CCR SOP Update: PM-9: *Research Team Training Requirements for IRB Modifications*

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ICH GCP

- E6(R2) Good Clinical Practice:
  - 2.8: *Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).*
  - 4.2.4: *The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial related duties and functions.*

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CCR SOP PM-9: Updates

- Updated SOP wording to "modification" from "amendment" to be consistent with regulatory terminology
- For major modifications, require a meeting and the use of the Modification Training Tool

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SOP PM-9 – Timeframe for Training

- Major modifications require a discussion (in person, virtual, hybrid) with team members and must be completed within 5 business days to ensure changes are promptly implemented.
  - If the discussion cannot take place within 5 business days, email outlining the changes and the approved modification documents should be sent and the meeting to discuss the modifications scheduled as soon as possible.
- Minor mods must have training within 10 business days.

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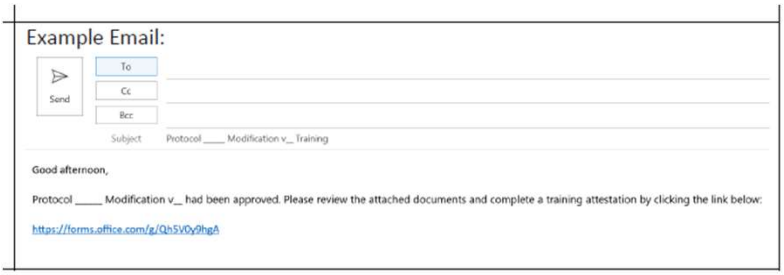
Tracking and Training Documentation . . .

- All training will be tracked and documented using the Microsoft Forms
  - Link to Microsoft Form will be emailed (with modification documents) by coordinator/designee to all team members
  - Even for attendees at meetings – they attest to understanding modification
  - Allow for consistency among teams



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. . .Tracking and Training Documentation

- Spreadsheet listing staff that completed Microsoft Form verification can be downloaded and saved in the regulatory file.
  - No longer need to track read receipt emails, etc.

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Microsoft Forms Demonstration

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QUESTIONS

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