



**Procedure Name:** Delegation of Authority & Signature Log  
**Effective Date:** February 26, 2010  
**Revision:** 01  
**Initiating Department:** Office of Clinical Trials  
**Procedure Number:** CR-005, Rev 1  
**Application:** Principal Investigators, Sub-Investigators, Clinical Coordinators  
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**OBJECTIVE:**

Describe the process for documenting the delegation of authority for human clinical trials.

**REFERENCES:**

<b>21 CFR 312.60</b>	General Responsibilities of Investigators
<b>FDA</b>	Guidance for Industry: Protecting the rights, Safety, and Welfare of Study Subjects – Supervisory Responsibility of the Investigators
<b>FDA Form 1572</b>	Statement of Investigator
<b>I21CFR 812.100</b>	General Responsibilities of the Investigator
<b>OPHS-IRB Manual Section 8.1</b>	Investigator’s Role and Responsibilities: Definition and Role of Principal Investigator (PI)

**SCOPE:**

US FDA regulations require that the Principal Investigator (PI) exercise personal supervision over the conduct of the clinical trial. Virtually all of the trial-related activities that occur at the clinical site are held to be the responsibility of the PI. However, clinical research is a team effort utilizing sub-investigators, clinical coordinators and staff members. Many of the trial-related activities are frequently delegated to clinical team members. FDA recognizes this reality and has established some basic requirements for delegation of authority.

**RESPONSIBILITY:**

The PI has the responsibility of ensuring that only individuals qualified by means of education, training and experience are charged with the authority to perform specified duties.

**Note** – while authority to conduct specified tasks may be delegated, the responsibility for those tasks always remains with the PI.

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**PROCEDURE:**

The PI will:

- 1.0 Review the protocol to identify those activities that are suitable for delegation to clinical staff and to determine if there are any specific requirements or qualifications detailed for those activities.

Note that any additional qualifications or restrictions detailed in the protocol take precedence over state law. For example, if state law permits a Licensed Practical Nurse to take medical histories but the protocol requires a Registered Nurse for the subject study, the protocol's requirements take precedence to the extent that they do not contravene state law.

- 2.0 It is recommended (but not required) that the PI prepares a detailed plan for providing the required supervision and oversight for the subject clinical trial. This plan should identify those tasks that are suitable for delegation, document any protocol-specified or state law required qualifications for those tasks and identify the staff members who may perform those tasks.
- 3.0 Prior to beginning trial-related activities and as needed when new staff are added to a trial, complete the information on the Delegation of Authority/Signature Log form (Attachment 1)
  - 3.1 Record the name of the PI, site # (if applicable), sponsors name and protocol number at the top of the form.
  - 3.2 Record the name of each person who will play a significant role in the clinical trial. Assure that all persons who will be delegated to perform any activity regulated by FDA such as informed consent, adverse event handling, etc. are detailed on the form.
  - 3.3 Record the date the entry is completed and if known, the date the responsibility will end. If no specific date is known, enter "on-going or study end".
  - 3.4 Describe the role of the delegate. Note that, since the PI is responsible for all aspects of the trial, it is not necessary to list the PI on the form.
  - 3.5 Enter the tasks the person will be performing by recording the number corresponding to the task (listed at the bottom of the form).
  - 3.6 Have the delegate both initial and sign the form.
- 4.0 Assure that the form is periodically reviewed to assure that it is kept up-to-date.
- 5.0 The form should be maintained in the trial's Regulatory Binder and becomes a part of the clinical trial's documentation.

**REVISION HISTORY**

Rev	DCO	Description of Change	Approved by
1	08-013	Edited for clarity and style	Michael V.W. Bergamini

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Principal Investigator: \_\_\_\_\_ Site # \_\_\_\_\_ Sponsor: \_\_\_\_\_ Protocol #: \_\_\_\_\_

Name/Title (Print)	Role	Responsibilities Enter numbers from below	Dates From - To	Initials	Signature

- |                                   |   |                                 |                             |
|-----------------------------------|---|---------------------------------|-----------------------------|
| 1. Budgets & Contracts            | 2. Initial Regulatory Submission        | 3. IRB Submission/communication | 4. Informed Consent Process |
| 5. Medical History                | 6. Physical Examination                 | 7. Specimen collection/handling | 8. Specialized testing      |
| 9. Dietary/lifestyle counseling   | 10. Lab result interpretation           | 11. AE Interpretation           | 12. CRF Completion          |
| 13. Med Dispensing/Accountability | 14. Recruiting/screening/enrolling logs | 15. Query Resolution            |                             |
- Add responsibilities as needed

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