REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

The importance of an accurate delegation log

ICH GCP Section 4.1.5 states: "The Investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties."

What does this mean?

- The PI is required to maintain a list of persons to whom significant study duties have been assigned, and they are to maintain that list throughout the life of the study. We utilize a Delegation of Authority Log (DOA) for this purpose.
- The PI must use qualified staff that align with the duties assigned (i.e., some tasks can ONLY be delegated to medical doctors or licensed nurses, etc.)
- The PI must ensure that each individual conducts ONLY the tasks that have been delegated to them, and only after receiving proper training. The training must be documented.
- The PI must make sure that their study staff does not perform any study activity prior to the recorded start date on the DOA.

Throughout the study conduct process, the PI remains responsible for the delegated tasks until they are completed, and the study is closed.

This document is an official regulatory document and is always requested during audits, inspections and monitoring visits.

GCP for Delegation Logs:

- The DOA should be completed before site activation or any study procedures begin.
- The DOA should be kept accurate at all times, including start AND end dates for all staff delegated study tasks.
  - As new staff join the study or staff tasks end (someone leaves), the DOA should be updated with start AND end dates as applicable **in real time**.
- The DOA should be filed as part of the Investigator Site File (ISF).
- If responsibilities change, the DOA should be updated **in real time**.
- Tasks should never be performed until start dates and signatures are secured on the DOA.
- Upon study completion, all site personnel listed on the DOA should have an end date.
- The PI should sign off on all task changes, staff start dates and staff end dates on the DOA.

IT IS THE PIs RESPONSIBILITY TO NOTIFY THE ARS IM REGULATORY CRP ASSIGNED TO YOUR STUDY OF ANY AND ALL STAFF CHANGES.

NOTE: This document needs to be kept on ALL studies that involve Human Subject Research – including Exempt studies.

If you have any questions, please do not hesitate to reach out to: IMRegulatory@uc.edu

For more information, please click: Tools and Templates

Thank you!