National Healthcare Group
Adding years of healthy life

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

Preparing for ECOS (Ethics & Compliance Online System)

Researchers – *Please Take Action!*

#1 **Renewing Expired Studies**

Expired studies **<u>will not be migrated</u>** to ECOS.

- If your study approval has expired but you intend to continue the study, please submit a <u>Status Report Form (SRF)</u> to renew it ASAP.
- In addition, submit a **Non-Compliance Report to DSRB if you had carried out research activities** during the approval lapse period.

What is ECOS?

ECOS 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.

#2 **Preparing DSRB studies for Migration into ECOS**

If you had submitted Non-Compliances, Serious Adverse Events, UPIRTSOs or Other Notifications to the DSRB, please respond promptly to ROAM queries so that your study can be readied for migration timely. For more information, please contact OHRPP@nhg.com.sg

#3 **Closure of Studies upon Completion of Data Analysis**

Studies that had completed (1) data collection & (2) analysis of individually identifiable data will no longer require DSRB oversight.

Please submit a Status Report Form (SRF) to inform the DSRB of study completion promptly.

#4 **Migration of Minimum Training Completion Records into ECOS**

Minimum training records of (a) Principal Investigators, (b) Site Principal Investigators and (c) Co-Investigators 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 reports (CITI, FCOI CITI, GCP) in your ROAM Profile, please do so quickly. 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

DSRB Update

Extension of Coverage Period for CY2023 FCOI Declarations

To facilitate the transit to ECOS, the validity period of CY2023 FCOI Declarations will also be extended till 30 Jun 2024. Investigators and study team members will be notified to submit e-FCOI Declarations for CY2024-2025 via ECOS subsequently.

Despite the above, if there are changes to your FCOI status, do continue to inform DSRB promptly for timely assessment of potential impact to your current study involvements.

RQM Updates

Updates to Proper Conduct of Research (PCR) SOPs

<u>PCR SOP 501-C01</u> Informed Consent Form and Process (Effective 31 Jul 2023):

<u>[Revised] Section 12.4</u>: For emergency human biomedical research, at the point of enrolment of each subject, appointed persons should certify 2 conditions are complied with:

(a) the research subjects are in a life-threatening situation &

(e) obtaining appropriate consent is not feasible because –

(i) the subjects will not have capacity within the time available to give their appropriate consent as a result of their medical condition or situation; and,

(ii) the subject's Legal Representative is not available.

<u>[Reminder] Section 12.9</u>: Prior to initiating the study, the Principal Investigator must provide the **DSRB and HSA** with documentation to indicate that this is a clinical trial of emergency situation.

RQM Updates

Proper Conduct of Research (PCR) SOP Reminder #1

Informed Consent Process - What should I document?

The study team member who conducted the informed consent discussion must personally sign and date the consent form and minimally record in the medical records/ source documents:

i) the protocol reference

ii) date of informed consent

iii) informed consent process (e.g. presence of prescribed/ impartial witness/ translator, use of assent form) and

iv) a signed copy was given to the subject.

Reference: 501-C01 Informed Consent Form and Process

Proper Conduct of Research (PCR) SOP Reminder #2

Proper Documentation Practice - Who recorded this?

It is important for source documentation to be attributable (i.e. able to identify the person who made the documentation) so that the data integrity is maintained. Good documentation practice would include signing and dating next to the information recorded or changes made during the study.

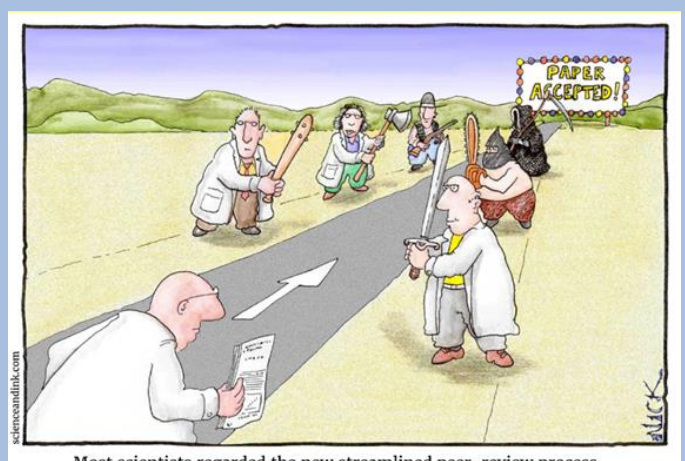
Reference: PCR SOP 501-B05 Documentation

Responsible Conduct of Research (RCR) Reminders

Peer Review *"Peers who are asked to make judgments about the quality of a proposed or completed project must do their best to determine whether the work they have been asked to review is internally consistent and conforms to the practices of their field of research."*

Nicholas H. Steneck ORI Introduction to the Responsible Conduct of Research, Revised Edition August 2007, Chapter 10 Peer Review

Click here to read more on RCR



Most scientists regarded the new streamlined peer-review process as "quite an improvement."

Cartoon from: Science and Ink (https://www.scienceandink.com/jobs_research_scientist.html) with credit to Nick Kim.

Education & Training

Chicken Soup For The Busy Coordinator

- ❑ **May 2023 - Storage/Usage/Supplying of Leftover Human Tissue from Current HBR**
- ❑ **June 2023 - Precautions for Handling and Collecting Biological Specimens during a Pandemic**
- ❑ **July 2023 - DSRB Application Submission: Selection of Domain & Category of Review for Research Studies**

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	
[NEW] **PCR 001**	**Subject Recruitment and Informed Consent** *PCR 001 contains enhanced interactive content & replaces PCR200*
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