Children's Hospital Boston

EQuIP Education and Quality Improvement Program

Staff Training Log

WHAT is a Staff Training Documentation Log?

The Staff Training Documentation Log is a means to track and document research staff training and education as conducted and/or completed.

Includes the following information

- Name of Research Staff
- SOP reviewed or training course attended
- Topics covered in the SOP or training course
- Signature(s)

WHEN is a Staff Training Log Required?

The Principal Investigator is responsible for ensuring that all research staff are qualified by education, training and experience to adequately perform their delegated study tasks. All active research staff must be adequately informed about the protocol, investigational materials (when applicable), and their specific study-related tasks.

The Staff Training Log serves as documentation that the individuals who have been delegated study tasks, have completed adequate training.

WHY would you need a Staff Training Log?

A Staff Training Log is a method to maintain complete and accurate documentation of all training provided by the principal investigator for their research staff as to verify their staff is qualified to perform delegated study tasks. Per federal regulations, while investigators may delegate certain study-related tasks to employees, colleagues or other third parties, they are still responsible for the ensuring adequate supervision of those individuals as they still assume the responsibility of all regulatory violations resulting from failure to adequately supervise the conduct of the study.

In assessing the adequacy of supervision by an investigator, FDA focuses on four major issues:

1. whether delegated individuals were qualified to perform such tasks,
2. whether study staff received adequate training on how to conduct the delegated tasks and were provided with an adequate understanding of the study
3. whether there was adequate supervision and involvement in the ongoing conduct of the study, and
4. whether there was adequate supervision or oversight of any third parties involved in the conduct of a study to the extend such supervision or oversight was reasonably possible.

Investigators should maintain a list of all research staff, their delegated study task(s), **the training they received that qualifies them to perform the delegated tasks**, and the time period they performed these tasks.

HOW do you use it?

Create a log that documents the date, type of training and a complete description of the topics covered during the training session. Training can be documented for each individual (training log v.1), or by training session effort (training log v.2).

WHERE do you put it?

If a sponsor provides a Staff Training Log, file as instructed. Otherwise, the log may be filed in a location easily accessible and available to reference and update as needed.

Applicable References for Consideration:

Guidance for Industry Protection the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators http://www.fda.gov/cber/gdlns/studysub.pdf