UC San Diego Senior Associate Vice Chancellor in Health Sciences Office of Clinical Research	SOP Number	OCR:011 Page 1 of 3
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SOP TITLE: DELEGATION OF AUTHORITY		

1 PURPOSE

1.1 The procedure describes the process by which the principal investigator (PI) may delegate, and document delegation of, authority to conduct clinical study procedures and tasks to sub-investigators and other study personnel.

1.2 The process begins when study-specific procedures and tasks commence for a clinical study.

1.3 The process ends when the study is closed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 A PI conducting clinical research is required to follow applicable regulations that govern informed consent of research participants (21 CFR 50-Informed Consent of Human Subjects and 45 CFR 46.116 General requirements for informed consent). If the study also involves investigational drugs or devices, the PI must also adhere to regulations at 21 CFR 312 Investigational New Drug Application or 21 CFR 812 Investigational Device Exemptions, respectively. The PI is responsible for compliance with the principles of Good Clinical Practice (GCP) and with other local and national regulations and guidance.

3.2 The PI who delegates study tasks or duties is responsible for providing adequate training, or, if training is provided by a sponsor or other entity, for ensuring that training has been completed and documented, for supervising delegates, and for ensuring that the delegated task is appropriate to the delegates' education, training and experience, including licensing requirements.

3.2.1 The delegation of authority (DOA) log should include, at a minimum, the information in OCR-107: Delegation of Authority Log. An equivalent log, such as a sponsor log, an electronic document, or other paper document may be used.

3.2.1.1 If an electronic document is used, it should be created and maintained electronically in a system that is compliant with 21 CFR Part 11 Electronic Records; Electronic Signatures.

3.2.2 The delegation log is considered a study "essential document" and should be created and maintained carefully.

3.3 Individuals who perform study-related duties and tasks that are part of their normal job description/duties are not required by this SOP to have a formal delegation of duty documented for a study. These types of duties would include, but are not limited to, performance of routine patient care duties that fall within their standard job description and do not involve any specific study-related tasks beyond their regular practice. Examples of personnel might include non-investigational pharmacy personnel, pathology/laboratory services personnel, nursing staff, IRB members, and technical staff (e.g., EKG technicians, imaging technicians, phlebotomists, patient care assistants).

4 RESPONSIBILITIES

4.1 The responsibilities of the PI described in the regulations may be delegated, with adequate oversight, to qualified and appropriately trained sub-investigators and other study personnel.

However, the PI retains ultimate responsibility for overall study conduct. Additionally, the PI should maintain documentation of the personnel to whom the tasks are delegated.

4.2 Sub-investigators and other study personnel are responsible for conducting study-related duties as authorized by the PI in accordance with GCP, applicable local and national regulations, and within their scope of practice.

5 PROCEDURE

5.1 Prior to commencing the study, the PI or designee will initiate the DOA documentation for each individual to whom study tasks or duties will be assigned.

5.1.1 The PI indicates which study tasks will be delegated and to whom the tasks are delegated.

5.1.2 The PI or designee completes the DOA log to indicate the assigned tasks and the date the delegation begins.

5.1.3 The individual to whom study tasks are delegated signs and dates the DOA log acknowledging the assigned tasks.

5.1.4 The PI signs and dates the DOA log to confirm the start date for delegation of the tasks to the specified individual.

5.2 When sub-investigators or other study personnel are added to or removed from the study, the PI ensures that the DOA log is updated.

5.2.1 When sub-investigators or other study personnel are removed from the study:

5.2.1.1 The delegation end date for the individual is entered and the PI signs and dates the DOA log signifying the end of the individual's authority to perform the delegated study task(s).[1]

5.2.2 When sub-investigators or other study personnel are added to the study, follow steps 5.1.1 to 5.1.4 above.

5.3 When the study is complete, the PI ensures the DOA log is completed as follows:

5.3.1 The delegation end date is entered[2] for each delegate on the log.

5.3.2 The PI signs and dates the end date for each delegate on the log.

5.3.3 The PI signs and dates each page of the log.

5.3.4 The DOA log is filed with the study records and retained according to the applicable record retention period.

6 MATERIALS

6.1 OCR-107 Delegation of Authority Log

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[1] If the individual has been delegated multiple tasks and will retain responsibility for some tasks, finalize the current log line and create a new log line with the updated information.

[2] At study close-out, the study close-out date should be entered as the delegation end date for all delegates.

7 REFERENCES

7.1 21 CFR 50-Informed Consent of Human Subjects
7.2 45 CFR 46.116 General requirements for informed consent
7.3 21 CFR 312 Investigational New Drug Application
7.4 21 CFR 812 Investigational Device Exemptions
7.5 21 CFR Part 11 Electronic Records; Electronic Signatures
7.6 International Council for Harmonisation E6 (R1) – Guideline for Good Clinical Practice