SOP#: PM-9	**Research Team Training Requirements for IRB Modifications**
Version #: 3.2	**Next Review Date: 03/2026**
Approved Date: 07/2024	**Review Interval Period: Biennial**
NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.07.15 10:31:02 -04'00'

POLICY

NIH IRB considers any change made after initial protocol approval a modification. The PI is responsible for ensuring that all NIH staff and contractors that are involved in research activities are trained on the updates when a modification is approved by the IRB. This training can be done via a meeting and/or email notification, depending on what changes were made during the modification and how the modification impacts the staff/contractors role based on their responsibilities on the study. This training must be documented and maintained in the protocol's Investigator Site File [(ISF) or regulatory file]. NIH staff/contractors include key research team members such as Clinical Research Coordinators, associate investigators, data managers and others (e.g., Patient Care Coordinators, and Clinical Center pharmacy and nursing staff).

IMPORTANT: The study sponsor may want all research team members on the Delegation log to receive modification training, not just research team members impacted by the modification. For example, OSRO requires training records for all research team members on the FDA Form 1572 and the Clinical Site Delegation of Authority Log.

For this CCR SOP only, there are two types of modifications, both require documentation of training:

1. Major: A major modification typically needs discussion about the impact of the changes and if actions are required, who will be responsible for those and in what timeframe (e.g., who will reconsent participants and by when). Major modifications may include changes to:
    - Eligibility
    - Study design
    - Drug administration
    - Dose modifications
    - Study procedures
    - Study-related risk including an updated Investigator Brochure (IB) or package insert that results in a modification to the protocol and/or consent
    - Informed consent document and/or requirement for reconsent/notification (e.g., this may include verbal notification or written letter sent to participants and documentation regarding new information without requirement for signed reconsent)
    - Update to Principal Investigator

2. Minor: a minor modification is usually editorial and/or administrative in nature and does not substantially change the protocol or informed consent document or require notification of previously enrolled participants.

   For example:

   - Protocol and/or consent template updates
   - Updates on the study population descriptions
   - Updates on full study title
   - Updates to recruitment materials
   - Timeline to complete baseline evaluations is changed
   - Additional details are added to the informed consent process, including the use of telephone consent or iMedConsent
   - Addition of interim analyses

Note: If the modification includes both major and minor changes, it will be considered a major modification.

CCR implementation expectation is that modification training should occur within five (5) business days for major modification and ten (10) business days for minor modifications of IRB approval to ensure changes are instituted promptly.

If the study is in data analysis only and the modification does not impact previously enrolled participants, training is not required. Also, study modification training is not required prior to the Site Initiation Visit or Study Start Up meeting, as the meeting will discuss the current version of the protocol, consent, and related documents.

IMPORTANT: Any staff added to the protocol must have documented training on the entire protocol, consent and related protocol documents. Please see CCR SOP PM-5: *Research Protocol Training Requirements.*

PURPOSE

To provide guidance to PIs and research teams related to appropriate protocol modification training and appropriate documentation using Microsoft Forms to track training completion.

Please note that some PROTECT modifications do not change the protocol itself or the consent document. These types of changes do not require documentation of modification training; however, it is best practice to communicate changes to relevant research team members. For example:

- Changes to research team (except change in PI)
- Translated consent document without any change to English approved consent document content
- Updated IB without new risk requiring modification to protocol and/or consent

RESOURCES

- FDA Guidance Document: Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects
- FDA: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry
- Office of Intramural Research Policies website
  - 300 – Investigator Responsibilities
- CCR SOP website
  - PM-5: *Research Protocol Training Requirements*

PROCEDURES

MAJOR MODIFICATION

Due to the nature of major modifications, ideally a meeting should take place which allows discussion among the research team. The meeting can take place virtually, in person or in hybrid format. If a team member is unable to attend a meeting, they are responsible for reviewing the modification documents and discussing questions with the PI. (See #4 below) In addition, the Modification Training Tool must be used to ensure all changes and action items are covered. Please see the tool and instructions located below this SOP on the CCR SOP website.

1. Protocol Support Office (PSO) Manager will forward all appropriate documents related to modification approval to PI and clinical research coordinator (CRC).
2. The PI or CRC is responsible for disseminating the modification information. This can be done by forwarding the PSO Manager email to the research team and adding the following information: “Please see attached for modification approval documents and we will be discussing at meeting on xx/xx/xxxx”
3. The PI or CRC will prepare for meeting by starting to complete the Modification Training Tool as much as possible. The Tool may be finalized during the meeting.
4. After meeting, CRC will send an email to all required research team members (those at the meeting and those who could not attend the meeting) and include: final Modification Training tool, cover memo, modified protocol and consent as applicable. This email will include a link to a Microsoft Form for research team members to confirm completion of training. Please see *Guidelines for Using Microsoft Forms for Modification Training Documentation* attached below this SOP.

MINOR MODIFICATIONS

For minor modifications, the PI may consider using email notification (with documentation per #2 below) in lieu of a meeting. The Modification Training Tool is optional.

1. PSO Manager will forward all appropriate documents related to modification approval to PI and CRC.

2. The PI or CRC is responsible for disseminating the modification information. This can be done by forwarding the PSO Manager email to the research team. This email will include a link to a Microsoft Form for research team member to confirm completion of training. Please see *Guidelines for Using Microsoft Forms for Modification Training Documentation* attached below this SOP.

FINAL STEP – FOR BOTH TYPES OF MODIFICATIONS

1. Send original training email with attachments (include Modification Training Tool if used) and Microsoft Forms spreadsheet with completion details (see *Guidelines for Using Microsoft Forms for Modification Training Documentation* for downloading and locking spreadsheet) to PSO Manager.
2. PSO Manager will save in protocol's ISF.