

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

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.

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

Example Email:

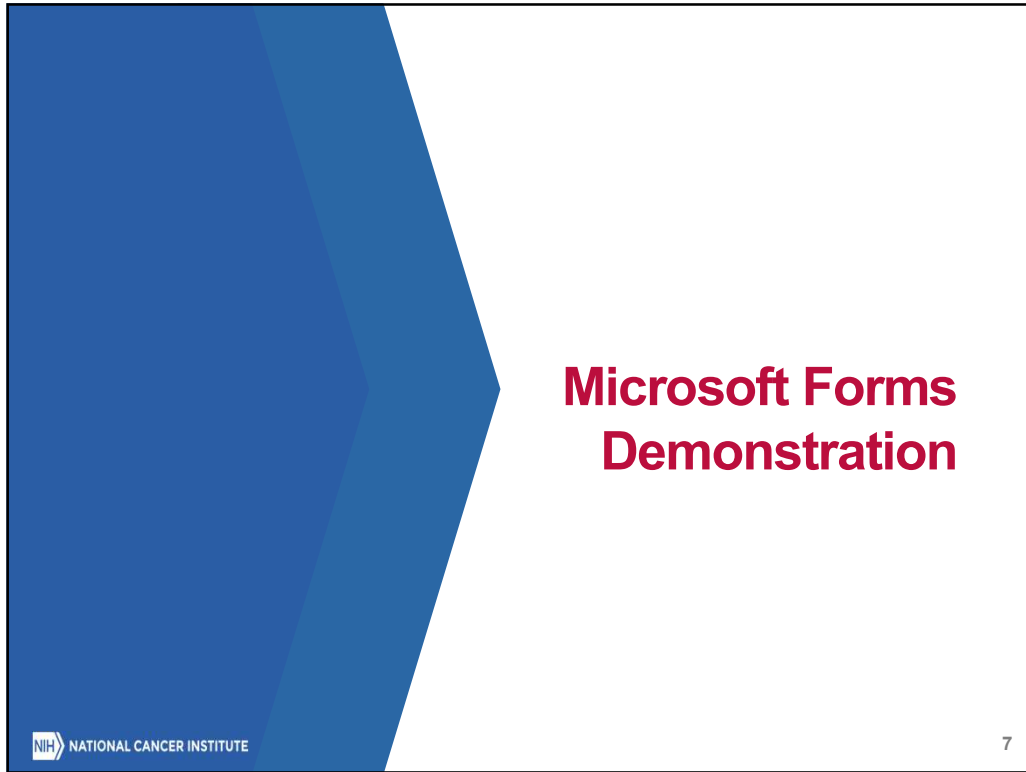
The screenshot shows an email client interface. On the left is a 'Send' button. To its right are three input fields labeled 'To', 'Cc', and 'Bcc'. Below these is a 'Subject' field containing the text 'Protocol ____ Modification v_ Training'. The email body starts with 'Good afternoon,' followed by a paragraph: 'Protocol ____ Modification v_ had been approved. Please review the attached documents and complete a training attestation by clicking the link below:' and a blue hyperlink: <https://forms.office.com/g/Q6SV0y9hg8>.

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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

NIH NATIONAL CANCER INSTITUTE

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This slide features a white background with a large blue arrow pointing to the right. The text 'Microsoft Forms Demonstration' is centered in a bold, dark red font. In the bottom left corner, the NIH logo and 'NATIONAL CANCER INSTITUTE' are displayed. A small number '7' is in the bottom right corner.

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QUESTIONS

DEPARTMENT OF HEALTH & HUMAN SERVICES
NIH NATIONAL CANCER INSTITUTE

www.cancer.gov www.cancer.gov/espanol

This slide has a solid blue background with a large white arrow pointing to the right. The word 'QUESTIONS' is centered in a large, white, sans-serif font. Below it are the logos for the Department of Health & Human Services and the National Cancer Institute. At the bottom, two website URLs are provided: 'www.cancer.gov' and 'www.cancer.gov/espanol'.

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