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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

X 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

X 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

X 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

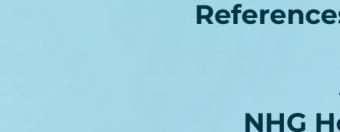
X What went wrong: Gaps in study responsibilities delegation and training

- 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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*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/ guidelines relating to the above scenarios/case study.