Amendment Training SOP (PM-9) Audit
Conducted Q2 FY 2023
[Previous audit conducted Q4 FY 2021 – those results in green]

66 protocol amendments reviewed (28 major amendments* / 35 minor amendments)
[75 protocol amendments reviewed (41 major amendments* / 34 minor amendments)]

Random selection of 66 (75) out of 127 (215) amendments approved between August 1, 2022 – October 31, 2022.
Training records were available for 42 (17 major/22 minor/3 admin) amendments (63%) [38 (26 major/12 minor) amendments (51%)].
	• There was adequate training documentation for 29 (8 major/18 minor/3 admin) amendments (44%) [17 (11major/6 minor) amendments (47%)].
	• Training was conducted (out of 42 [38] with documentation):
	  ○ via email for 33 (13 major/17 minor/3 admin) amendments (79%) [23 (17 major/6 minor) amendments (61%)],
	  ○ in person for 3 (2 major /1 minor) amendments (1%) [3 (1 major /2 minor) amendments (8%)],
	  ○ via email and in person for 8 (4 major /4 minor) amendments (19%) [8 (6 major /2 minor) amendments (21%)].
	• Training tool was used for 3 (1 major /2 minor) amendments (7%) [9 (7 major /2 minor) amendments (24%)].
	• Training log was used for 13 (7 major /6 minor) amendments (31%) [18 (11 major /7 minor) amendments (47%)].

Overall Findings (major/minor)	• Amendment training records were not located for 24 (11 major /13 minor) amendments (36%) [37 (15 major /22 minor) amendments (49%)]. • Of the 42 (17 major /22 minor/3 admin) [38 (26 major /12 minor)] amendments that had training records available for review: ○ Amendment training documentation was not adequate or late for 9 (21%) [17 (45%)] major and 4 (10%) [6 (16%)] minor amendments.
Detailed Findings	• **"**Read Receipt" return emails or primary training email were not available in regulatory files. • Amendment training was conducted more than 5 business days after the amendment IRB approval. • Only training log was available in regulatory files without specifying the process used to communicate amendment changes. • Training documentation did not specify who is responsible for action items and in what timeframe.

* Major amendments include but not limited to changes to eligibility, study design, drug administration, dose, study procedures, study related risks, informed consent document and/or requirement for reconsent.