Key Updates to Proper Conduct of Research (PCR) SOP

Summary of Changes

Version: 31 Jul 2025

List of SOPs with Changes

S/N	Doc No.	Doc Name	Type of Changes	Effective Date
1	501-A02	Responsibilities of the Research team	Major, Minor, Administrative	01 Sep 2025
2	501-A03	Training and Education	Minor, Administrative	01 Sep 2025
3	501-B03	Study Initiation		01 Sep 2025
4	501-B04	Interaction with DSRB	Major, Minor, Administrative	01 Sep 2025
5	501-C01	Informed Consent form and process		01 Sep 2025
6	501-C02	Subject recruitment and screening		01 Sep 2025
7	501-C03	Subject management during study		01 Sep 2025
8	501-C05	Unanticipated Problems Involving Risks to Subjects or Others and Expected Serious Adverse Event		01 Sep 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-A02	Definition 3 4.1 4.7	**<u>Oversight of Service Providers</u>** **1) Definition Added:** A new definition for "Service Provider" has been introduced. **2) Responsibilities of the Principal Investigator (PI):** i. Ensure that agreements with service providers clearly outline roles, activities, and responsibilities related to the research. ii. Maintain accountability for the research's conduct, including the quality and integrity of data, even when activities are delegated to service providers. iii. Maintain oversight of service providers (e.g. selection, ensuring adequate training of the persons performing the research activities, provide access to records as required, retention of essential records). The level of oversight should be proportionate to the significance of the data collected and the associated risks to participant safety and data reliability.	**Reference:** ICH GCP E6 (R3) section 2.3.1, Principle 10.2 and Glossary E.g. when PI outsource delivery of IP to a service provider, it should be delivered directly to the subject (not to an unauthorised recipient).
	4.5	Added responsibility for the PI to **implement appropriate measures to prevent recurrence for protocol deviations**, where applicable.	**Reference:** ICH GCP E6 (R3) section 2.5.3 Besides <u>documenting and explaining</u> deviations, the PI should also <u>implement preventive actions</u> to prevent the recurrence.

Key Updates

SOP No.	PCR Section	Summary of Changes	Note
501-A02	4.2 4.4 4.8q	**<u>Computerised Systems</u>** **1) Documented Procedures:** Ensure that there are documented procedures for the appropriate use of computerised systems related to data collection, handling, and management. **2) User Access and Training:** Implement user access controls and provide training to ensure proper usage of these systems. **3) Incident Reporting:** Report any incidents related to the use and operation of computerised systems **4) Data Protection:** Safeguard research data captured using systems deployed by the Investigator/Institution from unauthorized access, disclosure, dissemination, alteration, and from inappropriate destruction or accidental loss.	**Reference:** ICH GCP E6 (R3) section 2.12.9, 2.12.10 and 4.3 The PI is responsible for data management for systems deployed by the investigator/institution that maintain and retain trial data/information. If there is any incident relating to use of computerised system, to report to relevant parties, e.g. sponsor, IRB.
	4.7	Added "**direct access**" for authorized parties to research related records.	**Reference:** ICH GCP E6 (R3) section 2.12.14 The PI should ensure direct access to all requested research related records to relevant parties such as auditors, monitors and inspectors.

Key Updates

SOP No.	PCR Section	Summary of Changes	Note
501-A02	4.8p	Added requirement to keep **maintenance/calibration records** for equipment used in the research.	**Reference:** ICH GCP E6 (R3) section C3.3 The equipment used in the research should be regularly maintained/calibrated to ensure data reliability/accuracy.
	4.9	Added responsibility for the PI to **ensure unblinding information is protected**, e.g., documented roles and responsibilities, procedure to access, implement mitigation strategies to reduce inadvertent unblinding.	**Reference:** ICH GCP E6 (R3) section 4.1.2 and 4.1.3 Roles, responsibilities, and procedures for access to unblinded information should be defined and documented. Unblinded information should only be accessible to intended personnel, such as unblinded sponsor or site staff (e.g. unblinded monitor / pharmacist).
	6g	Added requirement to inform relevant parties **who is responsible to retain the essential records during the archival period,** upon study completion.	**Reference:** ICH GCP E6 (R3) section 2.12.13 It is important to keep track of who is responsible for retaining/retrieving the essential research records during the archival period, as the study may be audited or inspected, requiring the retrieval of study-related documents during the retention period.
501-A02 501-A03	4.2 4	Emphasized that individuals involved in the research should be **qualified by education, training and experience** to perform their respective task (s).	**Reference:** ICH GCP E6 (R3) section 2.2.1 and 2.2.2

