
SOP Number ADM-010-01
SOP Name Delegation of Authority SOP
Effective Date 01/SEP/2012

1.0 SCOPE

1.1 This SOP 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 or overseeing/managing aspects of the research). Sponsors, outsourced parties or agents are not covered by this SOP. Likewise, this procedure does not apply to the investigational pharmacy personnel, IRB or DSMB members and/or technicians (EKG technician, phlebotomists, patient care assistants, etc.) working with the PI. Since these individuals provide services related to the study as a normal part of their job description within UC Health, their routine duties do not need to be delegated according to this SOP.

2.0 PURPOSE

2.1 This SOP 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.

3.0 DEFINITIONS

3.1 None

4.0 PROCEDURES

4.1 Prior to initiation and throughout the study, the PI is responsible for reviewing the study requirements and determining assigned duties.

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

4.3 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.

4.4 At a minimum, all DOA Logs will document the assignment of the following:

4.4.1 Oversight for medical care of research participants (if applicable)

4.4.2 Carrying out the informed consent process and other study procedures

4.4.3 Oversight of local management of the coordination of the study

4.4.4 Safety reporting

4.4.5 Accurate and timely collection and entry of data

4.4.6 Regulatory and compliance functions, including IRB submissions and maintenance of the Regulatory Binder

4.5 At a minimum, all DOA Logs will list the following:

4.5.1 Personnel names

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- 4.5.2 Signature and written initials for each person
 - 4.5.3 Duties assigned to each person on the log
 - 4.5.4 Date duties were assigned (see below for further details)
 - 4.5.5 Date staff were relieved of duties
 - 4.5.6 Signature of the PI indicating that the duties were appropriately delegated and that each person is appropriately qualified and trained for their delegated duties
- 4.6 Initiation of the DOA Log:
- 4.6.1 The PI or other designated Personnel will initiate the DOA Log. The DOA Log is available as a standard template; however a comparable format may also be used in compliance with section 4.5 above.
 - 4.6.2 The following columns should be completed at the initiation of the DOA Log:
 - 4.6.2.1 Print full name (complete first and last name) in the “Personnel (Printed Name/Title)” column. Note: This field should not be typed.
 - 4.6.2.2 “Personnel Signature” – Signature must be full first and last name
 - 4.6.2.3 “Initials” – These must be entered by the person being delegated the duties
 - 4.6.2.4 “Start Date” – Insert start date
 - 4.6.2.5 “End Date” – Insert end date
 - 4.6.2.6 “Authorized Functions” – Circle numbers for all authorized functions
 - 4.6.3 Each person listed on the DOA Log will sign and date in the provided space indicating their acknowledgement and acceptance of the delegated duty(s).
 - 4.6.4 The PI will sign and date the DOA Log indicating its effective date.
- 4.7 Adding Personnel to an active DOA Log:
- 4.7.1 The DOA Log must be updated each time new Personnel are added.
 - 4.7.2 To add new Personnel to an existing DOA Log, the steps listed under 4.6.2 above should be completed except as follows:
 - 4.7.2.1 “Start Date” column – the date that the new Personnel will officially assume responsibility for delegated duties

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

4.8 Removing Personnel from an active DOA Log:

4.8.1 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.

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

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

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

4.9 Any deviation from this procedure must be documented and kept with the study records.

5.0 LIST OF ATTACHED FORMS

5.1 ADM-010-01 A1 Delegation of Authority Log

6.0 REFERENCES

6.1 [21 CFR 312.53](#)

6.2 [21 CFR 312.60](#)

6.3 [FDA Guidance for Industry: Protecting the Rights, Safety, and Welfare of Study Subjects- Supervisory Responsibilities of Investigators](#)

6.4 [FDA Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors FDA Inspections of Clinical Investigators](#)

6.5 [FDA Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance sections 4.1 and 4.2](#)

6.6 [FDA Compliance Guidance Part III - Inspectional, see "RESPONSIBILITY AND ADMINISTRATION"](#)

6.7 [PHS 398](#)

7.0 APPROVAL

VP of UC HEALTH RESEARCH OR DESIGNEE

DATE