understanding of the protocol, and advising the PI when protocol compliance is compromised.

5.3.1.2 Assisting with study start up and implementation.

5.3.1.3 Recruiting, screening, and enrolling study participants, including assessment of eligibility criteria through medical history review

5.3.1.4 Participant randomization.

5.3.1.5 Tracking study participant activity.

5.3.1.6 Completing data collection source documents and data reports.

5.3.1.7 Identifying, tracking and reporting adverse events and deviations.

5.3.1.8 Preparing regulatory documents as needed, including documents for Food and Drug Administration and IRB submissions (e.g., initial and continuing reviews and post-approval reports).

5.3.1.9 Complying with audit requests.

5.3.1.10 Protecting research data in accordance with UC San Diego privacy and security requirements.

5.3.1.11 Serving as a liaison between the research participants, the investigator(s), the IRB, and the sponsor.

5.3.1.12 Assisting with and/or conducting the informed consent process, as approved by IRB.

5.3.1.13 Facilitating compliance with GCP, applicable regulations, institutional policies and SOPs.

5.4 CCR Personnel

5.4.1 The PI may delegate study tasks or duties to the CCR personnel, who assist the PI in managing delegated study visit activities. Delegated tasks or duties typically include:

5.4.1.1 Clinical study procedures ordered for the study participant.

5.4.1.1.1 CCR personnel carry out procedures as ordered while ensuring study participant safety and comfort; acting within the scope of their training and/or licensure, as applicable; and in accordance with the study protocol, GCP, and CCR SOPs.

5.4.1.1.2 CCR personnel ensure continuity of care for participant(s) assigned to them by completing the care, procedure, or case, or by ensuring appropriate participant handoff and report to other qualified personnel.

5.4.1.1.3 CCR personnel promptly report any deviations from ordered study procedures to the CRC and/or PI, as required.

5.4.1.1.4 CCR personnel document all ordered procedures and participant assessments and make the study records available to the PI.

5.4.1.2 Facilitating compliance with study protocol, GCP, applicable regulations, institutional policies and SOPs.

6 MATERIALS

6.1 CCR-101: Delegation Log

7 REFERENCES

7.1 21CFR312.60 – General responsibilities of investigators
7.2 21CFR312.61 – Control of the investigational drug
7.3 21CFR312.62 – Investigator recordkeeping and record retention
7.4 21CFR312.64 – Investigator reports
7.5 21CFR312.66 – Assurance of IRB review
7.6 21CFR312.68 – Inspection of investigator's records and reports
7.7 21CFR312.69 – Handling of controlled substances
7.8 21CFR312.70 – Disqualification of a clinical investigator
7.9 21CFR Part 812 Subpart E – Responsibilities of Investigators (Medical Devices)
7.10 21CFR Part 812 Subpart G – Records and Reports (Medical Devices)
7.11 21CFR Part 50 – Protection of Human Subjects
7.12 21CFR Part 54 – Financial Disclosure by Clinical Investigators
7.13 21CFR Part 56 – Institutional Review Boards
7.14 FDA Guidance – Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects
7.15 45CFR Part 46 – Protection of Human Subjects
7.16 ICH guideline for good clinical practice (R2)

7.17 FDA Guidance