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Revision History		
Version No.	Effective Date	Description

1 Purpose

- 1.1 This Standard Operating Guideline 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

- 2.1 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 or Health Center, their routine duties do not need to be delegated according to this SOG.
- 2.2 This SOG may be used to guide the conduct of other types of clinical research studies (e.g. non-therapeutic, PI initiated studies) to promote quality and to meet Good Clinical Practice standards even if these 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.

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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

- 4.1 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.

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.
- 5.1.1 All members of the study team covered under section 2 above should be listed on the DOA Log.
- 5.1.2 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.

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- 5.1.3 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.
- 5.1.4 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.
- 5.1.5 Individuals without a dedicated or permanent role in the study or who are performing roles that are routine for their daily job, such as ACTRI research nurses, radiologist, EEG technicians, medical assistants, laboratory technicians, 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. 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.
- 5.1.6 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 provide a copy to the site for their files.

The sub-investigators investigator listed on FDA 1572 form for clinical trials involving investigational drugs should be included in the DOA.

5.2 The PIs, clinicians and staff typically have certain tasks assigned to them.

- 5.2.1 The following tasks are typically assigned to the PI and other licensed clinicians (PI, Sub-I, RATERs, Nurses):
 - 5.2.1.1 Oversight for medical care of research participants (if applicable)
 - 5.2.1.2 Carrying out the informed consent process
 - 5.2.1.3 Physical and Neurological Exams
 - 5.2.1.4 Assessments of Adverse Events and Safety reporting
 - 5.2.1.5 Review and interpretation of lab results and other study assessments
 - 5.2.1.6 Investigational product maintenance, dispensing, and accountability (either delegated to research pharmacy or CRC responsible for IP management)
 - 5.2.1.7 Oversight of local management of the coordination of the study

5.2.2 The following tasks are commonly delegated to clinical research or regulatory coordinators:

- 5.2.2.1 Obtaining and documenting informed consent

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- 5.2.2.2 Screening evaluations (e.g. questionnaires, ECG as applicable, vitals) assessment of eligibility criteria (certain scales), and randomization of participants.
- 5.2.2.3 Accurate and timely data collection and data entry
- 5.2.2.4 Collection of medical history and concomitant medications
- 5.2.2.5 Adverse Event reporting and follow up
- 5.2.2.6 Regulatory and compliance functions, including IRB submissions and maintenance of Regulatory Binder
- 5.2.2.7 CRF/eCRF - Case report form completion

5.3 The DOA is an official study “essential document,” and should be created and maintained with care.

5.3.1 If the document is destroyed or misplaced during the course of a study, it should be recreated as completely and as expeditiously as possible.

5.3.2 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 revise the log when needed. The Regulatory Coordinator is normally responsible for this task. In the absence of a Regulatory Coordinator role, this task maybe delegated to the main clinical research coordinator listed on the DOA.

5.3.3 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.

5.3.4 At completion of the clinical trial, the original delegation of authority log will be maintained with the other study essential documents.

5.3.5 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.

5.4 The DOA template should have a minimum set of elements, which are normally predetermined by the sponsor’s template. The DOA should be completed at the initiation of the study, ideally during the Site Initiation Visit (SIV).

5.4.1 Elements of a DOA:

5.4.2 Printing full name (complete first and last name) in the “Personnel (Printed Name/Title)” column. Note: this field should not be typed.

5.4.3 “Personnel Signature” – This requires a wet signature

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- 5.4.4 “Initials” – these must be entered by the person being delegated the duties
- 5.4.5 “Start Date” – Insert start date when individual was added to the study
- 5.4.6 “End Date” – Insert end date, this is the last date the individual participated in on the study.
- 5.4.7 “Delegated Functions” – Add the number of the function to the individual assigned to the task.
- 5.4.8 Each person listed on the DOA Log will sign and date in the provided space indicating their acknowledgment and acceptance of the delegated duty(s).
- 5.4.9 The PI will sign and date the DOA Log indicating its effective date

5.5 Adding Personnel to an active DOA Log:

- 5.5.1 The DOA Log must be updated each time new Personnel are added.
- 5.5.2 To add new Personnel to an existing DOA Log, the steps listed under 4.6.2 above should be completed except as follows:
- 5.5.3 “Start Date” column – the date that the new Personnel will officially assume responsibility for delegated duties
- 5.5.4 “Revised (PI Initials and Date)” column – initial and date by the PI documenting the PI’s approval of the delegation

5.6 Updating the DOA when there is a change of PI

- 5.6.1 Per UCSD’s Office of Research Compliance, 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.
- 5.6.2 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.
- 5.6.3 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.

5.7 Updating the DOA when Roles or Key Study Tasks Change

- 5.7.1 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).
- 5.7.2 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

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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.

5.7.3 The PI is required to initial and date changes to confirm and acknowledge any additional or deleted tasks.

5.8 Adding Personnel to an active DOA Log:

5.8.1 The DOA Log must be updated each time new Personnel are added.

5.8.2 To add new Personnel to an existing DOA Log, the steps listed under 4.6.2 above should be completed except as follows:

5.8.3 “Start Date” column – the date that the new Personnel will officially assume responsibility for delegated duties.

5.8.4 “Revised (PI Initials and Date)” column – initial and date by the PI documenting the PI’s approval of the delegation

5.9 Removing Personnel from an active DOA Log:

5.9.1 The DOA Log must be updated when a delegated individual’s role in the research changes, including when an individual will no longer participate as a member of the research team.

5.9.2 To update the DOA Log the following must be completed:

5.9.3 “End Date” column – enter the date on which Personnel are officially relieved of responsibilities.

5.9.4 “Revised (PI Initials and Date)” column – initial and date by the PI documenting the PI’s approval of the change

5.10 Any deviation from this procedure must be documented and kept with the study records in the study regulatory binder.

6 Appendices

6.1 Delegation of Authority Log Template

7 Materials Required

7.1 Delegation of Authority log

7.2 Study Protocol

7.3 FDA Form 1572 if applicable

8 References

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- 8.1 21 CFR Part 312.53 : Responsibilities of Sponsors and Investigators
- 8.2 21 CFR Part 312.60: General Responsibilities of Investigators
- 8.3 21 CFR Part 812: Responsibilities of Investigators
- 8.4 21 CFR Part 50: Protection of Human Subjects research
- 8.5 PHS 398
- 8.6 ICH Guidance for Industry E6(R2): Good Clinical Practice Sections 4.1 and 4.2
- 8.7 FDA Guidance for Industry – Protecting the Rights, Safety, and Welfare of Study Subjects Supervisory Responsibilities of Investigators (October 2009)
- 8.8 FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors FDA Inspections of Clinical Investigators
- 8.9 FDA Compliance Guidance Part III - Inspectional, see "Responsibility and Administration "

9 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