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Degrees of Delegation in Clinical Research

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U.S. federal regulations and guidelines specify principal investigator responsibilities. The FDA allows investigators to delegate tasks to individuals "qualified by education, training and experience (and state licensure where relevant) to perform the delegated task."[1] Regardless of any delegations, the investigator retains ultimate responsibility.

U.S. federal regulations allow study sponsors to transfer (i.e., delegate) their responsibilities to contract research organizations (CROs), with the requirement that they must maintain proper oversight.[2] Regardless of any delegations, the study sponsor retains ultimate responsibility.

Implementation of these regulations and guidelines requires a clear understanding of the term "delegation." The basic concept of delegation is well-known: the act of a giving a person the authority to act for or represent another or others. However, the *degree* of delegation can vary widely and should, therefore, also be specified. There are seven degrees of delegation, ranked here from lowest to highest:

1. Perform the task under my direct supervision.
2. Before performing the task, obtain my permission.
3. Before performing the task, ask my permission. If I don't respond with a specified period of time, go ahead with it.
4. Before performing the task, inform me that you plan to do so in a manner that gives me the chance to intervene.
5. Perform the task and inform me in a timely manner that you have done so.
6. Perform the task and keep me informed periodically (e.g., in a report).
7. Perform the task without informing me.

The first degree of delegation is barely delegation at all. The seventh degree of delegation constitutes abdication; although the investigator or study sponsor retains ultimate responsibility, they have no control or even knowledge of the activity.

The pertinent regulations and guidances do not specify the degree of delegation. However, ICH recommends policies and procedures for investigators consistent with the sixth degree of delegation:

- Routine meetings with staff to review trial progress and adverse events and update staff on any changes to the protocol or other procedures
- Routine meetings with the sponsor's monitors
- A procedure for the timely correction and documentation of problems identified by study personnel, outside monitors or auditors, or other parties involved in the conduct of a study
- A procedure for documenting or reviewing the performance of delegated tasks in a satisfactory and timely manner (e.g., observation of the performance of selected assessments or independent verification by repeating selected assessments)

- A procedure for ensuring that the consent process is being conducted in accordance with 21 CFR Part 50 and that study subjects understand the nature of their participation and the risks
- A procedure for ensuring that source data are accurate, contemporaneous and original
- A procedure for ensuring that information in source documents is accurately captured on the case report forms (CRFs)
- A procedure for dealing with data queries and discrepancies identified by the study monitor
- Procedures for ensuring study staff comply with the protocol and adverse event assessment and reporting requirements
- A procedure for addressing medical and ethical issues that arise during the course of the study in a timely manner[3]

Study sponsors, no doubt, have similar policies and procedures for delegation to CROs.

Many investigators (and study sponsors) may prefer a lower degree of delegation for certain important or high-risk activities and a higher degree of delegation for other activities, based on each activity's importance and level of risk. Rather than delegating all activities to the same degree, the delegation can be tailored to each activity's importance and/or risk level, as well as the relative expertise of the parties.

Investigators can specify the degree of delegation for specific activities on the site's delegation log.

This perspective on delegation can also be applied to activities in clinical research that are not governed by regulation.

References

1. Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety and Welfare of Study Subjects
2. 21 CFR 312.52, 21 CFR Part 812
3. https://ichgcp.net/clarification-of-certain-investigator-responsibilities

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