



ISSUE 33 DEC 2024

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

# ECOS (Ethics & Compliance Online System)

### All ECOS Modules Are Now Available

Users can now carry out the following tasks on ECOS

- 1. Update Minimum Training Certifications
- 2. Submit IRB Applications & Minimum Training
- 3. Monitor Study Progress through the Clinical Research Management System (CRMS)
- 4. Update and declare Financial Conflict of Interest to DSRB
- 5. Clarify and report Non Compliance and Serious Adverse Events to the Research Institution
- 6. Perform Principal Investigator Self Assessments
- Submit Standing Database Applications (Exclusive to NHG & NUHS custodians)
- 8. Correspond on research audit and monitoring tasks



https://for.sg/nbgeco

Refer to the user guides and support information for help.

#### **DSRB** Reminders

## Legal Definition of Minors in Singapore

In Singapore, anyone < 21 years old & have <u>never</u> been married are considered minors.

#### **Studies Recruiting Minors in Singapore**

For studies that intend to recruit minors, do ensure that the IRB Application Form is completed as follows:

- Section D4(a): Select "Children" as a study population
- Section L (Research Participants-Children): Justify their involvement in the research
- Section G13 (Inclusion Criteria): Provide the age range of the target population

Do include clear & succinct justifications for the IRB to understand your intent & assess the appropriateness to involve minors, which will help expedite the reviews.

#### **RQM Updates**

#### **Proper Conduct of Research (PCR) SOP Reminder**

#### **Ensuring Traceability of Research Participant**

In a recent audit, it was picked up that a research participant had indicated "Johnny Lim" as his name when signing off the Informed Consent Form.

When the study team attempted to verify the identity of "Johnny Lim" against the participant's medical records / source document file, the auditor was unable to locate the English name "Johnny" in the sources and thus unable to authenticate the identity of this participant.

Please ensure that source data are **attributable** – Data should be accountable and traceable by including **appropriate identifiers** (e.g. protocol number, subject full name, subject study ID, date and time of study procedure / data entry).

Reference: PCR SOP 501-B05 Documentation



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

### **RCR Updates**

### **Responsible Conduct of Research (RCR) Reminders**

Responsible Conduct of Research (RCR) isn't just about following rules - it's about shaping discoveries with integrity, transparency and respect for knowledge.



#### **Article Feature:**

(Click on link to read) Fake academic papers are on the rise: why they're a danger and how to stop them

[Source: By <u>Lex Bouter</u>, Vrije Universiteit Amsterdam, The Conversation - Articles on Research integrity]

Refer to <u>Responsible Conduct of Research (nhg.com.sg)</u> for more information on the RCR components.

#### **Education & Training**

### **Chicken Soup For The Busy Coordinator**

- Jul 2024 Responsible Conduct of Research (RCR) Authorship and Publications
- □ Aug 2024 Understanding ECOS CRMS Non-Investigator Roles
- **General Sep 2024 Pre-Screening Processes Whose Responsibility?**
- **Oct 2024** ECOS How to Manage Multi-Site Studies (via CRMS Module)
- Nov 2024 Best Practices to Ensure Timely Submission to IRB for Study Continuing Review

To savour past issues of Chicken Soup, 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  |
| PCR 002                 | Study Start-Up, Data Management, Investigational Product (IP) &<br>Safety Reporting |
| PCR 003                 | Research Data Collection & Budgeting  |
| PCR 400                 | Monitoring, Audits and Inspections  |

*For course registration and more details, Click <u>Here</u>. NHG Staff may self-register for direct access on <u>NHG eLEARN</u> Marketplace.* 

For enquiries, email: <u>research\_courseadmin@nhg.com.sq</u>