





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

ECOS Updates

Update to Standing Database (SDB) Submission Cut-Off Date

All SDB applications will need to be submitted before 01 April 2024, and an outcome must be reached before 01 June 2024.

The submission of new SDB applications will only resume upon the launch of the ECOS SDB Module in mid-2024.

Note: NHG institutions should submit their SDB applications via the <u>SDB Online</u> System (requires intranet access), while non-NHG institutions should submit via ROAM.

Researchers – Please Take Action!

User Account Migration to ECOS

To allow researchers to access their studies readily on ECOS, the following ROAM accounts will be preloaded into ECOS:

An individual who:

Is a Principal Investigator, Site-Principal Investigator or Co-Investigator in an Active Study*

or

- Is a ROAM Key Appointment Holder (such as Department Rep, Institutional Rep, DSRB Chair/Members etc.)
- approved/registered Standing Database, which is Ongoing (or recently expired from 1 November 2023 onwards).

*Active study refers to a DSRB-Approved Study, or an

Profile <u>before 01 April 2024</u>. Please ensure that your profile:

Users are to update their ROAM

- Has a valid, properly formatted email address
- ✓ Has a valid Primary Appointment information
- For Researchers Has Minimum **Training Certification updated**

Migration of Minimum Training Completion Records into ECOS

Minimum training records of (a) PIs, (b) Site PIs and (c) Co-Is of active studies will be

automatically migrated into ECOS. This is to facilitate future ECOS IRB application submissions. If you have not uploaded your minimum training completion certificates (CITI, FCOI

DSRB sufficient time to verify your training records. For clarifications, contact min ethics training@nhg.com.sg

Click here for minimum training resources: CITI Training; Financial Conflict of Interest

CITI, GCP) in your ROAM Profile, please do so before 01 March 2024, to allow the

(FCOI) CITI Training; Good Clinical Practice (GCP) Training

Migration of Financial Conflict of Interest (FCOI) Records into ECOS

If there are changes to your CY2023 FCOI status, please inform DSRB promptly for timely assessment of potential impact to your current study involvements. All changes to FCOI

declarations must be submitted **before 01 March 2024** to **DSRB_FCOI@nhg.com.sq.** If there are no changes, no action is required. The validity period of CY2023 FCOI Declarations is extended till 30 June 2024.

ECOS Launch Support Webpage

As part of NHG's preparations to ensure a smooth transition from the current ROAM System

to the new ECOS system, NHG OHRPP has created an ECOS Launch Support Website to act as a central information portal.

All announcements and guides related to the ECOS system and the decommissioning of the NHG ROAM System will be made available on the portal.

Please stay tuned to the ECOS Launch Support Website here for regular updates and

DSRB Update

announcements.



Re-Classification of Studies involving Anonymised Data / Human **Biological Material (HBM)** All new studies involving anonymised data / human biological materials will no longer

(RNR) Outcome. Previously approved applications using anonymised data / HBM may request to be reclassified as RNR. PIs should submit a Study Status Report Form (SRF) for DSRB to conduct

require review by DSRB. If submitted to DSRB, the study will receive a **Review Not Required**

the re-determination. Please submit the SRF requests before 01 February 2024.

Please view the announcement <u>here</u> for more information.



Revised GCP Minimum Training for PI, Site-PI & Co-I in Clinical Trials

Currently, only the PI and Site-PI conducting Clinical Trials are required to complete GCP training. Starting from 1 April 2024* -

- 1) PI, Site-PI, and Co-I must complete GCP training before submitting Clinical Trials applications to DSRB.
- 2) Study Team Members who perform the following significant trial related activities will also need to complete GCP training **before** their study involvement:
 - (i) Informed consent
 - (ii) Eligibility assessment
 - (iii) Investigational product management
 - (iv) Key efficacy and safety assessments

3) The DSRB will accept generic ICH-GCP courses such as CITI ICH-GCP as fulfilling the

training, at the discernment of the PI, before study involvement.

Study Team Members who perform other study tasks may need to undergo GCP

- minimum GCP training requirement.
 - * Applicable for both new and ongoing Clinical Trials

RQM Updates

Updates to Proper Conduct of Research (PCR) SOPs

PCR SOP 501-B08 Data Collection and Handling has been updated to include the following:

- a) Section 5.4 and 5.5: Clarification on the use of de-identified/ anonymised data
- b) Section 6.1.d: Revision of password requirement from 8 to 12 alphabets to align with HIM-DM guidelines
- c) Section 6.2: Include FormSG as a data capture tool
- d) Section 6.3: Clarification on storage requirements of hard copies and electronic copies of research information

The SOP is effective from 10 Nov 2023. Click here to download the documents.

Proper Conduct of Research (PCR) SOP Reminder #1

Which Version of the Informed Consent Form Should I Use? The most current version of the consent form approved by the IRB and regulatory

authority (if applicable) should be used as a guide while conducting the informed consent process. Superseded version(s) of blank consent forms should be removed, except for a copy to be

filed in the Investigator File for record-keeping purpose.

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

Essential Documents - Why Do I Need to Maintain An Investigator File (IF)?

Proper Conduct of Research (PCR) SOP Reminder #2

purposes: Facilitate the evaluation of research conduct and the quality of produced data. a.

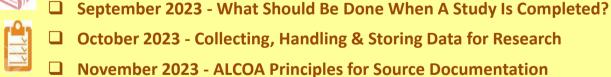
The Investigator File contains essential documents that serve various important

- Serve as evidence of compliance with applicable regulatory requirements and b. institutional policies during the research.
- Contribute to the effective management of research studies at the site. c. d. Assist monitors, auditors, and inspectors in verifying the compliance and
- Reference: PCR SOP 501-B05 Documentation

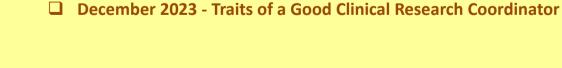
integrity of the collected data.

Chicken Soup For The Busy Coordinator

Education & Training



October 2023 - Collecting, Handling & Storing Data for Research



☐ August 2023 - Use of Social Media As a Recruitment Tool

To savour past issues of Chicken Soup, please Click Here



4 Courses are Available **Subject Recruitment and Informed Consent**

PCR 100	Study Start-Up:
	Case Report Form Design, Database Design, Using REDCap & Budgeting
PCR 300	Study Conduct II:

*The previous PCR200 has been replaced with PCR 001 (enhanced interactive content)

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

Documentation, Safety Reporting and Investigational Product (IP)

PCR 400

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@nhq.com.sq

Monitoring, Audits and Inspections