Key Updates to Proper Conduct of Research (PCR) SOP

Summary of Changes

Version: 06 Nov 2025

List of SOPs with Key Updates

S/N	Doc No.	Doc Name	Type of Changes	Effective date
1	501-B02	Pre-study activities	major, minor, administrative	1 Dec 2025
2	501-B05	Documentation		1 Dec 2025
3	501-B06	IP accountability		1 Dec 2025
4	501-B07	Study conduct—monitoring		1 Dec 2025
5	501-B09	Study completion activities		1 Dec 2025
6	501-B10	Handling audits/inspections		1 Dec 2025
7	501-C04	Biological specimen collection and handling	minor, administrative	1 Dec 2025

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 SOPs 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

SOP No.	PCR Section	Summary of Changes	Note
501-B02 501-B07	Definitions	Clarified that "**clinical trials"** regulated by Health Science Authority (HSA) under Health Product / Medicines Act are <u>interventional</u> investigations, which are distinct from "**observational trials"** which fall under Human Biomedical Research Act (HBRA) purview.	**Reference:** ICH GCP E6 (R3) Glossary Definition of "**clinical trials**" and "**observation trials**": https://www.hsa.gov.sg/clinical-trials/overview Researchers must be familiar with different study types to determine which local regulations apply.
501-B05 501-B10		**<u>Data Management</u>** • Added the defintions of "Metadata", "Audit Trail", "Data integrity", "Data Aquisition Tool". • Metadata is the contextual information required to understand a given data element. • Audit Trail is a complete record that tracks who made data entries or changes, when they did it, and why. • Data integrity includes the degree to which data fulfil key criteria of being **attributable, legible, contemporaneous, original, accurate, complete, secure** and **reliable** such that data are fit for purpose. • Data aquisition tool is a paper or electronic tool designed to collect data and associated metadata in a research study, such as Case Report Forms (CRFs), patient diaries, wearable devices, and patient-reported outcome questionnaires.	**Reference:** ICH GCP E6 (R3) Glossary E.g. Patient's blood pressure is 120/80 mmHg, the metadata is who measured it, when, and what device was used etc. Audit trails are part of metadata because they provide the context of what changes were made to data and by whom. Audit trails ensure data integrity and prove data reliability for regulatory compliance. This applies to both paper and electronic records.

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Key Updates

SOP No.	PCR Section	Summary of Changes	Note
501-B05	Definitions 8.6 10.2 10.4	**Study Documentation Practices** 1) Updated the definition of "**Source Records**", "**Certified Copy**" and "**Case Report Form**". 2) Avoid **unnecessary transcription steps** between the source record and the data acquisition tool to minimise transcription errors. E.g. • **Paper to paper to electronic**: Patient data recorded in medical chart → manually copied to paper CRF → manually entered into electronic system. • **Multiple manual transfers**: Laboratory results printed → manually copied to worksheet → manually entered into database. • **Redundant data entry**: Data entered into hospital system → printed out → re-typed into sponsor's electronic system. 3) Highlighted that data reported in Data Collection Forms / Case Report Forms should be **consistent with source records** and any changes to study records should be **traceable**. 4) Reminder that all study related test results should be reviewed in a **timely manner** by qualified study staff.	**Reference:** ICH GCP E6 (R3) 2.12.2 and 2.12.3 However, the PI should be the one to determine if the transcription steps are necessary or unnecessary. If the additional transcription is justifiable and required in view of study design/operation need, the study team should implement measures to minimise transcription errors, and all relevant documents should be maintained for verification purpose.
501-B06	4 6.1 8.2	**Investigational Product (IP) / Auxiliary Product (AP) Management** 1) The PI/Sponsor may **ship /supply/dispense** the IP/AP to subject's location or a location closer to the subject (e.g. at a local pharmacy or a local healthcare center). 2) The IP/AP may be **administered** at the subject's location by site staff, the subject themselves, a caregiver or a healthcare professional. 3) Clarified that records of IP / AP management should also include unique identification number of product and batch / serial number, and expiry date (if applicable). 4) Added that IP/AP should be maintained per applicable regulatory requirements with safeguards to ensure **product integrity** and **subject safety**.	**Reference:** ICH GCP E6 (R3) section 2.10.8 and 3.13.3

Key Updates

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501-B07	Definitions 3 4 8.1	**<u>Study Monitoring</u>** 1) Highlighted that the aim of study monitoring is to ensure the subjects' rights, **safety** and well-being and the reliability of study results as the study progresses. 2) Clarified that there are different types of study monitoring. • **Investigator site monitoring**: Onsite and/or remote monitoring of a study site (including facility such as local pharmacy and lab etc). • **Centralised monitoring**: An evaluation of accumulated data, performed in a timely manner, by the sponsor's qualified and trained persons. 3) Monitoring activities could include **Source Data Verification (SDV)** and **Source Data Review (SDR)** to ensure data collected are accurate, complete and verifiable from source records. 4) Sponsors should determine the **extent, frequency** and **nature of monitoring** based on **identified risks**. To consider factors such as the objective, purpose, design, complexity, blinding, number of research subjects, investigational product, current knowledge of the safety profile and endpoints of the research. 5) Elaborated on the information to be included in a **study monitoring plan** (e.g. monitoring strategy, responsibilities, monitoring tools to be used, focus on aspects that are critical to quality – subject safety and study end points etc).	**Reference:** ICH GCP E6 (R3) section 3.11.4 • Investigator site monitoring is usually conducted by study monitors assigned by sponsor and includes the review of study documents (e.g. investigator files, source records). • Centralised monitoring is usually done by medical monitor, data scientist/ data manager, biostatistician etc. • **SDR** → Check on study processes and compliance • **SDV** → Check on data accuracy (e.g. compare CRF against original medical records)

