Summary of Protocol Training SOP Audit

April 2024

(Previous audit June 2023 numbers in green)

As a part of CCR Quality Management activities, we conducted an audit of documentation of protocol training for new ORN and NP/PA staff, start dates July 2023 through December 2023. We reviewed documents that were available in the protocol's regulatory file at the time of the audit in April 2024. PROTRACT Query System (PQRS) was searched to determine what protocols each new staff were listed on in PROTECT.   A total of 25 cases were reviewed for documentation of protocol training and being added to delegation log, per the CCR SOP PM-5 *Research Protocol Training Requirements*. Ten (40%) (33%) had both adequate documentation of protocol training and the staff were added to the delegation log.

Other findings related to SOP PM-5:

- Four (10) staff members were not added to the delegation log, and there was not documentation of protocol training in the regulatory file.
- In two (1) instances a staff member was added to the delegation log for the study but there is no documentation of protocol training in the regulatory file.
- In three (4) cases the staff member were not added to the delegation log available for review or no delegation log in the regulatory file but documentation of protocol training was available.
- Five (4) cases had training documented but it was greater than the timeframe required in the SOP (from 3 months to 7 months AFTER start date on delegation).

Other issues found during the audit:

- One (5) protocol did not have ANY delegation log in the regulatory file.
- PI signed Documentation of Protocol Training form 4 months after staff member.

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.