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

DSRB Reminders

ECOS 2024 #1 FOCUS AREA – EXEMPT STUDY CLEAN UP

In this ECOS series, we will highlight actions you need to take to prepare you and your ROAM study for the move to ECOS.

#1 EXEMPT STUDY CLEAN UP

DSRB needs you to identify exempt studies that need to migrate into ECOS. Exempt studies that are completed or terminated will not be migrated into ECOS. Only ongoing exempt studies approved from April 2022 will be exported into ECOS.

Researchers – Please take action

1. If your Exempt study is **Completed or Terminated**, please submit a Status Report Form (SRF) to inform DSRB of your study status. Ensure you retain a copy of relevant DSRB documents, as your study data will be put into cold storage with limited access.
2. 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, please 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.

Minimum CITI Training Requirements for Submissions to Domain F (Population Health)

Reminder: PIs, Site PIs and Co-Investigators from NHG & partner institutions submitting studies to Domain F are required to complete:

(i) 10 Core Modules (7 fundamental research ethics modules and 3 modules specific for NHG investigators), and
(ii) 5 SBE (Social, Behavioural and Educational) related elective modules

DSRB applicants that do not demonstrate fulfilment of these minimum training will be requested to complete the modules, and can expect a delay in receiving their review outcomes.

Click Here to read more about minimum CITI training requirements for DSRB submissions.

Useful Resources

Download the Research Participant Brochure!

Do you require resources for your Research Participant?

The Research Participant Brochure provides research participants with an overview of clinical research, what to expect for their participation and useful contact information. Scan the QR Code to download the Brochure in English.

For other useful resources, Click Here.

RQM Updates

Updates to Proper Conduct of Research (PCR) SOPs

Clarification on Qualified Pharmacists Obtaining Consent in Clinical Trials (CTs) Led by Pharmacist PIs

The PCR SOP 501-C01, Informed Consent Form and Process, has been revised to clarify when pharmacists can take consent in HSA regulated Clinical Trials (CTs)

- If the CT PI is a pharmacist, informed consent can be taken by investigators who are qualified pharmacists
- If the CT PI is a qualified practitioner (medical practitioner or dentist), pharmacists cannot obtain consent. Informed consent will still need to be taken by investigators who are qualified practitioner. Refer to PCR SOP 501-C01 Informed Consent Form and Process

RQM Updates

Proper Conduct of Research (PCR) SOP Reminder #1

Can I Collect Subject Identifiers on Data Collection Forms?

Study team should not collect information directly identifiable to a subject (such as name, identity card number, address, etc) on Data Collection Forms/ Case Report Forms unless it is to be used as a source document where source data is being collected.

Each subject should be assigned a unique subject identification code to be used on the study documents e.g. DCFs, CRFs, serious adverse event reports. In addition to the subject identification code, subject initials may also be entered. The link between the subject identification code and the subject identifiers should be stored in a separate document.

In some instances, combination of data elements collected on DCFs / CRFs may potentially identify a subject. Care should be taken to ensure that the information collected is appropriately coded such that it cannot be traced back to the individual without the linking code unless it is to be used as a source document.

Ref: PCR SOP 501-B08 Data Collection and Handling.

Proper Conduct of Research (PCR) SOP Reminder #2

Documentation of Adverse Event (AE)

The Investigator should document information, assessment and management of the Adverse Event (AE) experienced by the Subject in the source documents / medical records. Information should include and not limited to:

- details of the event (e.g. date of onset and end date, treatment provided – if any, outcome of event)
- the expectedness, causality and severity of event assessed by qualified Investigator.

The PI must report the AE to the IRB, Regulatory Authority and/or Sponsor according to applicable guidelines and timeframe.

Ref: PCR SOP 501-C05 Unanticipated Problems Involving Risks to Subjects and Others and Expected Serious Adverse Event.

Responsible Conduct of Research (RCR) Reminders

"Effective collaboration begins with a clear understanding of roles and relationships, which should begin the day the collaboration is established by discussing and reaching agreement on the details of the collaborative relations."

Nicholas H. Steneck ORI Introduction to the Responsible Conduct of Research, Revised Edition August 2007, Chapter 8 Collaborative Research

https://babettetenhaken.com/wp-content/uploads/2016/06/JJAVA-fotolia.jpg

Education & Training

Chicken Soup For The Busy Coordinator

- ❑ **Nov 2022 - Regulatory Guidance on Consent Requirements for Clinical Trials involving Collection and Use of Human Tissue**
- ❑ **Dec 2022 - Guidelines to Contacting & Recruiting Potential Research Subjects**
- ❑ **Jan 2023 - Using FormSG as a Research Data Capturing Tool**

*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	
PCR100	**Study Start-Up:** **Case Report Form Design, Database Design, Using REDCap & Budgeting**
PCR200	**Study Conduct I:** **Subject Recruitment & Informed Consent**
PCR300	**Study Conduct II:** **Documentation, Safety Reporting and Investigational Product (IP)**
PCR400	**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