National Healthcare Group
Adding years of healthy life

OHRPP Post-Its

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

ECOS Reminders

Researchers – *Please Take Action!*

#1 If your **Exempt study** was approved before 1 Apr 2022, and expected to continue beyond April 2024, please inform your institutional research office. Do specify that your Exempt study DSRB/XXXXX will require migration to ECOS. This update is critical for DSRB to migrate your ongoing exempt study into ECOS.

For more information, contact OHRPP@nhg.com.sg

What is ECOS?

ECOS (Ethics & Compliance Online System) is the new review system for DSRB & CIRB, launching in 2024.

ECOS will enable researchers to manage research studies from cradle to grave in a single portal. NHG ROAM & SingHealth iSHaRe will sunset in tandem.

#2 If your **Exempt study** is **Completed or Terminated**, please submit a Status Report Form (SRF) to inform DSRB of your study status. Alternatively, scan the FormSG QR code here to submit a declaration on the study status.

Be sure to retain a copy of the study DSRB documents, as ROAM access will be cut off from April 2024.

for.sg

https://for.sg/closeexemptstudy

Standing Database Custodians – *Please Note*

ROAM-X Standing Database (SDB) applications will be progressively migrated into ECOS. However, ROAM SDB applications will not.

NHG Custodians with ROAM SDBs that are expected to continue beyond 2023 are encouraged to resubmit an ROAM-X SDB application before 31 December 2023. By doing this, the custodian's SDB application will also be availed in ECOS.

For more information, contact your institution CRU or the Research Data Secretariat at RDOCSecretariat@nhg.com.sg

DSRB Reminders

DSRB Submission Requirements for Incidental Findings (IFs) Management Plan

Where applicable, research studies should have an IF management plan that is aligned with its institution's IF policy. This plan must address the following 8 points:

Describe the IFs that may be returned	**The individual (and their qualifications) returning IFs to participants**
Verification plans for suspected IFs	**Indicate the communication mode & limits of re-contact**
State the party/s responsible for determining whether IF is clinically significant & actionable	**State the counselling/referral plans for participants**
Clinical validation plans for IFs, if results obtained were not of clinical grade	**Other relevant considerations (e.g. public health implications, participants <21 years old)**

RQM Updates

Updates to Proper Conduct of Research (PCR) SOPs

599-005 Guidance Document on Electronic Informed Consent Process has been updated and effective from 28 Mar 2023.

The key updates include:

- Recommendation to add a statement in the ICF to inform all parties that the ` e- Signature is legally binding
- Clarification on types of e-Signatures that can be used
- Considerations when conducting remote consent

Click here to download the documents.

RQM Updates

Proper Conduct of Research (PCR) SOP Reminder #1

Must I Retain the Documents (e.g. randomisation envelopes) After Randomisation Procedures Are Performed?

It is imperative for study randomisation to be performed in accordance to the study protocol. Randomisation documents (e.g. Randomisation Assignment Confirmation, Randomisation Master List, Randomisation Envelopes) are source documents and they served as a record to verify that the study randomisation was performed accurately. These documents should be appropriately maintained in the Investigator/ Pharmacy files for Investigator-Initiated trials or Master file for Industry-Sponsored Trials.

Reference: 501-C02 Subject Recruitment and Screening

Proper Conduct of Research (PCR) SOP Reminder #2

Tracking of Study Supplies During Research

Study supplies (e.g. Investigational Products, Auxiliary Products) used for the purpose of research should be tracked to ensure its inventory is meant for its intended purpose.

The study supplies received, stored, dispensed, used, and returned / destroyed should be recorded. The PI/ Study team may use and edit the following PCR Templates to support their documentation:

- 509-004: Device Accountability Log
- 509-005: Investigational Product Inventory Log
- 509-012: Investigational Product Dispensing & Accountability Log (Multiple Subjects)
- 509-013: Investigational Product Dispensing & Accountability Log (Per Subject)

Reference: 501-B06 Investigational Product Accountability

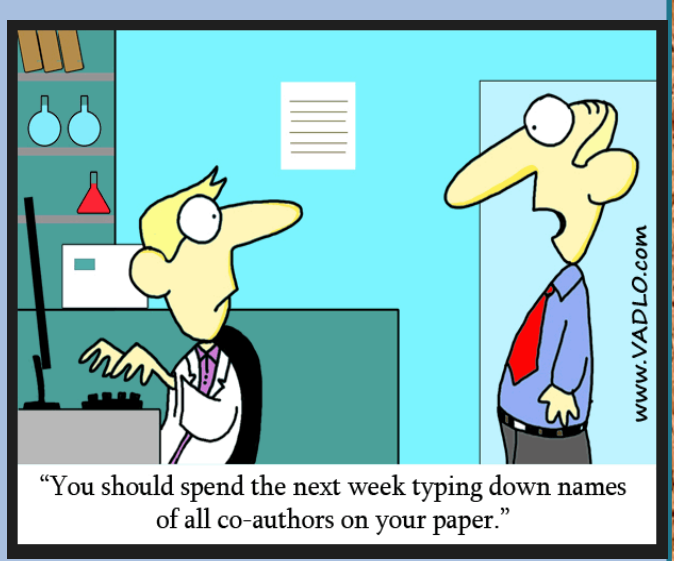
Responsible Conduct of Research (RCR) Reminders

Authorship and Publication

"Authorship is generally limited to individuals who make significant contributions to the work that is reported. Researchers should appreciate the minimum standards of responsible publications, understand the elements of a responsible publication, appreciate what contributes to responsible authorship and be aware of practices to avoid."

- Nicholas H. Steneck ORI Introduction to the Responsible Conduct of Research, Revised Edition August 2007, Chapter 9 Authorship and Publication)

Read more here...



Cartoon by: www.VADLO.com & https://www.researchgate.net/post/Paper-authorship-for-students

Education & Training

Chicken Soup For The Busy Coordinator

- ❑ **Feb 2023 - Tips to Prevent Informed Consent Non-Compliances**
- ❑ **Mar 2023 - How to Obtain Informed Consent From Subjects With Cognitive Impairment?**
- ❑ **Apr 2023 - What is Collaborative Research?**

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	
[NEW] **PCR 001**	**Subject Recruitment and Informed Consent** *PCR 001 contains enhanced interactive content & replaces PCR200*
PCR 100	**Study Start-Up: Case Report Form Design, Database Design, Using REDCap & Budgeting**
PCR 300	**Study Conduct II: Documentation, Safety Reporting and Investigational Product (IP)**
PCR 400	**Monitoring, Audits and Inspections**

For course registration and more details, please Click Here.
NHG Staff may self-register for direct access on NHG eLEARN Marketplace.

For enquiries, email: research_courseadmin@nhg.com.sg