

Summary of Protocol Training SOP Audit

June 2023

As a part of CCR Quality Management activities, we conducted an audit of documentation of protocol training for new ORN staff, start dates August 2022 through February 2023. We reviewed documents that were available in the protocol's regulatory file at the time of the audit. The ORN Team Leads provided the protocol assignment list for each new coordinator. A total of 42 cases were reviewed for documentation of protocol training and being added to delegation log, per the CCR SOP PM-5 *Research Protocol Training Requirements*. Fourteen cases (33%) had both adequate documentation of protocol and the staff were added to the delegation log.

Other findings related to SOP PM-5:

- Four cases had training documented but it was greater than 1 week after the staff being added to the delegation log.
- One staff member was added to the delegation log for the study but there is no documentation in the regulatory file of protocol training.
- In 14 cases, the staff member was not added to the delegation log available for review in the regulatory file.

Other issues found during the audit:

- Nine protocols have a delegation log in the regulatory file that had not been updated for more than 1 year.
- One protocol has a delegation log in the regulatory file that only contains staff names; no start dates nor signatures.
- Five protocols do not have ANY delegation log in the regulatory file.

The teams will be notified of individual results. In addition, CCR SOP PM-5 will be updated to add a "window" for completion of training in relationship to when the new staff member is added to the delegation log.

Reminder: Staff must be listed on the delegation log for the protocol, with a start date, PRIOR to performing any research activities for the protocol. Protocol training, including review of all applicable protocol documents, must be documented and maintained in the regulatory file.