National Healthcare Group
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OHRPP Post-Its

ISSUE 24
APR 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

Update to DSRB Informed Consent Form (ICF) Template

DSRB has added a new paragraph at the end of the ICF template to inform subjects on the use of e-consent (i.e. use of electronic signatures).

- It is a generic statement and can be used in all ICFs.
- Existing studies using e-consent are strongly encouraged to submit a Study Amendment to update their ICFs with this additional statement.
- All new DSRB study applications should craft their ICF using the latest DSRB ICF Template [Doc No. 207-001] (Version 13, Dated 31 January 2022).

Reminder: Assessing and Managing Incidental Findings (IFs) in Human Biomedical Research (HBR) Regulated by the Human Biomedical Research Act

Principal Investigators and study teams planning to conduct HBR studies are reminded to assess if there is a possibility of IFs and develop a study-specific IF Management Plan that is aligned with your institution's IF policy. To ensure appropriate and sufficient information about the IF Management Plan is provided to DSRB for review, please read the NHG Guidance Document on Management of Incidental Findings. This would minimise queries and help to expedite the DSRB review process.

For researchers from non NHG institutions, do contact your Research Office/Clinical Research Unit for a copy of your institution's IF policy.

RQM Updates

Updates to Proper Conduct of Research (PCR) SOPs: Changes to Assent Requirements and Documentation

With effect from 01 Mar 2022,

i. Minors who are **12 years old and above**, with sufficient understanding and intelligence should sign the ICF together with consent from their legal representative.
ii. Assent should be obtained from minors who are **6 years old and above (including those above 12 years old if they lack of sufficient understanding and intelligence)** together with consent from their legal representative).
iii. Where possible, the child should **personally** write his/ her name and assent date in the assent form.
iv. If the child is unable to personally write his/ her name and/or date on the assent form, the child could **affix his/her thumbprint** (where possible). The **impartial witness** (i.e. not a member of the study team) should complete the child's name and/or assent date, personally sign and date on the assent form and an explanation should be documented in the source documents (e.g. assent form, medical records).

All new studies approved and ongoing studies requiring assent to be obtained from **01 Mar 2022** should follow the revised requirements. Study teams are not required to retrospectively apply the assent documentation requirements if the minor has provided assent before 1 Mar 2022.
It is also recommended that where possible, PIs and study teams should engage an independent assessor to determine whether the child (aged 12 years old and above) has sufficient understanding and intelligence to provide consent.

Please refer to PCR SOP 501-C01 Informed Consent Form and Process and 207-008 DSRB Assent Form Template for more details.

Proper Conduct of Research (PCR) SOP Reminder #1

Informed Consent Process - When is a Prescribed Witness required?

If you are conducting a Human Biomedical Research (HBR) study that is regulated by the Human Biomedical Research Act (HBRA), appropriate consent must be taken in the presence of a prescribed witness.

The requirement for a prescribed witness can be exempted if:

(A) the research is **NOT** invasive and **NOT** interventional and **NOT** Restricted HBR

or

(B) the research is invasive and/or interventional, but

- The intervention involves no more than minimal risk to the research subject;
- The research subject is able to read and sign the appropriate consent form; and
- The research is not restricted HBR

Note: For a HBR study where the subject is unable to read/ understand the language of the Informed Consent Form (ICF), the presence of the witness should also fulfil the impartial witness requirements.

Reference: PCR SOP 501-C01 Informed Consent Form and Process

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Proper Conduct of Research (PCR) SOP Reminder #2

Proper Documentation Practice: How should study documents be amended?

Where a change or correction to study documents (e.g. essential documents, DCFs / CRFs & source documents) is required, the change should be made without obscuring the original data. For example, crossing out the original entry with a single line and not using any correction fluid/ tape.

The person making the correction should also initial and date against the change. Where necessary, the change should also be explained.

For more information on documentation, please refer to PCR SOP 501-B05 Documentation.

Responsible Conduct of Research (RCR)

Conflict of Interest.

Due to the complex and demanding nature of research today, researchers' interests and obligations could often be conflicted. Researchers are expected to serve on committees, mentor junior researchers, provide feedback on manuscripts etc. whilst pursuing their own research. It is important to understand that conflicts of interests are not inherently wrong. However, steps should be taken to ensure that conflicts do not interfere with the responsible conduct of research.

https://www.megapixl.com/conflict-management-illustration-49225576
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Click here to read more on Conflict of Interest.

Education & Training

Chicken Soup For The Busy Coordinator

- Oct 2021 - When Is Re-consenting of Research Subjects Needed?
- Nov 2021 - Common Findings related to Investigational Product (IP) Management
- Dec 2021 - When and How to Register for a Standing Database
- Jan 2022 - Safety Event Reporting Guidelines to DSRB
- Feb 2022 -Informed Consent Process during COVID-19 Period

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PCR100	**Study Start-Up:** **Case Report Form Design, Database Design, Using REDCap & Budgeting**
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PCR300	**Study Conduct II:** **Documentation, Safety Reporting and Investigational Product (IP)**
PCR400	**Monitoring, Audits and Inspections**

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For enquiries, email: research_courseadmin@nhg.com.sg