NHG Health

OHRPP Post-Its

ISSUE 36
NOV 2025

Office of Human Research Protection Programme (OHRPP) Post–Its:
Bringing you the latest updates on research policies, educational resources and event information

ATTENTION

ICH E6 (R3) GOOD CLINICAL PRACTICE (GCP) GUIDELINE
Takes effect 1 January 2026

Updated DSRB Informed Consent Form (ICF) Template

Key Updates to **ICF template** (Version 15, dated 21 Nov 25*)*:
- Sample text for new consent elements per ICH-GCP E6 (R3)
- Expanded "methods of payment" explanations
- Sample text for HBRA-compliant negative statement requirements

[Action Required]:
- New studies: Strongly encouraged to use updated ICF template.
- Ongoing studies: Conduct gap analysis and update ICF where necessary.

Access Summary of Changes and Template here.

Key Updates to Proper Conduct of Research (PCR) SOPs

(1) **Investigational Product (IP) Management** *(PCR SOP 501-B06)*
- Allowance for direct-to-subject shipping and subjects' location administration options by various personnel

(2) **Documentation** *(PCR SOP 501-B05)*
- Source records now require ALCOAC standards (added "Complete")
- Avoid unnecessary transcription steps between source records and data acquisition tools
- Enhanced archival requirements of essential records.

(3) **Monitoring Approaches** *(PCR SOP 501-B07)*
- Updated centralised monitoring definition
- Enhanced monitoring plan requirements and risk-based considerations.

Read full SOPs here.

Reminder to complete ICH E6 (R3) GCP Training

Principal Investigators (PIs) and Co-Investigators (Co-Is) must complete ICH E6 (R3) GCP training before you can submit new clinical trial applications and amendments on ECOS. *More information here*.

DSRB Updates

CY2026 Financial Conflict of Interest (FCOI) Declaration

Existing FCOI declarations expire 31 Dec 2025.
Do submit an updated FCOI declaration on ECOS from 01 Dec 2025 to 31 Jan 2026.

Updated FCOI Guide and FAQ will be available here.

Specifying Data Extraction Period for Medical Records

For studies accessing medical records, clearly state the data extraction period in Section E3 or G7 of IRB Application Form.

Acceptable Formats:
- Start and end dates in DDMMMYY (e.g. 01 Jan 25 to 31 Dec 25)
- Time period prior to enrolment (e.g. from 2 years before enrolment date)
- Time period with reference to study involvement (e.g. from 2 years before enrolment until end of study/withdrawal)

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RQM Updates

Proper Conduct of Research (PCR) SOP Reminder #1

Avoid using Microsoft OneDrive to keep research documents

OneDrive linked to individual M365 accounts becomes inaccessible when staff exit / leave employment, compromising document availability and retention compliance.

Requirement: Store essential records in corporate-approved secure data storage facilities e.g. Synapxe-managed systems, Storage Area Network (SAN), institutional SharePoint to ensure continuous access and compliance.

Reference: *PCR SOP 501-B08: Data Collection and Handling*

Proper Conduct of Research (PCR) SOP Reminder #2

Recruitment of Potential Research Participants

- Researchers not on the clinical care team must obtain permission from potential subjects before making contact (e.g. invitation letters or electronic messages).
- Researchers may collaborate with the clinical care team to obtain referrals.
- The clinical care team must obtain and document permission from potential subjects before referring them to research teams.

Note: All recruitment methods require institutional compliance and IRB approval.

Reference: *PCR SOP 501-C02: Subject Screening and Recruitment*

Education & Training

New NHG Health Learning Management System

NHG Health eLearn is transitioning to a new system on 23 Feb 2026. Access to current system ends after transition. Incomplete courses must be restarted in the new system.

All OHRPP courses including mandatory minimum trainings will be impacted *e.g.* HBR ERC Online V.3, HBRA - HTF Course V.2 and PCR courses.

[Actions by 23 Feb 2026]:
- Complete outstanding courses
- Download e-certificates

For enquiries contact eLEARN Administrator nhggroup.elearn@nhghealth.com.sg

RESOURCES FOR RESEARCHERS

Chicken Soup For The Busy Coordinator
Bite-size resource for Clinical Research Coordinators

Proper Conduct of Research (PCR) Courses
Learn how to conduct your research properly

Join OHRPP on Viva Engage
Get updates on research guidelines, best practices, OHRPP news & happenings!

Responsible Conduct of Research (RCR)
Doing Science Right, find out more about RCR