| Title: Delegation of Authority Log | Version Number: #1 | Effective Date: 24 SEP 2024 | Page **1** of **6** |
|---|---|---|---|

## 1. Purpose

This SOG establishes the method by which the PI delegates study-related duties to applicable personnel. The method includes maintenance of the Delegation of Authority (DOA) log.

## 2. Scope

This SOG applies to the Principal Investigator (PI), sub-investigators (or co-investigators), study coordinators, and other study staff that are delegated study-related duties by the PI (including persons involved in writing the protocol, reviewing or overseeing/managing aspects of the research). Sponsors, outsourced parties or agents are not covered by this SOG. Likewise, this procedure does not apply to the investigational pharmacy personnel, IRB or DSMB members and/or technicians (EKG technician, phlebotomists, lab processing technicians, etc.) working with the PI. Since these individuals provide services related to the study as a normal part of their job description within the ACTRI, their routine duties do not need to be delegated according to this SOG.

This SOG may be used to guide the conduct of other types of clinical research studies (e.g. non-therapeutic or PI initiated studies) to promote quality and to meet Good Clinical Practice standards even if their sponsors (FDA, not-for-profit organizations) do not require a DOA log.

## 3. Definitions and Acronyms

**Clinical Research:** Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

**Clinical Trial:** Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

**DOA:** Delegation of Duty

**CFR:** Code of Federal Regulations

**FDA:** United States Food and Drug Administration

**GCP:** Good Clinical Practice

**ICH:** International Council on Harmonization

**IRB:** Institutional Review Board

**PI:** Principal Investigator

**SOG:** Standard Operating Procedure

## 4. Responsibilities

This policy applies to Principal Investigators (PI), Clinical Research Coordinators (CRC), Regulatory Coordinators (RC) and all study staff directly responsible for research studies related tasks and/or management of regulatory documents. Personnel affiliated with ACTRI, such as research nurses, medical assistants, laboratory technicians, and pharmacy or imaging staff, fall outside the scope of this SOG. Although these individuals provide services essential to the study as part of their roles within UC Health, their day-to-day duties are not regulated by the procedures delineated in this SOG.

## 5 Procedure

**5.1 Prior to initiation and throughout the study, the PI is responsible for reviewing the study requirements and determining assigned duties. that delegation of study-related tasks is appropriate to the education, training, and experience (including state licensure where applicable) to the individual.**

**5.2**

**5.2 All members of the study team covered under section 1.1 above should be listed on the DOA Log.**

**5.3 In delegating duties, the PI is responsible for ensuring that he/she follows applicable federal and state regulations, institutional policies and any protocol/study specific requirements.**

1. The PI should ensure
    1. The investigator should maintain a list of appropriately qualified persons to whom trial-related duties have been assigned. This list is maintained on a Delegation of Authority log, which a template is usually provided by the study sponsor.
    2. Tasks considered to be clinical or medical in nature must be delegated to sub-investigators or study staff with appropriate education, experience, and licensing or credentials to perform those tasks.

3. The following tasks are commonly delegated to study sub-investigators:
    - Obtaining informed consent
    - Screening evaluations (e.g. neurological and physical exams), assessment of eligibility criteria (e.g. MDSUPDRS, EDSS), and randomization of participants
    - Orthostatic vital signs
    - Evaluation of adverse events
    - Prescribing study treatment, or making medical determinations for treatment adjustments
    - Review and interpretation of lab results and other study assessments
    - Assessments of primary and secondary endpoints
    - Investigational product maintenance, dispensing, and accountability (either delegated to research pharmacy or CRC responsible for IP management)
4. The following tasks are commonly delegated to clinical research coordinators or other study staff:
    - Obtaining informed consent
    - Screening evaluations (e.g. questionnaires, ECG, vitals) assessment of eligibility criteria (certain scales), and randomization of participants
    - Obtaining medical history
    - Source document creation
    - CRF - Case report form completion
    - IRB submissions (typically delegated to the Regulatory Coordinator)
    - Collection and maintenance of regulatory documents (typically delegated to the Regulatory Coordinator)

2. The PI may use a Delegation of Authority log provided by the study sponsor. PI may use a comparable departmental or divisional form to document the delegation of duties for studies where the sponsor does not provide a study specific template.
    1. The Delegation of Authority log should be completed at study initiation (e.g. site initiation visit) and should be kept up-to-date throughout the trial to account for new study personnel and turnover. Individuals without a dedicated or permanent role or who are performing roles that

are routine for their daily job (e.g. ACTRI clinical staff including nurses, medical assistants, radiology staff, residents, pharmacy technicians, sonographers, lab techs, phlebotomists, etc.) do not need to be individually listed on the studies Delegation of Authority logs. These individuals are not considered study staff and work on a rotating basis within their department, and their qualifications, training, and work performed is monitored by their department heads.

