# OHRPP Post-Its

ISSUE 34
MAY 2025

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

## OHRPP Updates

### Completion of AAHRPP^ Re-accreditation Site Visit (15 - 17 April '25)

A BIG THANK YOU to all Institutions, researchers, research offices, staff and IRB members for your time and participation in this AAHRPP re-accreditation visit. Over 50 individuals across various NHG and Partners institutions were interviewed as part of the re-accreditation review.

We currently await the review outcome and will share with you as soon as it is available.

*^AAHRPP: Association for the Accreditation of Human Research Protection Programmes - A US-based non-profit accrediting body that promotes high-quality research through accreditation of human research protection programmes worldwide.*

## Partnership & Outreach Updates

### Mutual IRB Recognition and Single IRB Review for Collaborative Studies (Effective 1 April 2025)

If you are a Public Healthcare Institution (NUHS/NHG/SingHealth) researcher & you are collaborating with peers from A*STAR, NTU or NUS on a research study, please know that your study will only need to be reviewed by 1 IRB*. The review outcome will be mutually recognised between A*STAR IRB, SingHealth CIRB, NHG DSRB, NTU-IRB and NUS IRB.

*Please refer to the *Mutual Recognition FAQ* to determine the IRB that will review your collaborative study.

## DSRB Updates & Reminders

### DSRB Forms for Offline Submission During ECOS Downtime

DSRB has made available offline DSRB forms as a contingency measure to handle unexpected prolonged ECOS downtime due to cybersecurity threats or other emergencies.

Please know that these forms are intended for exigencies of service and will not be accepted during regular ECOS operations.

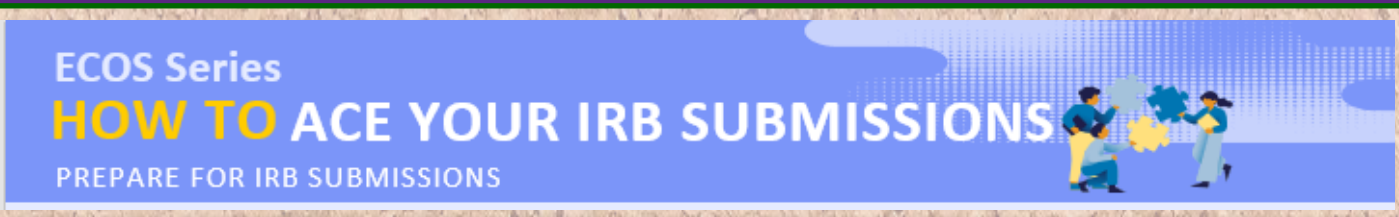
### Managing Confidentiality Risk in Medical Records Review Studies

Accessing medical records and extracting patient information for research poses a risk of confidentiality breaches due to the identifiable information involved.

To Minimize DSRB Queries on your IRB application:

- ☑ Select "Social risk" in IRB Application Form (Section E7/G16)
- ➢ Indicate the risk mitigation measures that the study will undertake
- ➢ If seeking a waiver of consent, an example of risk mitigation measure is to engage a Trusted Third Party (TTP) to (1) de-identify personal data post-collection & (2) keep the re-identification key.

### *[Coming Soon]* Quick Tips to Ace Your IRB Submissions




Get ready to ace your IRB submissions with our upcoming 'How To' series!

This series offers essential quick tips to a successful IRB submission.

Look out for the EDM in your mailbox!


## Regulatory Updates

### Revised ICH GCP E6 (R3) Implementation Requirements

**ICH E6 (R3) GCP** Principles and Annex 1 will be effective **1 Jan 2026** in Singapore.

Research teams and sponsors involved in **Clinical Trials regulated by HSA** should ensure the following for compliance:

1. Review the revised guideline thoroughly to be familiar with the changes.
2. Be **trained** on relevant GCP (R3) sections applicable to delegated roles & responsibilities and **document** all relevant training completed (e.g in Training Log) to be filed in the Investigator Site File.
   - ❖ *Access HSA's Webinar recordings, slides and training materials on ICH E6 (R3) GCP guideline on HSA website.*
3. Conduct gap analysis and implement necessary changes to processes.

*For more information, visit HSA website or contact HSA_CT@hsa.gov.sg for any clarifications.*

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## RQM Updates

### Proper Conduct of Research (PCR) SOP Reminders #1

#### Who Should Document The Informed Consent Process?

It is essential that the study team member who conducts the informed consent discussion also takes responsibility for documenting the informed consent process. This ensures consistency and accuracy in the records, as the individual who engages with the participant is best positioned to capture the discussion and any specific circumstances surrounding the consent.

*Reference: PCR SOP 501-C01 Informed Consent Form and Process*

### Proper Conduct of Research (PCR) SOP Reminder #2

#### Maintaining Biological Specimen Log

The biological specimen log captures a record of all biological specimens collected, processed, stored or shipped for the research study. This ensures traceability of each specimen collected. You may use *PCR Template 509-009 Biological Specimen Log* for keeping such records.

*Reference: PCR SOP 501-C04 Biological Specimen Collection and Handling*

### Responsible Conduct of Research (RCR) Reminders


## Education & Training

### Chicken Soup For The Busy Coordinator

- Jan - Study Audit or Inspection – The Activities Involved Before, During & After
- Feb - Standing Databases: How to Store Research Data for Future Research?
- Mar - How Should Consent Be Obtained for the Collection of Tissue?
- Apr - Preventing Information Discrepancies between IRB App Form & Study Docs

*To savour past issues of Chicken Soup, please Click Here*

### Want to Learn How to Conduct Your Research Properly? Attend Proper Conduct of Research (PCR) Courses Online @eLEARN

| 4 Courses Are Available | |
|---|---|
| PCR 001 | Subject Recruitment and Informed Consent |
| PCR 002 | Study Start-Up, Data Management, Investigational Product (IP) & Safety Reporting |
| PCR 003 | Research Data Collection & Budgeting |
| PCR 400 | Monitoring, Audits and Inspections |

*NHG Staff may self-register for direct access on NHG eLEARN Marketplace.*
*For non-NHG staff, please Click Here or email research_courseadmin@nhg.com.sg*