Key Updates to Proper Conduct of Research (PCR) SOP

Summary of Changes

Version: 20 Apr 2026

PCR SOP with Key Updates

Doc No.	Doc Name	Type of Changes	Effective date
501-B08	Data Collection and Handling	Major, minor, administrative	2 Jun 2026

Note:

1. *Researchers should read the full details of PCR SOPs and ICH GCP (R3) for better understanding of the changes.*
2. *These changes to the PCR SOP are mainly based on the updated guidance from ICH GCP (R3). The requirements of PCR SOPs apply to all research, including clinical trials and HBR. If a PCR SOP update is specific to clinical trials, it will be clearly stated.*

Key Updates

PCR Section	Summary of Changes	Note
 5.3	**1 Data capture & risk-based verification** a) Data must include relevant metadata. b) Extent and need of data verification depends on data criticality, not "one-size-fits-all". c) PI and/or sponsor determine what data is critical.	**Reference:** ICH GCP E6 (R3) section 4.2.1 Data Capture • Metadata is information about data – it describes, tracks, or manages the primary research data. • Study teams should pre-identify critical data elements, tailor the data verification and document rationale accordingly.
 7.1f	**2 Metadata & audit trail requirements** a) Requirement to record, maintain and review metadata (e.g. audit trail) associated with high-criticality data. b) Examples of metadata include (not exhaustive): ✓ Logs of user account creation, user roles and access ✓ Data changes (what, when, who, why) ✓ Workflow actions (status changes, routing of work) ✓ Document version control ✓ Lab reference ranges and timestamps ✓ Dates of data review, lock, and analysis	**Reference:** ICH GCP E6 (R3) section 4.2.2 Relevant Metadata, Including Audit Trails • Besides raw/study data, study teams should also ensure systems/individuals can generate/capture the metadata elements.
 7.4	**3 Data review and correction** a) Requirement for planned, risk-based review (based on study design) and correction of data and metadata. b) Data corrections must be attributed to the person or system making the change, justified and supported by source records around the time of original entry, and completed promptly.	**Reference:** ICH GCP E6 (R3) section 4.2.3 Review of Data and Metadata and section 4.2.4 Data Corrections • There should be continuous oversight rather than end-of-study checks. • Record data review activities and ensure corrections are traceable to individuals or systems.

Key Updates

PCR Section	Summary of Changes	Note
7.4.1	**4 Timely access & review by the PI** Requirement that the PI must have timely access to study data (including external data sources) and be responsible for its review.	**Reference:** ICH GCP E6 (R3) section 2.12.3 • Reinforces PI accountability and oversight. • Ensures early detection of issues affecting eligibility, treatment, or safety. • PI should ensure access to all relevant data streams (e.g. central lab, imaging, ePRO), unless restricted by protocol (e.g. blinding).
7.5	**5 Data finalisation prior to analysis** a) Establish reasonable processes for data management activities including capture, verification, validation, review and error correction to ensure sufficient data quality. b) Maintain documentation for key activities such as data reconciliation, error rectification, handling missing data, data extraction and analysis set determination.	**Reference:** ICH GCP E6 (R3) section 4.2.6 Finalisation of Data Sets Prior to Analysis • The extent and rigour of these processes should be proportionate to the study's risk level - higher risk studies require more comprehensive data management procedures and documentation.
8	**6 Data transfer, exchange & migration** a) Establish processes to maintain data integrity and confidentiality during transfer and sharing activities, including protection of research data and metadata. b) Document all data exchanges and transfers for traceability, and implement reconciliation procedures to prevent data loss or unintended modifications.	**Reference:** ICH GCP E6 (R3) section 4.2.5 Data Transfer, Exchange and Migration • Any transfer (e.g. between systems, collaborators, vendors) should be documented. • After transfer, data should be reconciled to prevent loss or alteration.

