

# Tool Summary Sheet

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| **Tool:** | Training Log  |
| **Purpose:** | To record all training completed by site study staff members that is not otherwise documented by a training completion certificate.  |
| **Audience/User:** | Study Coordinators, Principal Investigators (PIs), other site staff, clinical monitor |
| **Details:** | This tracking log should provide a comprehensive list of all training completed by site study staff that is not documented by other written means, such as a completion certificate. It is required for both observational and interventional clinical research studies. This log is designed to be study specific and site-specific. |
| **Best Practice Recommendations:** | * Record training in the log as it is completed, to ensure completeness and accuracy of the data.
* Ensure wet ink signatures recorded on training log are attributable, legible, and contemporaneous.
* Ensure electronic signatures meet applicable requirements (e.g. FDA 21 CFR Part 11).
* This log need not include training that is documented by a completion certificate or other written documentation.
* The site study staff member listed on each line should sign to verify that the training has been completed.
* This log should be reviewed regularly by the Principal Investigator and/or clinical monitor
* Indicate the method training was delivered. If training was guided by study staff member, indicate name of person providing training.
* Record title of training completed and/or study documents reviewed under ‘Training Topic.’
* Add grant information such as number, institution, and PI if applicable
* Number each page and maintain this log in the Essential Documents Binder, behind the ‘Clinical Research and Study Training’ tab. (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File (ISF), and Study File.)
* Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
* At the conclusion of the study, identify the final page of the log by checking the box in the footer.
* Remove this Tool Summary Sheet before use of the log.
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## Tool Revision History:

| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| --- | --- | --- |
| **1.0** | **05Feb2010** | **First approved version** |
| **2.0** | **02Mar2010** | **Removed automatic page numbering** |
| **3.0** | **04Jan2012** | **Added Tool Summary Sheet; no revisions to the log** |
| **4.0** | **14Mar2012** | **Updated Tool Summary Sheet; Clarified ‘Printed Name’ in log** |
| **5.0** | **27Aug2021** | **Annual review; Updated Tool Summary Sheet; added ‘Training Method’ and changed ‘Title of Training’ to ‘Training Topic’** |

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| **Site Investigator Name:**  | **Protocol Number:**  | **Site Name:**  |

# Training Log

| **Printed Name** | **Signature** | **Training method (Self/Guided)** | **Training Topic** | **Date of Training** |
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Check if final page of log: ☐