Delegation of Responsibility/Site Signature Log

Investigator Responsibilities

Federal regulations require an Investigator[1] to personally conduct and adequately supervise a clinical study of a drug, biological product, or medical device.[2] While the principal investigator (PI) is ultimately responsible for the conduct of the study, certain study tasks conducted at the trial site may be delegated to other members of the research team.[3]

Current FDA recommendations for documenting delegated tasks

The 2009 FDA Guidance[4] provides recommendations for documenting tasks delegated by the PI to other members of the research team. This procedural guidance is summarized below, as well as exemplified in a Delegation of Responsibility/Site Signature Log template below. In summary, the PI should:

- **Maintain a list of appropriately qualified persons** to whom the investigator has delegated significant trial-related duties.[5] This list should describe the delegated tasks, identify the training that individuals have received that qualifies them to perform the delegated tasks, and identify the dates of involvement in the study;

- **Ensure that any individual to whom a task is delegated is qualified by education, training, and experience** (state licensure) to perform the delegated task.[6] Appropriate delegation is primarily an issue for tasks considered to be clinical or medical in nature, such as evaluating study subjects to assess clinical response to an investigational therapy (e.g., global assessment scales, vital signs) or providing medical care. Most clinical/medical tasks require formal medical training and may also have licensing or certification requirements. PIs should take such qualifications/licensing requirements into account when considering delegation of specific tasks. In all cases, a qualified physician (or dentist) should be responsible for all trial-related medical (or dental) decisions and care;

- **Be responsible for conducting studies in accordance with the protocol**.[7] In some cases a protocol may specify the qualifications of the individuals who are to perform certain protocol-required tasks (e.g., physician, registered nurse), in which case the protocol must be followed even if state law permits individuals with different qualifications to perform the task.[8]

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[1] Investigator -- as defined in 21 CFR 312.3(b) and 21 CFR 812.3(i).
[2] Per 21 CFR 312.60, 812.100.
[3] Per E6(R2) Good Clinical Practice, dated 9/28/2015, which includes an *Integrated Addendum to ICH E6(R1): Guideline for GCP* at Section 4.2.5.
[4] The FDA "Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects," dated October 2009.
[5] ICH GCP Guidance for Industry E6 Good Clinical Practice - Consolidated Guidance, Section 4.1.5. (See Section 8.3.24). An investigator may elect to combine the Delegation of Responsibility log and the Signature Sheet.
[6] Note: The BIMO Inspection Manual directs FDA auditors to: "Document …[w]hether the authority for the conduct of the various aspects of the study was contracted and/or delegated properly so that the investigator retained control and knowledge of the study…If there are questions about appropriate delegation, obtain information (e.g., curriculum vitae, medical or other license) about the qualifications of the person performing the task."
[7] Per 21 CFR 312.60, Form FDA-1572, 21 CFR 812.43 and 812.100.
[8] (See 21 CFR 312.23(a)(6) and 312.40(a)(1)).

Delegation of Responsibility/Site Signature Log

Investigator Name:		**Sponsor/Protocol No.:**	
IRB No.		**Site Number:**	

Site Study Personnel	Title	Delegated Responsibilities*	Signature	Initials	Start Date	End Date

***Legend for Delegated Study Tasks:** *(Note: The following are examples. Add/delete tasks to meet study-specific needs)*

1. Administer Consent	6. Randomize Subjects	11. Query Management
2. Screen evaluations	7. Dispense Study Drug/Device	12. Maintain Regulatory Documents
3. Obtain Medical History	8. Drug/Device Accountability	13. Data and Safety Monitoring
4. Perform physical examination	9. Complete Source Documents	14. Other (list):
5. Assessment of Eligibility Criteria	10. Complete Case Report Forms	_____
		_____

Signature of Principal Investigator:_____ **Date:** _____

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