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# Delegation of Duties

**By Norman M. Goldfarb**

An investigator is the "person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator."[1]

According to a recent FDA final guidance, "investigators who conduct clinical investigations of drugs, including biological products, under 21 CFR Part 312 commit to personally conduct or supervise the investigation….When tasks are delegated by the investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated and the investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study… The investigator should maintain a list of appropriately qualified persons to whom significant trial-related duties have been delegated."[2]

These requirements beg the question: What does it mean to delegate a duty?

## Properties of Delegation

When someone delegates a duty, he or she entrusts that duty to the delegate. The delegate takes on responsibility for the duty, but the delegator also retains the same level of responsibility for proper performance of that duty. The only difference is that the delegator moves from a hands-on to a supervisory role.

Delegation of a duty is normally to a subordinate. Because the delegator retains responsibility for the duty, delegating it to a colleague who is not a subordinate in essence makes that person the delegator's subordinate for the limited purpose of performing that duty.

Duties can be delegated for a defined or indefinite period of time. They cannot be delegated permanently, but they can be abdicated (surrendered) by an individual or reassigned by a higher authority. Whereas a delegator has the authority to cancel or modify a delegation, he or she cannot easily take back duties that have been abdicated or reassigned.

Not all duties can be delegated. For example, a principal investigator (PI) may not delegate his or her overall responsibility for a clinical trial. Phantom investigators in essence delegate duties that legally cannot be delegated and/or delegate duties without maintaining adequate supervision.

Delegation of a duty does not inherently mean delegating the authority to further delegate the duty. For example, a PI may delegate informed consent to a subinvestigator, but that does not mean the subinvestigator can pass the delegation on to another subinvestigator, even if that person is completely qualified.

"Delegation" is often shorthand for "delegation of authority," because it usually means granting authority to make decisions. However, in clinical research, the term "delegation of duties" serves.

There are five levels of delegation:

1. Perform Duty A when I direct you to perform it.
2. Perform Duty B after obtaining my approval.

3. Perform Duty C after notifying me, so I have the opportunity to participate, e.g., by giving you advice or doing it myself.
4. Perform Duty D and tell me later what happened.
5. Perform Duty E and do not tell me what happened unless I ask.

As the level of delegation increases, the delegator becomes less involved in the duty. The delegator can tune the level of delegation to the delegate and nature of the duty. For example, he or she may delegate routine blood draws to an experienced study nurse at level 5, but intravenous therapy to an inexperienced nurse at level 2.

Delegation of a duty often requires clarification of the specific duty being delegated. For example, a PI may delegate mental acuity assessments of apparently normal patients, but not those with signs of cognitive impairment. PIs should clearly understand and communicate their delegations. Misunderstandings can seriously impact study performance and working relationships. However, it is impractical to clarify every delegation in every circumstance. Fortunately, individuals and organizational cultures tend to have consistent patterns of delegation that will be revealed by thoughtful consideration of a small sample. Exceptions can be added when observed, e.g., "you can interrupt me for that in the front nine, but not the back."

**References**


1. ICH Guideline for Good Clinical Practice E6(R1), 1.34 and 4.15, http://www.ich.org/LOB/media/MEDIA482.pdf
2. FDA Guidance for Industry: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects, http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Resource_Center/Articles/Draft%20Guidance%201.pdf


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