NHG Health

OHRPP Post-Its

ISSUE 35
SEP 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

Get trained on ICH E6 (R3) GCP

All Investigators and study team members involved in Health Sciences Authority (HSA) regulated trials should read the updated ICH E6 (R3) GCP Guideline and perform gap analysis of clinical trial protocols and procedures.

Read Revised ICH E6 (R3) GCP Training & Documentation Requirements.

IMPORTANT ***[For NHG Health Staff involved in Clinical Trials]***

Complete CITI-ICH E6 (R3) GCP Training & upload on ECOS before **1 October 2025.** From 1 Oct 2025, Principal Investigators (PIs) and Co-Investigators (Co-Is) without an updated ICH E6 (R3) GCP training cannot submit new IRB applications or study amendments for clinical trials on ECOS.

Click here for actions required.

Know Your Proper Conduct of Research (PCR) SOPs

PCR SOPs are being updated to align with the revised guideline.

Major Updates include:

- PI must maintain clinical trial oversight through clear agreements with service providers, adequate training, and accountability for research conduct and data quality *(PCR SOP 501-A02)*
- PI must assess whether re-consent is required when new information emerges and consider varied consent approaches that suit the subject population *(PCR SOP 501-C01)*
- PI should inform participants of results or treatment received if information is available from sponsor after unblinding, according to subject's preference to be informed *(PCR SOP 501-C03)*

Read the full version of the SOPs here.

Impact of ICH E6 (R3) GCP Guidelines on DSRB Review

Assess your current Consent Forms

[Actions Required] **For Study Teams with Ongoing HSA-Regulated Trials:**

- Complete gap analysis of current consent forms
- Implement necessary alignment changes

While changes are not mandatory before 1 Jan 2026, if your risk assessment indicates that it is beneficial for subjects to be informed, do submit an amendment early.

Click here for more details.

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Impact of NHG rebranding on documentation

Guidance on Administrative Modifications Due to Rebranding

Administrative changes related to rebranding (e.g., logo, website links, contact emails) will NOT require IRB amendment submissions.

- Maintain a tracked changes version or a file note in the Investigator file to document the revisions.
- Perform a practical impact assessment and decide if it is necessary to inform existing subjects.
- During Study Renewal: Include a statement in Study Status Report (SSR) confirming changes are due to rebranding updates in Section 5(b)(i).
- All other protocol modifications require standard IRB amendment procedures. Ensure updated contact information is functional.

Note: This also applies to tissue bank and tissue collection forms.

Click here for more information.

DSRB Updates

Updated DSRB Informed Consent Form (ICF) and Assent Form Templates *[Effective 1 Aug 2025]*

Key Updates:
The revised templates were harmonised with SingHealth CIRB templates for streamlined cross-cluster submissions:
• Informed Consent Form Template (Version 14.1) - clarifies NGEMR data access provisions
• Assent Form Template (Version 03) - Enhanced for child participants.

[Action Required]
• New studies: Strongly encouraged to use updated templates
• Ongoing studies: No revision required unless adding new objectives

Access Templates here.

OHRPP Updates

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