Key Updates

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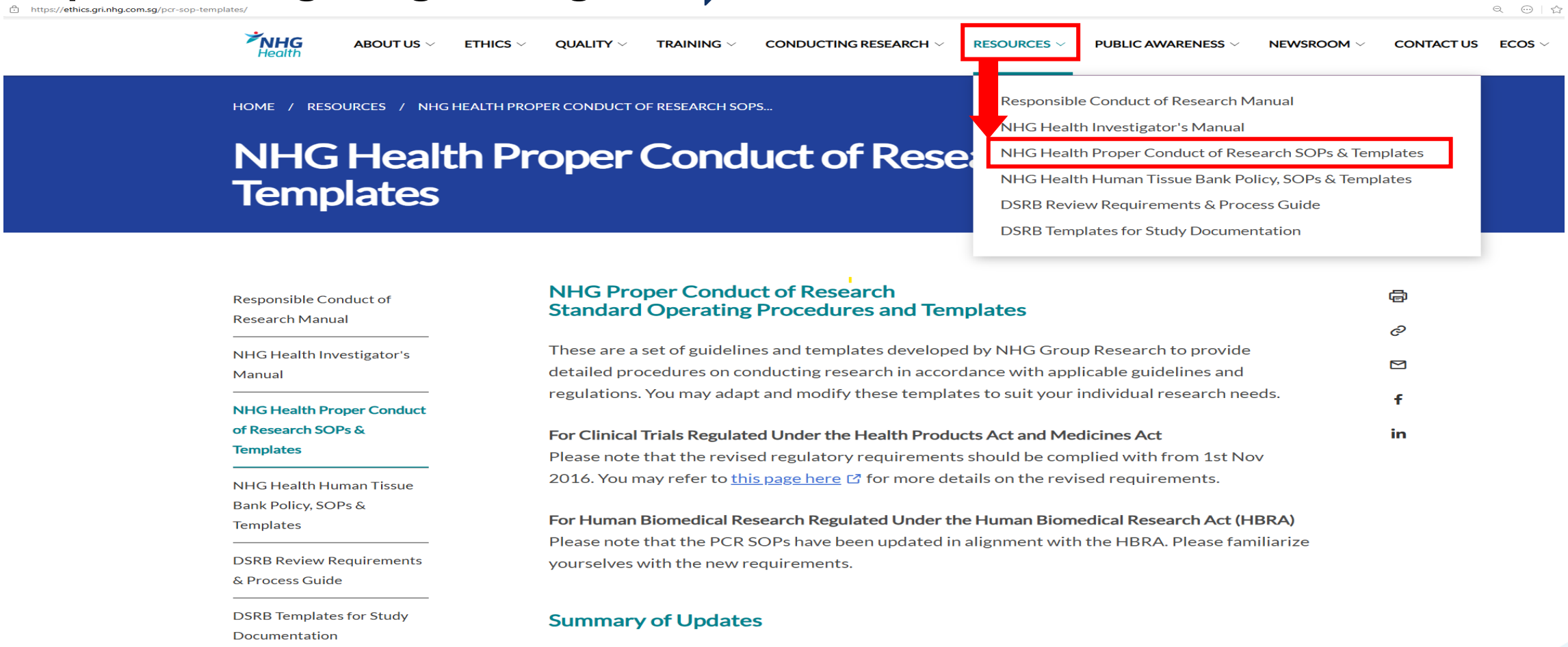
501-B09	7	**Study Archival** After study completion, the study team should take measures to ensure study records remain **available**, **accessible**, and **readable** while preventing unauthorized access and accidental or premature destruction.	**Reference:** ICH GCP E6 (R3) section 2.12.12 Some examples for 'readability': • The passwords to open encrypted/password protected files should be consolidated and archived together upon study completion. • The files should be able to be opened using the saved format/software at any time during the archival period when needed.
501-C04	5 11f	**Biological Specimen Management** Clarified that - 1) Tasks on biological specimen management should be assigned to relevant study team member and documented in the study delegation log. 2) Processes such as collection, chain of custody, processing, analysis and retention or destruction of biological specimens should be documented.	**Reference:** ICH GCP E6 (R3) section 2.7 and Appendix 3 Study teams can design a study-specific **Biological Specimen Log** to track biological specimen management activities. Study team may refer to the NHG PCR SOP 509-009 Biological Specimen Log as an example.

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.