National Healthcare Group
Adding years of healthy life

OHRPP Post-Its

ISSUE 26
OCT 2022

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

Regulatory Updates

HSA Guidance on GCP Compliance Inspection Framework

HSA has updated the Guidance on Good Clinical Practice (GCP) Compliance Inspection Framework to include remote & hybrid approaches to GCP inspections. A summary of other key changes is included in the updated guidance.

HSA Guidance on conduct of clinical trials in relation to COVID-19 situation

Read the revised Guidance on the conduct of clinical trials in relation to the COVID-19 situation to understand:

- How to conduct clinical trials on public health emergency [Section 2]
- How to document contingency measures properly [Section 3.5]
- What to consider before you do a home visit [Section 3.7.8]
- What are the required Sponsor notifications to HSA for contingency measures prior to implementation [Section 4]:
    a) Direct to Patient services for Investigational Product supply;
    b) Remote Source Document Verification plans.

DSRB Reminders

Tips to Expedite the Review of your Study Amendments

DSRB categorises amendments into either Administrative, Minor or Major categories. Major amendments take longer time for approval as they require Department Representative(s) and Institution Representative(s) endorsements and will require a Full Board review. Ref: NHG Investigator's Manual Chapter 4.5.2

If you have 1 minor amendment (ex. adding on a co-investigator) and 1 major amendment (ex. protocol changes that effect the risk-benefit ratio), you can consider submitting the minor amendment first. Ex. To add on a co-investigator into the study team so that you can proceed with recruitment activities quickly. The major protocol amendment can be submitted after the first amendment has been approved.

Annual Financial Conflict of Interest (FCOI) 2023 Declaration Cycle Commencing in December!

The 2023 FCOI declaration exercise will be commencing from 01 December 2022. Researchers and study team members should complete their FCOI declarations and submit it to the FCOI Secretariat by 31 January 2023.

Click Here for the FCOI Declaration Form (version 01 July 2022) and to find out more about the FCOI declaration and training requirements.

Reminder: Submit Study Status Report Form (SRF) for Completed and Terminated Exempt Studies

If you had completed or terminated your exempt study, please inform the DSRB by submitting an SRF. This update will help the DSRB identify when they no longer require active oversight of your exempt study documents and therefore can be archived. Click Here for a guide on how to submit an SRF.

RQM Updates

Proper Conduct of Research (PCR) SOP Reminders #1

If the subject is illiterate, which Informed Consent Form (ICF) should I use?

If the subject is illiterate (i.e. unable to read or write), the consent process must be **communicated in a language understood by the subject**. The impartial witness must ensure that the information in the Informed Consent Form (ICF) and any other written information was accurately explained to, and apparently understood by the subject and that consent was freely given by the subject. Hence, the impartial witness must be able to read and understand the language of the ICF used.

Ex. If subject is illiterate and can converse in Hokkien only, the study team must engage an impartial witness who can read the English ICF and explain it in Hokkien to the subject as part of the informed consent process. Ref: 501-C01 Informed Consent Form and Process

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RQM Updates

Proper Conduct of Research (PCR) SOP Reminder #2

Can my recruitment strategy include:
pre-screening medical records to identify potential participants?

Yes, you can include accessing medical records for pre-screening activities if you have ethically permissible access. Individuals with ethically permissible access may include healthcare professionals involved in the clinical care of a patient (e.g. nurses, doctors, pharmacists, technicians) and designated research staff as described in the DSRB application form. The application form should be endorsed by the department and institution representatives and approved by DSRB. Ref: 501-C02 Subject Recruitment and Screening

Responsible Conduct of Research (RCR)

Mentorship and Trainee Responsibilities

"The ultimate goal of research training is to produce independent researchers who can establish their own research programs, take on trainees, and help research dependent disciplines grow. The mentor's final responsibility to trainees is to help them get established as independent researchers." - Nicholas H. Steneck ORI Introduction to the Responsible Conduct of Research, Revised Edition August 2007, Chapter 7 Mentor and Trainee Responsibilities

Click here to read more on RCR

"Everyone was there to shake my hand, when I won the Spelling Bee, but you were there to hold my hand when I was practicing for the Spelling Bee."

Cartoon by: (Aaron Bacall) https://open-shelf.ca/wp-content/uploads/2016/11/Mentoring-cartoon-Spring-2014-e1478873893406.jpg

Education & Training

Chicken Soup For The Busy Coordinator

- ❑ July 2022 - Research Data Management (Data Collection, Storage and Transfer)
- ❑ Aug 2022 - Subject Management During Covid-19 - The use of e-Informed Consent
- ❑ Sep 2022 - Electronic Filing of Essential Documents
- ❑ Oct 2022 - Using REDCap as Data Collection Tool for Research

*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