Key Updates

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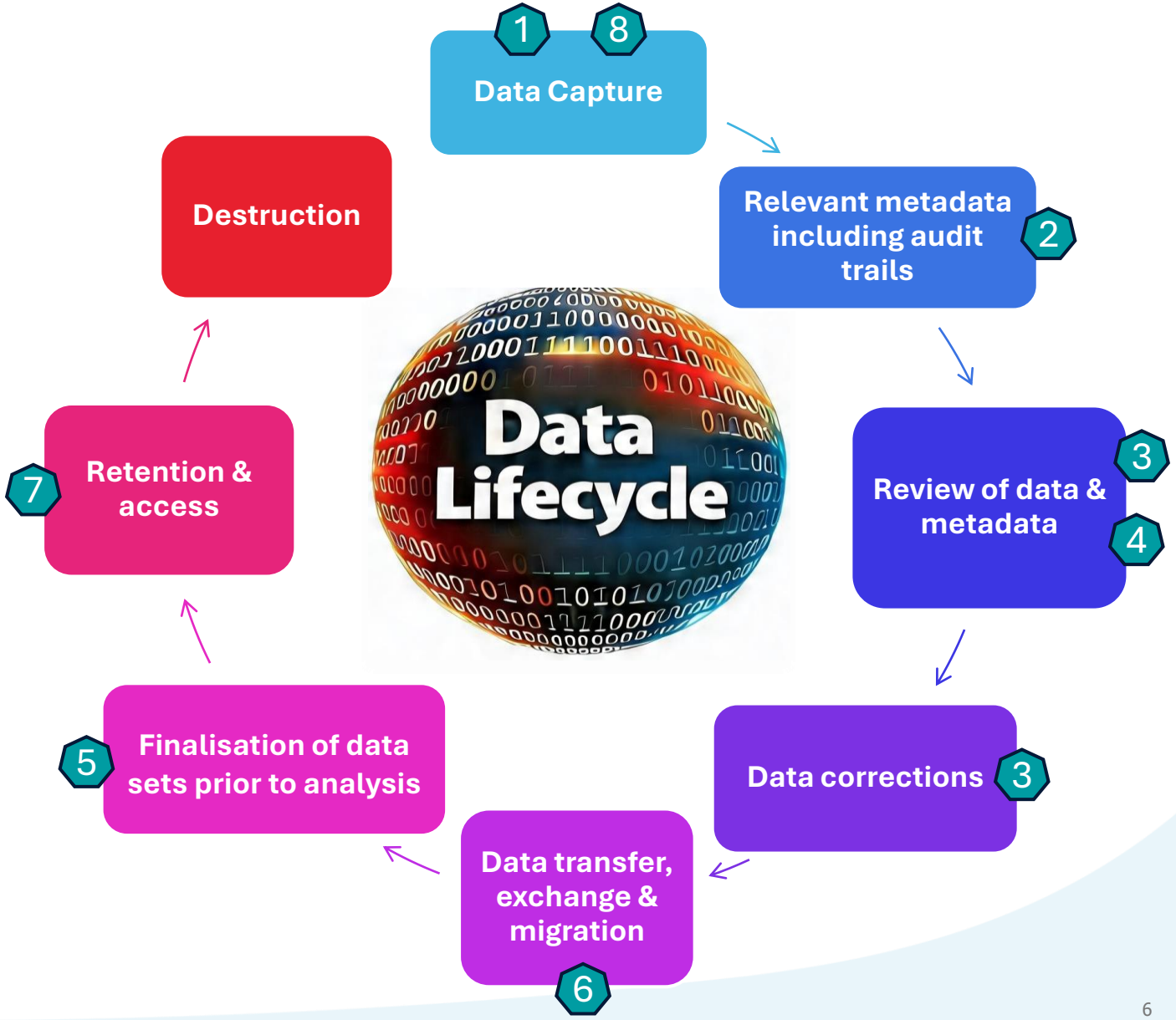
9.3	7 **Data retention & archiving** Research data and relevant metadata should be archived in a way that ensures retrieval, **readability** and protection from unauthorised access or alterations throughout the retention period.	**Reference:** ICH GCP E6 (R3) 4.2.7 Retention and Access • Readability refers to the ability to access, open, and interpret archived data in a meaningful way over time.
11	8 **Computerised systems** New section added to SOP for HSA regulated studies a) Requires documented procedures for computerised systems used in clinical trials b) Procedures must ensure appropriate use of systems for essential data collection, handling and management c) References ICH GCP E6 (R3) section 4 for detailed data governance requirements	**Reference:** ICH GCP E6 (R3) section 4.3 Computerised Systems, 4.3.1 Procedures for the Use of Computerised Systems and section 4 Data Governance • Computerised systems could be used for various purposes e.g. e-Consent, e-CRF, e-PRO (patient reported outcome).

