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 Updates

Suspension of Recognition for NUS iGCP Course

The course recognition for "Good Clinical Practice (iGCP) for Healthcare Professionals Online Course" conducted by the National University of Singapore (NUS) is currently suspended pending its update on local regulatory requirements*. Do click here for alternate GCP courses recognised by the DSRB.

**To run a clinical trial locally, principal investigators should be knowledgeable about the relevant regulatory requirements, such as the Health Products Act. Thus, when reviewing alternate GCP courses for recognition, the DSRB will consider if teachings on Singapore's regulatory requirements and legal framework for clinical trials is covered in the course.*

Reminder: Requirement to Submit Financial Conflict of Interest (FCOI) Declaration Even if You Had Missed the Annual Declaration Cycle

Investigators and study team members who are involved in the design, conduct or reporting of research that is conducted under the oversight of NHG or its partner institutions should ensure that they have submitted a valid FCOI declaration.

Even if you had missed the 2021 Annual FCOI Declaration Cycle in January, you should submit your declaration to the FCOI Secretariat at DSRB_FCOI@nhg.com.sg if the declaration requirements apply to you.

If the FCOI declaration had not been submitted by any investigator or study team member, the Principal Investigator will need to submit a Non-Compliance Report to report the lapse to DSRB.

Click Here for the FCOI Declaration Requirement and to download the FCOI Declaration Form.

Regulatory updates

MOH Human Biomedical Research (HBR) & Human Tissue Framework (HTF) Decision Tools

MOH had launched 2 Decision Tools to guide stakeholders if their study is a HBR and whether they are conducting tissue banking activities that needs to be regulated. Refer to "Decision Trees" section of MOH HBRA Webpage .

The tools are meant as a guide. You may still wish to check with an IRB on the study classification and approach your research office to understand more about your institution requirements.

Education & Training

Chicken Soup For The Busy Coordinator

- **Apr 2021 - Biological Sample Management**
- **May 2021 - How to Prepare for a Study Review or Audit**

To savour past issues of Chicken Soup, ***CLICK HERE***

Upcoming Proper Conduct of Research (PCR) Courses:

Want to learn how to conduct your research properly?

[PCR 100] Study Start-Up: Budgeting, Case Report Form Design, Database Design
[PCR 200] Study Conduct I: Subject Recruitment & Informed Consent
[PCR 300] Study Conduct II: Documentation, Safety Reporting & Investigational Products
[PCR 400] Monitoring, Audits and Inspections

For course details and registration, please click ***HERE***.

For enquiries, email Research Education at *research_courseadmin@nhg.com.sg*

RQM Updates

Updates to PCR SOPs

The following PCR SOPs had been updated, with changes effective from 7 April 2021:

1. 501-A03 Training and Education
2. 501-B02 Pre-Study Activities
3. 501-C01 Informed Consent Form and Process
4. 501-C02 Subject Recruitment and Screening
5. 599-005 Guidance Document on Electronic Informed Consent Process

Click here to download the documents.

Proper Conduct of Research (PCR) SOP Reminder #1

Why is there a Need to Maintain the Subject Screening and Enrollment Log?

Using the Subject Screening and Enrollment Log, the PI/ study team can track the subjects who had consented to participating in the study. If the subject was eventually not enrolled (e.g. screen failure), the reason may be documented on the log to avoid recruiting the same subject twice.

For studies granted a waiver of consent (e.g. retrospective medical records review), the log may help the PI/ study team to track the records screened and data collected to adhere to the recruitment target.

The PI/ study team may use PCR Document 509-007: Subject Screening and Enrollment Log and edit the template according to the study requirements.

Reference: 501-C02 Subject Recruitment and Screening

Proper Conduct of Research (PCR) SOP Reminder #2

Want to Add a New Co-Investigator or Collaborator in the Study Team?

Before performing any study-related task and procedures, he/ she must:

- Be approved by the IRB – Prevent unnecessary delays by ensuring the CV, CITI or other training evidence is properly submitted.
- Be delegated by the PI – Document the role and responsibilities clearly on the Study Delegation Log and have it endorsed by the PI.
- Be trained for the research role – Document the completion of all relevant study-related trainings.

Reference:

1. 501-A03 Training and Education
2. 501-B03 Study Initiation

Responsible Conduct of Research (RCR)

Research misconduct is defined as:

- **Fabrication** - The deliberate making up of data or results and recording or reporting them.
- **Falsification** - The manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** - The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Researchers and Research Institutions bear the primary responsibility for reporting and investigating allegations of misconduct. To read more, Click Here.