Key Updates

SOP No.	PCR Section	Summary of Changes	Note
501-B03	5.5	**Change in Principal Investigator (PI):** 1) When there is a change in the PI, the study team should create a new delegation log that supersedes the previous version. 2) The new PI is responsible for re-assigning delegated tasks to each study team member and endorsing these assignments.	**Reference:** ICH GCP E6 (R3) section 2.3.3 HSA: https://www.hsa.gov.sg/clinical-trials/conducting/principal-investigator
	5.6	**Delegation of Responsibilities:** Delegation may not be required for research activities performed as part of clinical practice, but documentation of departmental involvement and PI authorization is necessary.	Large teams involve in research could include radiologists, nurses, pharmacy technicians etc.
	5.7	**Large Team Involvement:** 1) For large teams involved in research, the PI may delegate a supervisory staff member to the study team. 2) The PI must ensure that the supervisory staff is trained on the study protocol and that the study staff under their supervision are also trained. Training should be documented.	Staff of supervisory position could include head of department, nurse manager or head pharmacist).
	7.4	Prior to study initiation, PI and study team should **define what is considered source record(s), the methods of data capture and their location**. This should be documented and updated when needed.	**Reference:** ICH GCP E6 (R3) section 2.12.2

Key Updates

SOP No.	PCR Section	Summary of Changes	Note
501-C01	Definition	**Definition Updates:** 1) Update to the terms “Impartial witness”, “Informed Consent”, “Assent” and “ Legally Acceptable Representative”. 2) A new definition for “Signature" has been introduced.	**Reference:** ICH GCP E6 (R3) Glossary Informed Consent Form (ICF) can be paper or electronic. A signature may be physical or electronic.
	4.2.1 4.2.2 4.2.3 4.4.2	Added reminders for research staff to refer to the relevant local regulations for the full list of consent elements that need to be included in the ICF.	▪ **For Clinical Trials regulated by HSA:** Refer to ICH GCP section ICH GCP E6 (R3) section 2.8.10. ▪ **For HBRA regulated research studies:** Refer to HBRA section 12 (1).
	5.5 10.10	**Continued Consent** 1) Assess new information to determine if re-consent is necessary. Document communication and confirmation from the subject to continue participation. 2) A process for consent should be considered if, during the course of the research, the minor reaches the age of legal consent.	**Reference:** ICH GCP E6 (R3) section 2.8.2 and 2.8.12
	5.4 10.10	**Mode of Consent:** 1) Included considerations for varied approaches to be adopted in the consent process, e.g. images, video. 2) Consider the **target population characteristics (e.g. elderly). Paper-based approach** should be as an alternative when consent is taken using computerized system.	**Reference:** ICH GCP E6 (R3) section 2.8.1 and 2.8.12

Key Updates

SOP No.	PCR Section	Summary of Changes	Note
501-C02	8.2	Emphasized that investigators should be prepared **from the start of the trial to perform unblinding** in case of emergency, in accordance with the study protocol.	**Reference:** ICH GCP E6 (R3) section 2.11
501-C03	8.1	**Update of Research Results and Treatment to Subjects** When a subject decides to stop treatment or withdraw from the research or reach the routine end of the research: **Where relevant**, the investigator should **inform the subjects about the research results and treatment** received when this information is available from the sponsor, **with due respect to the subject's preference to be informed.**	**Reference:** ICH GCP E6 (R3) section 2.9.3 The PI should evaluate the necessity of updating research results and treatment information to the subjects in their studies.
501-B04	3.2	**Reporting to DSRB** The following needs to be promptly reported to DSRB: ▪ Any changes increasing the risk to subjects and/or significantly affecting the conduct of research ▪ New information that may adversely affect the safety of the subjects or the conduct of the research	**Reference:** ICH GCP E6 (R3) section 1.4.8