Key Takeaways:

- Data governance must be clearly stated and documented, not left to interpretation.
- Identify critical data elements that impact subject safety, data integrity, & study conclusions to determine appropriate data governance measures.
- Metadata (including audit trails) should be maintained with the study data.
- Risk-based thinking should be embedded throughout the data lifecycle (e.g. data capture, review, finalisation) with reasonable processes proportionate to the study's risk level.

PCR SOP Changes Across the Data Lifecycle

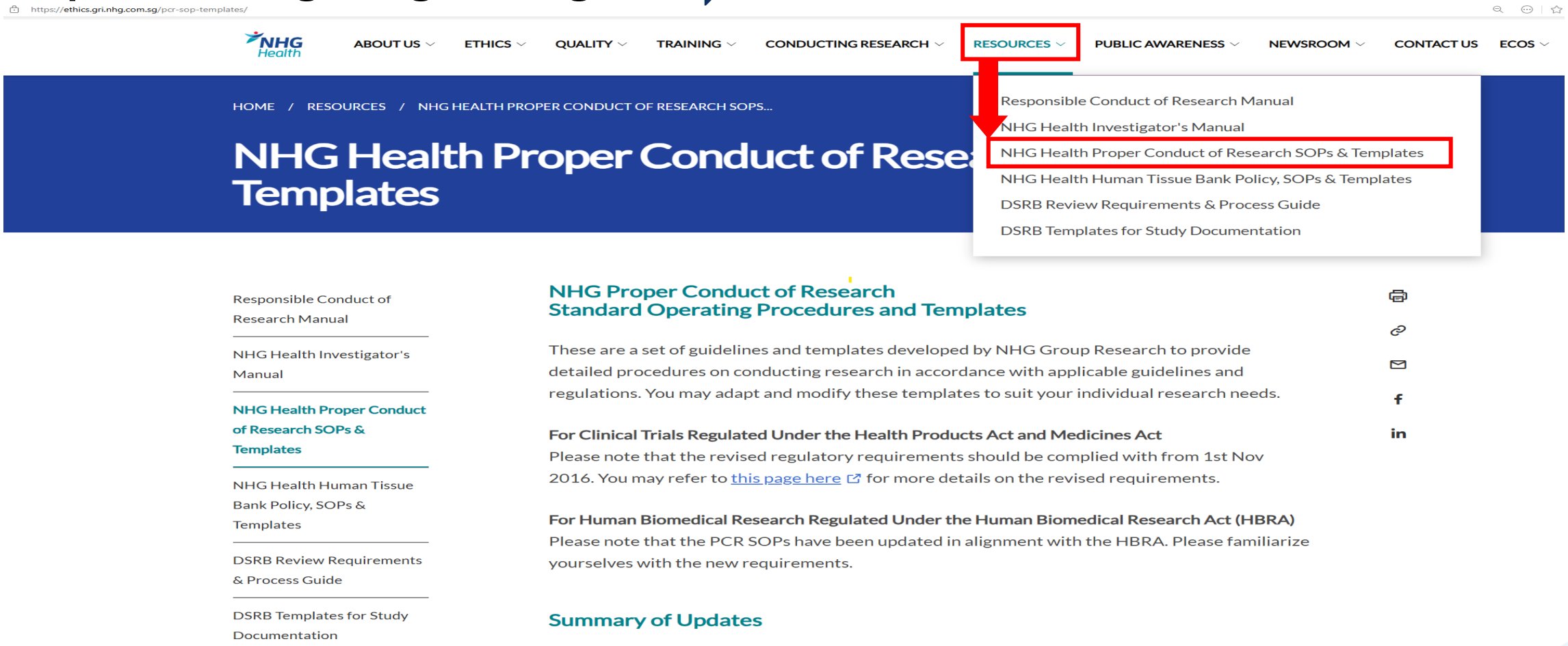
Major Changes
1 Data capture & risk-based verification
2 Metadata & audit trail requirements
3 Data review and correction
4 Timely access and review by the PI
5 Data finalisation prior to analysis
6 Data transfer, exchange & migration
7 Data retention & archiving
8 Computerised systems



Access to PCR SOPs and Templates

NHG Intranet access only

https://ethics.gri.nhg.com.sg/ → **Resources**



If you are not from NHG Health, please contact your Institution Research Office for a copy of PCR document.