Logs

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The Training Log is a record of training provided, e.g. protocol training or other study-specific training of staff. This should include a site initiation visit (SIV) attendance log.

Screening / Enrollment / Withdrawal Log: Captures subjects who have been screened to determine initial eligibility for enrollment, and all subjects who sign a consent form. Review the IRB Recruitment Guidelines for additional information

Subject Visit Tracking Log: Tracks all enrolled subjects' visits, reason for early termination and keeps visits scheduled as per protocol. If a subject is found to be ineligible, withdraws consent, or is lost to follow-up, s/he is still counted as enrolled and should be included when reporting enrollment numbers to the IRB.

Staff Signature/Delegation of Responsibility Log: Documents the study-related procedures delegated to staff. The PI should initial, sign and date this list, and update it as new staff or study procedures are added to the protocol.

Monitoring Log: Documents any form of study oversight/monitoring as defined in the IRB approved protocol summary.The monitor and designated site staff both sign the log to verify the date the monitor was present. For consecutive days, enter each day separately.

Adverse Event (AE/SAE) Tracking Log: Tracks and ensures timely reporting of all applicable adverse events to the IRB. Includes correspondence, copies and acknowledgements of reports for internal SAEs reported to the IRB and Sponsor and FDA as applicable. Use the AE/SAE log for each subject enrolled in studies that involve drug intervention. UCLA adverse event guidance can be found here.

Minor Deviations/ Violations Tracking: Includes a record of all minor deviations from the approved protocol and facilitates reporting at continuing review per IRB Protocol Deviation/Exception/Violation Guidance.

Tissue Log: Tracks tissue samples collected during research and subjects' tissue consent options. Describes the requirements for sharing and/or transferring tissue samples from tissue repository banks.

Tips / Additional Information

Logs should be updated as soon as possible after a recordable event occurs, preferably on the same day.

Templates can be customized to fit a specific study or added to existing electronic versions currently maintained on site.

Applicable GCP sections:

- 8.3.20 – 8.3.25

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