National Healthcare Group
Adding years of healthy life

# OHRPP Post-Its

ISSUE 25
JUL 2022

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

## DSRB Updates

### #1 Annual Financial Conflict of Interest (FCOI) Declaration

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.

Please submit your FCOI declaration Form to the FCOI Secretariat at DSRB_FCOI@nhg.com.sg if:

a. You had missed the 2022 Annual FCOI Declaration Cycle in January, or

b. There had been a change in your FCOI declaration status

If there was a lapse in the submission of the Annual FCOI Declaration, the Principal Investigator would need to submit a Non-Compliance Report to report the lapse to DSRB.

### #2 All Translated Informed Consent Forms (ICFs) & Study Documents DO NOT NEED to be submitted to DSRB

All translated ICFs and study documents (ex. posters, flyers, brochures, patient diaries/cards, questionnaires, assessments etc.) will not need to be submitted to DSRB for acknowledgement. Study teams may track the use of translated study documents using the PCR Template 509-018 Study Documents Translated Tracking Log. Study teams must ensure that the letter of certification from the translator or translation service (if any) are kept in the Investigator File.

## RQM Updates

### Proper Conduct of Research (PCR) SOP Reminder #1

#### Can Subject Logs (e.g. Screening and Enrolment Log, Subject Identification Log) Be Maintained Electronically?

The study team 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. Therefore, it is important to maintain an audit trail and ensure information is attributable and adequate (i.e. sufficient information to reconstruct/support study events).

Hence, it is recommended to maintain hard copies wherever possible. If the essential documents are needed to be maintained electronically but the system used is unable to support functions like audit trail, the study team can consider to review, print and verify (i.e. sign and date) the information regularly to ensure this.

**Reference:**

1. 501-B05 Documentation

### Proper Conduct of Research (PCR) SOP Reminder #2

#### What Should I Do When My Study Team Member Leaves?

The PI may delegate study-related tasks to qualified/trained research study team members. When a study team member leaves the study team, the PI should:

- Ensure the study team member's end date of involvement in the study is indicated and authorised (by the PI) on the Study Delegation Log
- Submit an amendment to inform the IRB (if applicable)
- Remove the study team member's access to electronic systems and study team supplies/ documents
- Adequate handover and/or identify replacement of duties (where necessary)

**Reference:**

1. 501-A02 Responsibilities of the Research Team
2. 501-B03 Study Initiation

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## RQM Updates

### Responsible Data Management Practices

Integrity in the collection, use, and sharing of data is a fundamental element of responsible research conduct.

Durable records derived from the research (e.g. laboratory and field notes and transcripts, etc.) must be retained and remain accessible in order to justify the research outcomes.

When in doubt on data management requirements, do refer to institutional data policies or funding agencies for advice.

Click here to read more on Data Management

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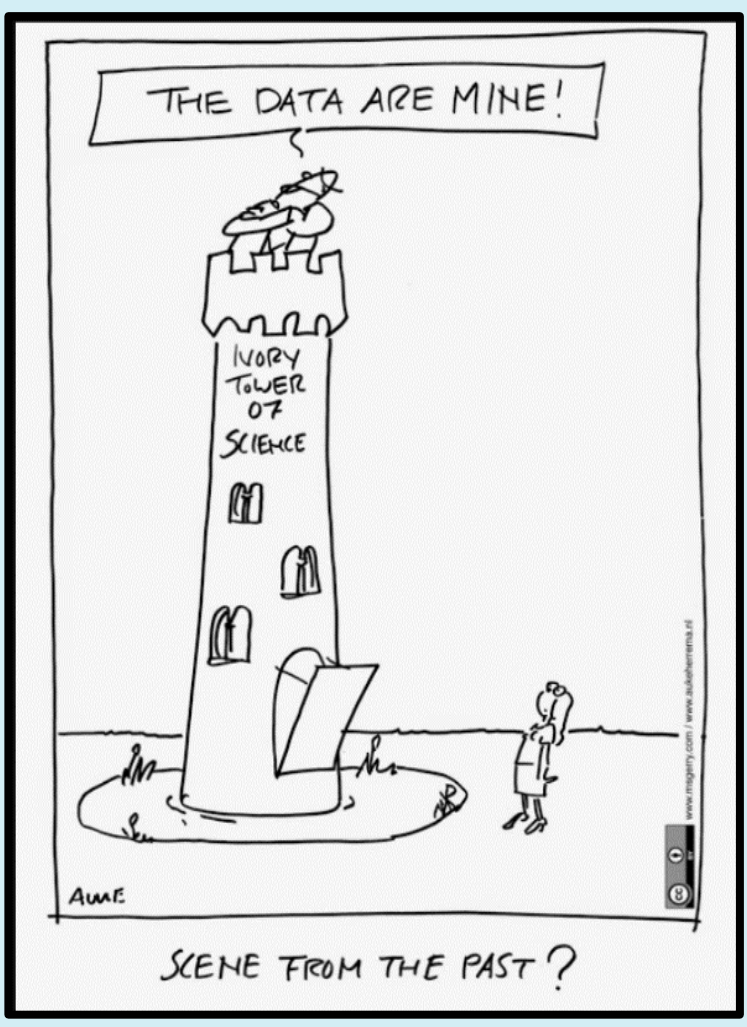


## Education & Training

### Chicken Soup For The Busy Coordinator

- Mar 2022 - Responsible Conduct of Research (RCR) - Research Misconduct
- Apr 2022 - Changes to Assent requirements and Documentation –How Does It Impact Your Study?
- May 2022 - How to Handle Leftover Tissues for Future Unapproved Research and Legacy Human Biological Material (LHBM)
- June 2022 - The Responsibilities of PI, Co-I and Clinical Research Coordinators

*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:**<br>**Case Report Form Design, Database Design, Using REDCap & Budgeting** |
| **PCR200** | **Study Conduct I:**<br>**Subject Recruitment & Informed Consent** |
| **PCR300** | **Study Conduct II:**<br>**Documentation, Safety Reporting and Investigational Product (IP)** |
| **PCR400** | **Monitoring, Audits and Inspections** |

*NHG Staff may self-register for direct access on NHG eLEARN Marketplace.*
*For enquiries, email: research_courseadmin@nhg.com.sg*