2. Individuals working outside the University of California Healthcare system (e.g. home nursing services) will also not be listed on the site's Delegation of Authority log, as their training and oversight will be ensured and monitored by the sponsor. In these cases, the sponsor will be responsible for completing a DOA and they may provide a copy to the site for their files.

3. The names of sub-investigators assisting the investigator in the conduct of the study should be listed on form FDA 1572 for clinical trials of investigational drugs.
    1. Generally, only physician and mid-level (Nurse Practitioners, Physician Assistants, etc.) sub-investigators who have a permanent and specific role in the clinical trial and are directly involved in the treatment or evaluation of research participants should be included on the FDA 1572 and all should be listed in the DOA Log. However, there are some sponsors that will request that all staff completing assessments directly with the participants to be listed on the 1572.

4. The DOA is an official study "essential document," and should be created and maintained with care. If the document is destroyed or misplaced during the course of a study, it should be recreated as completely and as expeditiously as possible.
    1. Corrections made to the delegation of authority record should follow standard "good clinical practice" procedures: single line-through incorrect entry, enter appropriate information, initial & date correction - do not use white-out or otherwise obliterate the original entry. Only delegated members of the study can make revisions to the log when needed. The Regulatory Coordinator is normally responsible for this task, but task maybe delegated to the main clinical research coordinator if no Regulatory Coordinator is part of the study staff.

5. The delegation of authority record may be created and maintained electronically in a system compliant with 21 CFR Part 11 requirements for electronic records and electronic signatures. However, UCSD currently lacks an electronic records

system that meets the compliance standards of 21 CFR Part 11 for electronic signatures. As a result, all signatures and dates on the delegation of authority (DOA) document must be obtained in ink, rather than electronically.

6. At completion of the clinical trial, the original delegation of authority log will be maintained with the other study essential documents.
    1. A copy of the delegation of authority log may be provided to the Sponsor upon request but the original will need to remain at the study site.

2. **Principal Investigator Change**
    1. There are two options for updating the delegation log for a change in PI. Either option is acceptable, depending upon the sponsor's preference and the needs of the PI and/or study team. Option A is recommended as it is less burdensome.
        1. Option A – The departing PI assigns an end date to their line on the delegation log. The new PI completes a new line and enters their start date, which should be the same date or next day following the end date of the departing PI. The new PI specifies, either in the comments section or a Note to File, that he/she has reviewed all delegated tasks and agrees with the delegations made by the departing PI.
        2. Option B – An end date is listed for all personnel on the delegation log. The departing PI signs off on all end dates effectively 'closing' the delegation log. The new PI creates a completely new delegation log.

3. **Roles or Key Study Tasks Changes**
    1. If the role of a staff member changes during the trial, an end date should be entered at the time the role is no longer being completed by the individual (e.g., a CRC, becomes a Rater).
    2. If there are any changes to study tasks for an individual, the current delegation line should be updated with an end date. A new line is then started with the updated delegated study tasks. End dates should be assigned, and the new study tasks entered on a new line. Simply adding a new role to the current delegation is not sufficient to properly delegate a new task to study staff.
    3. The PI is required to initial and date changes to confirm and acknowledge any additional or deleted tasks.

**Appendices**

- DOA templates

**Materials Required**

- Delegation of Authority log
- DOA SOG
- FDA Form 1572 if applicable

**References**

- 21 CFR Part 312.53 : Responsibilities of Sponsors and Investigators
- 21 CFR Part 312.60: General Responsibilities of Investigators
- 21 CFR Part 812: Responsibilities of Investigators
- 21 CFR Part 50: Protection of Human Subjects research
- 21CFR Part 56: Institutional Review Boards
- ICH Guidance for Industry E6(R2): Good Clinical Practice
- FDA Guidance for Industry – Investigator Responsibilities (October 2009)

**Document Approval**

- Name and Title of Approver
- Date in the format (MM/DD/YYYY)
- Insert Name and Title below Signature

Approved By: Date:

_____ _____
Insert Name and Title

**Revision History**

| **Revision History** | | |
|---|---|---|
| **Version No.** | **Effective Date** | **Description** |
| | | |
| | | |
| | | |