Chicken Soup
for the Busy Coordinator

NHG Health

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Managing Clinical Research Coordinator (CRC) Transitions Effectively for Study Continuity

CRCs play a pivotal role in keeping research activities on track - from visit scheduling to data accuracy. But what happens when a coordinator leaves abruptly, and handover is incomplete?

Principal Investigator (PI) Dr Bright

Midway through a longitudinal research study on sleep habits, CRC Ms. Caring resigned in short notice **without performing a handover.** **Key source data and documents** stored in her personal corporate OneDrive were **lost** as her account was deleted. Few months later, the study led by PI, Dr Bright was unexpectedly selected for Audit. The audit findings revealed several major compliance issues.

PI Oversight

What went wrong: Lapse in PI oversight

- Delayed awareness of missing data and documentation.

What should be done: Reinforce PI oversight and communication

- PI to review study delegation logs and essential records during transition.
- Notify sponsor (if applicable) promptly of personnel changes affecting study conduct.

Handover

What went wrong: No structured handover, undocumented outstanding tasks

What should be done: Ensure proper handover

- Use a handover checklist documenting: ongoing participant statuses, data entry progress, ethical/IRB approval timelines (if applicable) and file locations.
- Conduct a meeting (PI + outgoing + incoming coordinator) to review pending items.
- Archive handover notes in the Investigator File.

Data Management

What went wrong: Poor data management

- Essential records stored in personal OneDrive.

What should be done: Strengthen data and file management

- Essential records should not be stored in personal OneDrive.
- Store research essential records in corporate approved secure data storage facilities managed by Synapxe, Storage Area Network (SAN), SharePoint or equivalent and institution endorsed systems.
- Manage access granted to all relevant authorized and delegated study team members.
- Apply data retention and backup measures per sponsor and institutional policy.

Delegation & Training

What went wrong: Gaps in study responsibilities delegation and training

- No documentation of study responsibilities delegation reassignment or training for incoming staff.

What should be done: Maintain up-to-date delegation and training compliance

- Ensure duties reflect actual responsibilities in delegation logs (PCR 509-002 Study Responsibility or Delegation Log).
- Complete required minimum trainings based on study type (e.g., CITI, GCP, HBR, protocol, study specific trainings etc.) and file certificates of new team members before task initiation.
- Maintain training logs, dated and signed.

Staff transitions are inevitable but proper documentation, training, and active PI oversight can ensure studies continue smoothly and safely.

References: PCR SOP 501-A02 Responsibilities of the Research Team
PCR SOP 501-B08 Data Collection and Handling
509-002 Study Responsibility or Delegation Log
NHG Health Investigator's Manual Chapter 3: The Study Team

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