

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

DSRB Updates & Reminders

Always Use the latest DSRB Informed Consent Form (ICF) Template

Benefits:

- Ensure that your ICF is compliant with HBRA and ICH E6 (R3) GCP Guideline
- Receive fewer queries from DSRB!

Access the DSRB ICF Template (Version 15 dated 21 Nov 2025) [here](#).

Recruitment of Participants Who Speak Foreign Languages

If you intend to recruit participants who can only understand foreign languages (i.e. not Chinese, Malay or Tamil), remember to select "Others" and specify the foreign language(s) in Section J11(a) of the ECOS IRB Application Form.

It is strongly recommended to use a translated Informed Consent Form or a translated short consent form in the participants' language when obtaining informed consent.

POP QUIZ

WHICH IS CORRECT?

A study has recruited 200 participants, per IRB approval. 10 participants withdrew; the team wishes to replace them. What should they do?

- A) Recruit replacement participants
- B) Seek IRB approval before recruiting additional participants
- C) Replace participants only if withdrawals occur early in the study

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RESEARCH COMPLIANCE UNIT

CORRECT ANSWER: B
KEY TAKEAWAY - The IRB approval specifies the maximum number of subjects who can be approached/consented, not the number who complete the study. Withdrawals don't create "recruitment slots". Exceeding 200 would be considered a protocol deviation.

Research Quality Management

Key Updates to Proper Conduct of Research (PCR) SOPs

The Data Collection and Handling SOP (PCR SOP 501-B08) has been updated to align with ICH E6 (R3) GCP. If you are involved in clinical trials, here is what you need to do differently:

Prioritise critical data. Focus your verification and review efforts on data that are critical to your study's outcomes, rather than verifying all data equally.

Maintain traceable audit trails. All meta/data corrections must be documented with details of who made the change, when, and why.

PIs are accountable for data oversight. Ensure you have processes in place to regularly review study data and not rely solely on your team to flag issues.

Plan for data finalisation and archival early. Do not leave data transfer and archival processes to the close-out phase.

Review your computerised systems. Ensure any systems used for data collection is fit-for-purpose.

Reference: [PCR SOP 501-B08 Data Collection and Handling](#)

Proper Conduct of Research (PCR) SOP Reminders #1 Strengthening Monitoring Oversight in Industry-Sponsored Human Biomedical Research (HBR)

If you are working with an industry sponsor, ensure their monitoring activities cover:

Informed consent processes. Verify that participants are being consented in accordance with approved procedures.

Data integrity. Confirm that study data is accurate, complete, and traceable.

Contemporary IRB approval. Check that your sponsor is tracking IRB approval expiry dates and submitting renewals in a timely manner.

For more information, please visit [NHG Health OHRPP – Research Monitoring](#) or email to nhqgroup.researchquality@nhghealth.com.sg

Partnership & Outreach Updates

NHG Health DSRB Onboards New Partner - Communicable Diseases Agency (CDA)

NHG Health DSRB has been appointed to review studies for CDA.

Planning a collaborative study involving both NHG Health and CDA sites? [Submit](#) it as one comprehensive study with both institutions included.

Visit [ECOS](#) or the NHG Health [research website](#) for more information.

DSRB Green Lane Partnerships: Your Trial matters to us

Engage with DSRB early for Industry Sponsored Studies requiring fast-track review. Partner with us for faster turnaround and expert guidance.

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