

SOP#: PM-9

Research Team Amendment Training

Version #: 1.0

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NCI Clinical Director Signature:


William Dahut, MD 1/14/2021

POLICY

The PI is responsible for ensuring that all appropriate staff are trained/notified about all protocol amendments. This training/notification must be documented and maintained in the protocol's regulatory file. Appropriate staff can include key research team members such as research nurses, associate investigators and others (e.g., data managers, Patient Care Coordinators, and Clinical Center staff). Amendment training/notification should occur within five business days of IRB approval to ensure changes are instituted promptly.

For this SOP, when referring to "amendment," this includes any changes to the informed consent/assent document, even if the protocol itself was not amended. It also includes notification of changes to participants with or without an informed consent/assent document change (e.g., verbal script or written letter to participants to notify of changes without requiring signed re consent).

PURPOSE

To provide guidance to PIs and research teams related to appropriate protocol amendment training/notification and documentation.

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

PROCEDURES FOR TEAM AMENDMENT TRAINING/DOCUMENTATION

There are a variety of processes that may be used to communicate amendment changes. These include:

- In person discussion (individually or in a team meeting)
- Email notification

OPTION 1: IN-PERSON DISCUSSION

For major amendments, the PI should consider an in-person discussion. A major amendment 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 reconstent participants and by when). Major amendments may include changes to:

- Eligibility
- Study design
- Drug administration
- Dose modifications
- Study procedures
- Study-related risk
- Informed consent document and/or requirement for reconstent/notification (e.g., this may include verbal notification or written letter sent to participants regarding new information without requirement for signed reconstent)

Documentation of the in-person discussion may be managed one of several ways:

- Use team meeting minutes – must include what was discussed, who attended and if actions are required, who is responsible for which action and in what timeframe.
- Use Amendment Training Tool – see Appendix A for tool and instructions

In order to clearly document who was trained, you can use the Amendment Training Record – see Appendix B. The training document should be sent to the PSO Manager for saving in the regulatory file.

OPTION 2: EMAIL NOTIFICATION

For minor amendments, the PI may consider using email notification. Minor amendments are usually editorial and/or administrative in nature and do not change the informed consent document or require notification of previously enrolled participants.

For example:

- Protocol template updates
- Updates on the study population descriptions
- Updates on full study title
- Updates on IB for safety and efficacy data (no change in consent)
- Timeline to complete baseline evaluations is updated as 14 days from 5 days
- Additional details are added to the informed consent process, including the use of telephone consent
- Changes to the Study Personnel Page (SPP), if Key Study Personnel are included on the protocol document (e.g., some CTEP studies)
- Add interim analyses

The PI is responsible for ensuring that correct information is provided to the team but the sending of the email can be delegated to an appropriate team member.

- If sending an email, it must contain a summary of information in the amendment. This email should be sent to the PSO Manager for saving in the regulatory file.
 - The person sending the email must select “Request a Read Receipt” under the “Options” tab in the new email. This will allow the sender will get an email when the recipient reads the email.
 - These “Read Receipt” return emails are sent to the PSO Manager for saving in the regulatory file.
 - Consider using the Amendment Training Record to track who has read the email – see Appendix B.

APPENDIX A

AMENDMENT TRAINING TOOL

Principal Investigator	
Protocol Title	
Protocol #	
Protocol Version Date	
Consent Version Date	

PROTOCOL CHANGES

N/A; no protocol document changes.

Section	Study Changes	Action Needed / Responsible Person	Target Date of Completion
Objectives			
Eligibility			
Screening			
Baseline			
Study Design			
Drug Administration			
Procedures			
Study calendar/new procedures			
Toxicities/new risk			
Questionnaires			
Safety/non research labs			
Research Labs			

This section follows the protocol template language as it includes; objectives, eligibility, screening, baseline, study design, drug administration, questionnaires, and correlatives. Specific protocol layouts will vary as indicated. Use section titles applicable for the protocol, bulleted list of changes, action needed, and a date completed to track the applicability and/or completion of each task. Protocol

amendment action needed can include any number of changes including ordering new lab supplies, updating lab contacts, CRIS order set updates, and may require updated training to clinic, nursing, and day hospital staff. If no changes or action is needed, use “N/A.”

CONSENT CHANGES

N/A; no consent/assent document changes or notification requirement.

Action Needed	Responsible Person	Target Date of Completion
Summary of consent changes		
Re-consent current patients		
Inform current pts of changes and document in CRIS – Verbal notification		
Inform current pts of changes and document in CRIS – Written notification (e.g., send letter)		

This section tracks the action items around the changes to the consent. If no action is needed, use “N/A.”

OTHER ACTIONS – IF APPLICABLE

Action	Responsible Person	Target Date of Completion
Review recruitment website to ensure accuracy		
Assess need to update CRIS order sets		
Assess need for additional supplies		
Assess database (e.g. C3D, RAVE) for any required changes		
Other		

Each protocol has its own nuances and may have aspects that require review/updates. List the updated changes and track the completion of the action items. Amendment changes may require updates to study specific forms, require updated lab contacts, new lab supplies, sample processing changes, and patient education. If no action is needed, use “N/A.”

APPENDIX B

**NIH Center for Cancer Research
PROTOCOL AMENDMENT TRAINING RECORD**

PI:

Protocol #:

Protocol Title:

Amendment Version Date / Informed Consent Version Date:

Date of Training / Email Read Receipt (mm/dd/yy)	Name of the Trainee	Role in Study	Trained by (include PI and/or designee)	Comments