<table>
<tr><td colspan="2">Amendment Training SOP (PM-9) Audit
Conducted Q4 FY 2021

75 protocol amendments reviewed (41 major amendments* / 34 minor amendments)</td></tr>
<tr><td>Random selection of 75 out of 215 amendments approved between February,1 2021 – June 30, 2021. Training records were available for 38 (26 major/12 minor) amendments (51%).</td><td>• There was adequate training documentation for 17 (11major/6 minor) amendments (47%).
• Training was conducted:
o via email for 23 (17 major/6 minor) amendments (61%),
o in person for 3 (1 major /2 minor) amendments (8%),
o via email and in person for 8 (6 major /2 minor) amendments (21%).
• Training tool was used for 9 (7 major /2 minor) amendments (24%).
• Training log was used for 18 (11 major /7 minor) amendments (47%).</td></tr>
<tr><td>Overall Findings
(major/minor)</td><td>• Amendment training records were not located for 37 (15 major /22 minor) amendments (49%).
• Of the 38 (26 major /12 minor) amendments that had training records available for review:
o Amendment training was conducted more than 5 business days after the amendment IRB approval for 6 (23%) major and 3 (25%) minor amendments.
o Amendment training documentation was non adequate for 11 (42%) major and 3 (25%) minor amendments.</td></tr>
<tr><td>Detailed Findings
(major/minor)</td><td>• “Read Receipt” return emails were not available in regulatory files (2 major /1 minor).
• Only training log was available in regulatory files without specifying the process used to communicate amendment changes (2 major /2 minor).
• Training documentation did not specify who is responsible for action items and in what timeframe (10 major).</td></tr>
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- 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.