National Healthcare Group
Adding years of healthy life

OHRPP Post-Its

ISSUE 32
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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 Updates

Updates to IRB Exempt Categories

Effective *1 April 2024, changes to* the Exempt Categories include:

Exemption Category 2 - Educational Tests, Surveys, Interviews, or Observations:
Non-anonymous educational tests, surveys, interviews, or observations may now be allowed if DSRB determines that adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data are in place.

Exemption Category 4 – Secondary research for which consent is not required:
It is no longer a requirement for data or biospecimens to be existing, provided the information is either publicly available, or recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained and the investigator does not contact the subjects, and will not re-identify subjects.

Please view the announcement here for more information.

CY2024 Financial Conflict of Interest (FCOI) Declaration For period 1 July 2024 to 31 Dec 2025

CY2024 FCOI declaration cycle is ongoing and you may submit your FCOI declaration form to the DSRB via ECOS.

To NHG Principal Investigators: Do note that yours & your co-investigators' FCOI declarations will need to be submitted and validated in ECOS as part of any new study submission.

ECOS Onboarding Updates

ECOS Resources & Launch Support Website

The ECOS Launch Support for NHG Website acts as a central information portal.

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

The following ECOS Resources are available:

- ✓ **ECOS Announcements**
- ✓ **ECOS User Guides**
- ✓ **ECOS FAQ**
- ✓ **ECOS Training** (Webinar Slides & Recording, Videos)

Do check back the Support Website regularly for updates and new additions

ECOS

ECOS Launch Support for NHG HOMEPAGE

for.sg

https://for.sg/ecos

ECOS End User HELPDESK Support

ECOS

If you require ECOS technical support, please contact the respective support agents listed below:

- ❖ **NHG users: ITDHELP@nhg.com.sg**
- ❖ **NUHS users: ITDHELP@nuhs.edu.sg**
- ❖ **SingHealth users: it.helpdesk@singhealth.com.sg**
- ❖ **Non-PHI / All Other users: https://for.sg/ecos-support-request**

IMPORTANT:
For Users from **Public Healthcare Institutions (PHI),** please download and complete the **ECOS Support Request Form** before contacting your Institution ITD Helpdesk to log a Support Request.

RQM Updates

Updates to Proper Conduct of Research (PCR) SOPs

PCR SOP 501-A03 **Training and Education** has been updated with the following:

a) ICH GCP course may be used as an alternative minimum requirement for biomedical research studies only. It does not apply to population health studies. (Section 9.4)

b) Aligned GCP training requirement with HSA. This applies to PI, Co-Is and other study team members involved in significant trial related activities. (Section 10.1)

c) Removed GCP waiver criteria and listed examples of acceptable types of GCP courses. (Section 10.2)

This SOP has been effected from 1 Apr 2024.

RQM Updates

Proper Conduct of Research (PCR) SOP Reminder #1

Documentation of Study-related Trainings

It is the responsibility of the PI to ensure that all members of the study team are trained for their role in the study prior to performing study related activities. The trainings conducted should also be documented.

The study team may refer to PCR Form 505-001: Training Record Form on information to be recorded. (Ref: PCR SOP 501-B03 Study Initiation)

Proper Conduct of Research (PCR) SOP Reminder #2

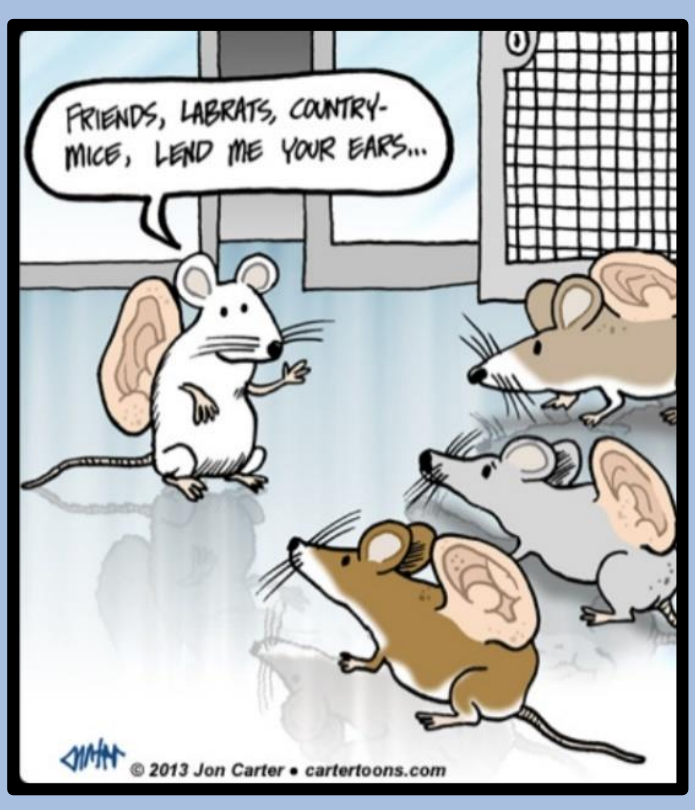
Informed Consent Process
- Who Can Obtain Informed Consent From the Participants?

Informed consent discussion should be conducted by the Principal Investigator or any qualified^ member of the study team who is listed in the study responsibility log as well as the IRB application form as the designated persons/ roles for conducting the informed consent discussion.

^Depending on the nature of the study, there may be additional regulatory or IRB requirements. For example, for clinical trials regulated by Health Sciences Authority (HSA), only qualified practitioners can obtain informed consent from trial participants. Where the clinical trial is led by a pharmacist PI, co-investigators who are qualified pharmacists may also be authorized by the PI to obtain consent.

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

Responsible Conduct of Research (RCR) Reminders



Cartoon by: Jon Carter @2013
(https://www.cartertoons.com/product/mouse-speech/)

The Welfare of Laboratory Animals for Medical Research

"If you expect to use or study living animals in your research, regardless of the level of invasiveness, familiarize yourself with your responsibilities and check with someone in a position of authority before making any plans or undertaking any work."

Nicholas H. Steneck ORI Introduction to the Responsible Conduct of Research, Revised Edition August 2007, Chapter 4 The Welfare of Laboratory Animals

Click here to read more on RCR.

Education & Training

Chicken Soup For The Busy Coordinator

- ❑ Jan 2024 - Subject Recruitment: Performing Subject Eligibility Assessment & Documentation
- ❑ Feb 2024 - Ethics and Compliance Online System (ECOS) - Researcher's Checklist
- ❑ Mar 2024 - What You Should Know About Documentation & 'Certified True Copies'
- ❑ Apr 2024 - Ethics and Compliance Online System (ECOS) Launch
- ❑ May 2024 - What Should Be Done If Subject Recruitment Was Not Done According to IRB Approved Protocol?
- ❑ Jun 2024 - ECOS - How to Add Team Members in Clinical Research Management (CRMS)

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 002 *(Previously PCR 300)*	**Study Start-Up, Data Management, Investigational Product (IP) &** ***(NEW)*** **Safety Reporting**
PCR 003 *(Previously PCR 100)*	**Research Data Collection & Budgeting**
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