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

Submission of Study Status Report to Inform DSRB If Study No Longer Involves Only Data Analysis

Unless otherwise determined by the DSRB, studies that have submitted a Study Status Report Form (SRF) to the DSRB indicating the study status as "Ongoing, Last Participant, Last Visit Over & Only Data Analysis Ongoing" can enjoy a waiver from continuing review once the SRF has been approved. However, PIs of such studies are reminded to inform DSRB immediately, via a SRF submission, once an amendment changes the study status such that it no longer involves only data analysis (e.g. collection of additional data, reactivation of recruitment of subjects).

Click HERE to the NHG Investigator Manual's Addendum for more information.

Reminder: Tracking Subject Enrolment and Number of Medical Records Reviewed/Biological Samples Collected to Prevent Over-Recruitment and Non-Compliance

PIs and Study Teams are reminded to adhere to the DSRB approved number of subjects, medical records and biological samples for their studies. Over-recruitment or collection and use of data/biological samples beyond the DSRB approved number is considered a non-compliance that must be reported to the DSRB. To prevent the non-compliance, PIs and Study Teams should actively keep track of the number of recruited subjects and collected data/biological samples for each study site. If there is a need to increase the sample size, a Study Amendment should be submitted for DSRB approval prior to recruitment of additional subjects or collection of additional data/biological samples.

Click HERE for more information on creating and submitting a Study Amendment to DSRB.

Regulatory updates

HSA's Clinical Trial e-Consent Guidance & CRM Non-Compliance Reporting Form Feature

HSA has published the following on their website:
a. Clinical Trial Guidance on Electronic Consent (downloadable from HSA's website)
b. CRM Notification Non-Compliance Form via FormSG
(https://form.gov.sg/5f0fc43b9e6a4a0011f18fe0)

Should you have further queries or require any clarifications, you may contact HSA at HSA_CT@hsa.gov.sg

IMPORTANT NOTICE: [HSA Clinical Trials] Updates on the Implementation of the Cell, Tissue and Gene Therapy Products Framework (1 Mar 2021)

The Health Sciences Authority (HSA) has introduced a new category of health products to be regulated under the Health Products Act, namely, cell, tissue and gene therapy products (CTGTP). The new controls take effect on 1 March 2021. The new and amended regulations i.e. the **Health Products (Cell, Tissue and Gene Therapy) Regulations 2021, Health Products (Clinical Research Materials) Regulations 2021 and Health Products (Clinical Trials) Regulations 2021** can be found on the Singapore Statutes Online website**.**

HSA had also updated the regulatory guidance to reflect changes resulting from the implementation of the CTGTP framework. All clinical trial regulatory guidance can be found on the HSA website.

RQM Updates

Proper Conduct of Research (PCR) SOP Reminder #1

Informed Consent Form (ICF) - Should A Complete Copy Of The Signed ICF Be Filed In The Investigator File?

Principal Investigator (PI) and designated staff should ensure that the research study information (hardcopy or electronic) is recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

As such, a complete copy of the signed ICF (i.e. study information and signed consent page) should be filed in the investigator file so that the study team can verify the information that was provided to the subject during the actual consent process.

Reference: 501-B05 Documentation

Proper Conduct of Research (PCR) SOP Reminder #2

What Type Of Trainings Should Be Completed Before A Study Team Member Can Commence Study Activities?

Trainings to be completed would depend on the study role (e.g. Principal Investigator, Co-Investigator, Study Coordinator) and responsibilities to be delegated to the study team member. Trainings could include (but not limited to):

1) Minimum training requirements set by the IRB [e.g. Collaborative Institutional Training Initiative (CITI), Good Clinical Practice (GCP), Financial Conflict of Interest (FCOI) training]

2) Minimum training requirements set by the Research Institution (RI) where the study is conducted [e.g. Human Biomedical Research Act (HBRA) minimum training]

3) Protocol specific training (e.g. protocol requirements, recruitment and informed consent process)

4) Additional relevant training or certification which would be required to support the delegated responsibilities (e.g. phlebotomy course, equipment training)

All completed trainings should be documented and filed in the investigator file.

Reference: 501-A03 Training and Education

Responsible Conduct of Research (RCR)

"If something doesn't smell right or it's something you have to hide, stop doing it. Seek wise counsel before proceeding."

To find out more about RCR, click HERE.

Education & Training

Chicken Soup For The Busy Coordinator

- **Dec 2020 - Pointers for Electronic Consent (e-Consent)**
- **Jan 2021 - Database Collection and Database Maintenance**
- **Feb 2021 - E-investigator file- How & where to maintain it**
- **Mar 2021 - Mentor & Trainee Relationship (RCR)**
- **Apr 2021 - How to collect & handle biological samples? What information needs to be included/ excluded?**

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

Want to learn how to conduct your research properly?
Contact the Research Education team to enquire about
PCR (Proper Conduct of Research) Workshops.
Email: research_courseadmin@nhg.com.sg