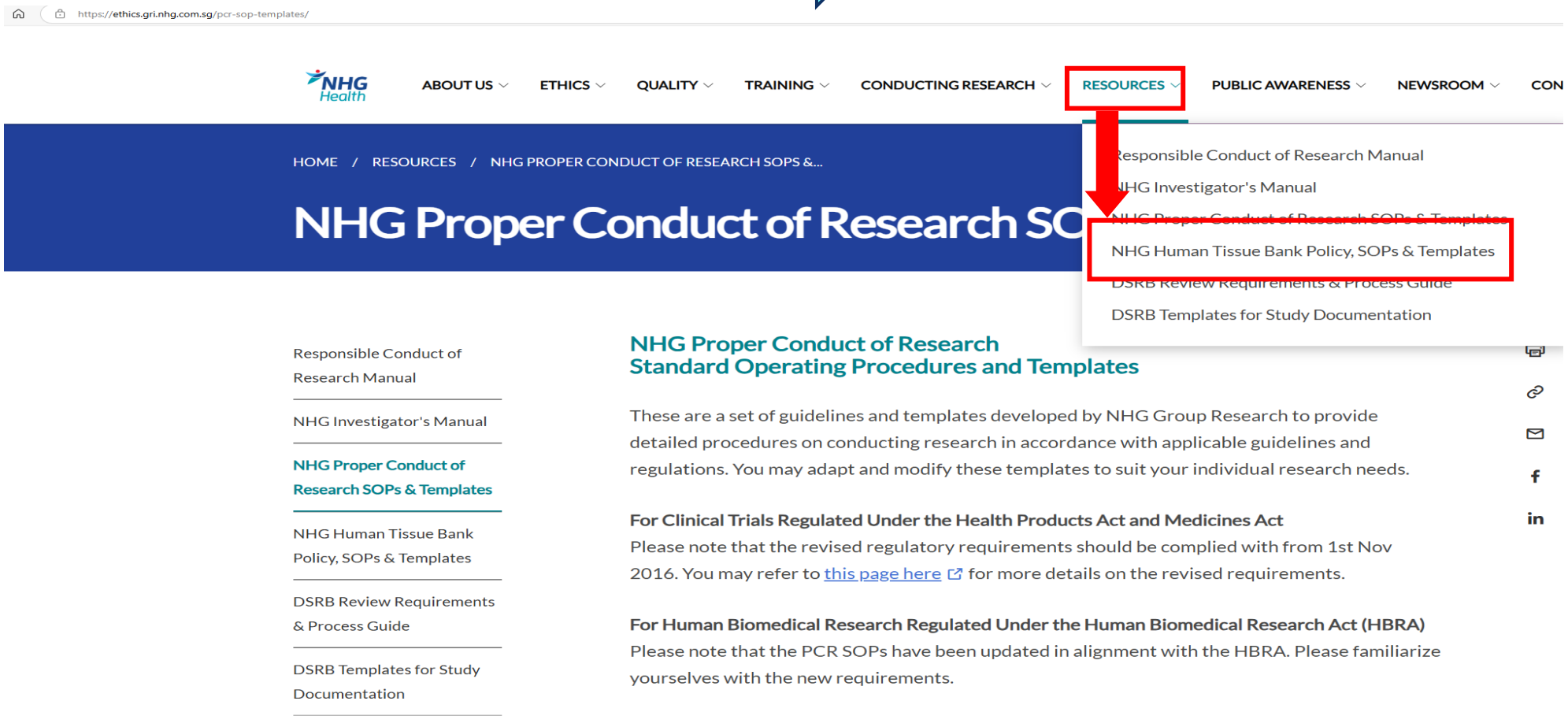
Key Updates

SOP No.	PCR Section	Summary of Changes	Note
501-B04 and 501-C05	Definition	**<u>Update to " Serious Adverse Event" Definition</u>** Any unfavourable medical occurrence that results in or contributes to death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in or contributes to persistent or significant disability / incapacity, results in or contributes to a congenital anomaly/birth defect <u>or results in such other event as may be prescribed.</u> **An important medical event that may not be immediately life-threatening or result in death or hospitalisation, that may jeopardise the participant or that may require intervention to prevent serious outcomes should generally be considered as serious.**	**Reference:** ICH GCP E6 (R3) Glossary Definition of SAE is applicable for all research types (e.g. Clinical Trials, HBRA regulated studies).
501-C05	Definitions	**<u>Definition Updates:</u>** Update to the terms "Adverse Event" and "Unexpected adverse drug reaction".	**Reference:** ICH GCP E6 (R3) Glossary
	4	**<u>Safety Events Reporting:</u>** The following should be in the study protocol - **1) Reporting timeline** for reportable adverse events 2) Where applicable, the reporting of "**unfavourable medical events occurring in subjects before investigational product administration (e.g., during screening)"** to Sponsor	**Reference:** ICH GCP E6 (R3) section 2.7.2
	7.1	Added **"incidents in the use and operation of computerised systems** which may have a significant and/or persistent impact on the research data or system security.**"** as a potential UPIRTSO reportable to DSRB.	**Reference:** ICH GCP E6 (R3) section 2.12.10
	6.1.4 7.1	Added clarification to report UPIRTSO and expected SAE **for events that occur in Singapore or outside Singapore.**	No change to current practice. Currently, DSRB reviews both overseas and local safety events.

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.

THANK YOU!