|  |
| --- |
| **Study Stage:** Start-up - Termination |



**Purpose:** When conducting a clinical trial, it is the Investigator’s responsibility to ensure each member of the study team is trained on the protocol as it applies to their job function. This template can be used to keep track of protocol training.

**Useful to:** Investigators, Project Managers, Study Coordinators, and Monitors

**Instructions:**

* The log (s) should be completed during the start-up stage of the study, prior to study initiation, and for protocol amendments.
* Each column of the log should be filled out as completely as possible.
* A legible printed name is required in addition to the signature (electronic or written) of each participant.
* Columns such as the study role may be completed in advance by the study coordinator or PI.
* Whenever a new study team member is added, protocol training for the new member should be added to this document.
* Whenever a protocol amendment that is more than an administrative change to the protocol or a procedure is made and approved by the IRB, training of all study staff to this new protocol should be documented. Instead of using this log for amendment training you could utilize an email to the study team similar to the Cancer Center CTSU language. See the suggested language in the template area.

**Best Practice Recommendation:**

* If the study sponsor provides a protocol training log the study team should use it.
* The log is recommended for all studies (including investigator-initiated studies that are non-FDA regulated).
* File in an appropriate location to be easily accessible for monitoring visits, internal auditing and in order to have complete study records.

**Template History:**

**Reference(s):**

ICH GCP 4.2.4 (R2)

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

FDA 21CFR312.30: Protocol amendments

[CFR - Code of Federal Regulations Title 21 (fda.gov)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.30)

**Protocol Training: O-CTSU**

<https://myoctsu.med.umich.edu/SPGs/600/617%20Amendment%20Approval%20Notification.pdf>

**Last updated:** 6/07/2022

**Version:** 2.3

|  |  |
| --- | --- |
| **Study Name:** | **IRB HUM #** |
| **Principal Investigator:** |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Printed Name and Signature** | **Study Role** | **Date Trained** | **Method** | **Protocol Version** | **Topics (see key)** |
|  |  |  |  |  |  |
|  |  |
|  |  |  |  |  |  |
|  |  |
|  |  |  |  |  |  |
|  |  |

**Topics (Examples):**

1: Protocol overview 4: Scheduled visits and windows 7: Screening, Examination, and End of Study Visits

2: Inclusion/exclusion Criteria 5: AE/SAE/UAPand UA reporting 8: Study Objectives

3: Database Entry Training 6: Protocol deviations and reporting 9: Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

By signing below, I affirm that each staff member verifies that s/he has had the opportunity to review the relevant study materials and that s/he agrees to conduct the study in accordance with the current protocol

PI signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Protocol Training Email Template for an Amendment:**

Once The IRB has approved an amendment notify the study team of the approval (do this as soon as possible after the amendment is IRB approved).

Notification can consist of correspondence that contains the following information:

* Protocol and Amendment #
* A Summary of Changes
* Tracked changes version of the protocol
* Tracked changes of the informed consent, if applicable
* Information on Re-consenting, if applicable
* Suggested language: **This Email notification will serve as documentation of Protocol training for the attached amendment.** Please review the attached information and contact (add necessary study team members) with any questions.