National Healthcare Group
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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 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 SDB Online 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.)

**Active study refers to a DSRB-Approved Study, or an approved/registered Standing Database, which is Ongoing (or recently expired from 1 November 2023 onwards).*

Users are to update their ROAM Profile before 01 April 2024.

Please ensure that your profile:

- ✓ 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 CITI, GCP) in your ROAM Profile, please do so **before 01 March 2024**, to allow the 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 (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.sg*.

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 announcements.

DSRB Update

Re-Classification of Studies involving Anonymised Data / Human Biological Material (HBM)

All new studies involving anonymised data / human biological materials will no longer require review by DSRB. If submitted to DSRB, the study will receive a **Review Not Required (RNR)** Outcome.

Previously approved applications using anonymised data / HBM may request to be re-classified as RNR. PIs should submit a Study Status Report Form (SRF) for DSRB to conduct the re-determination. Please submit the SRF requests **before 01 February 2024**.

Please view the announcement here for more information.

DSRB Update

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

   Study Team Members who perform other study tasks may need to undergo GCP training, at the discernment of the PI, before study involvement.

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

Proper Conduct of Research (PCR) SOP Reminder #2

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

The Investigator File contains essential documents that serve various important purposes:

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

b. Serve as evidence of compliance with applicable regulatory requirements and institutional policies during the research.

c. Contribute to the effective management of research studies at the site.

d. Assist monitors, auditors, and inspectors in verifying the compliance and integrity of the collected data.

Reference: PCR SOP 501-B05 Documentation

Education & Training

Chicken Soup For The Busy Coordinator

- ❑ August 2023 - Use of Social Media As a Recruitment Tool
- ❑ September 2023 - What Should Be Done When A Study Is Completed?
- ❑ October 2023 - Collecting, Handling & Storing Data for Research
- ❑ November 2023 - ALCOA Principles for Source Documentation
- ❑ December 2023 - Traits of a Good Clinical Research Coordinator

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