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

Activities that Do Not Require IRB Review

Research that requires IRB review: Activities that involve systematic investigation and are designed to develop or contribute to generalisable knowledge

Research that does not require ethics oversight: (Examples)

a. Case reports of less than 3 subjects

b. Outbreak investigations e.g. to determine the source of the outbreak and take actions to prevent and control transmission of the disease

c. Quality Assessment (QA)/Quality Improvement (QI) projects – if it doesn't meet the definition of research and there are no additional risks/burdens identified by the QA/QI checklist

For more information, please refer to the NHG Investigator Manual (Chapter 1.5) on the determination of whether a study would require IRB review and the MOH guidance document on Table Differentiating Research from Research-like Activities.

Alert: Financial Conflict of Interest (FCOI) 2022 Declaration Cycle is Starting!

The annual FCOI declaration exercise where you will be required to declare your FCOI status for the year 2022 will be commencing between 01 Dec 2021 & 31 Jan 2022.

Click Here to download the latest FCOI declaration form (version 30 November 2020) and to find out more about the FCOI declaration and training requirements.

RQM Updates

Updates to Proper Conduct of Research (PCR) SOPs

The following PCR SOPs have been updated and effective from 12 Nov 2021:
- 501-A02 Responsibilities of the Research Team
- 501-B02 Pre-Study Activities
- 501-B05 Documentation
- 501-B06 Investigational Product Accountability
- 501-B07 Study Conduct - Monitoring
- 501-B10 Handling Audits

Click here to download the documents.

Proper Conduct of Research (PCR) SOP Reminder #1

Informed Consent Form (ICF) - Tracking of translated Informed Consent Forms and Short Consent Forms.

Today, translated ICFs & Short Consent Forms may be used without DSRB approval.

The PI is responsible to verify the accuracy and completeness of each of these translated forms prior to use.

The PI may use or modify the PCR Document 509-017 ICF Tracking Log to list and track the different translated documents that the study team may use for consenting.

Reference: 501-C01 Informed Consent Form and Process

Proper Conduct of Research (PCR) SOP Reminder #2

What should I do when my study has completed/ terminated?

The Principal Investigator (PI) should inform the relevant parties, including the IRB, Regulatory Authority (if applicable) or Institution Research Office (if applicable).

The PI/ study team may refer to PCR Document 504-004: Study Closure Checklist for a list of study closure activities.

Additionally, if the PI intents to keep the research data &/or human tissue for future use, the PI should follow institutional and regulatory requirements for retention.

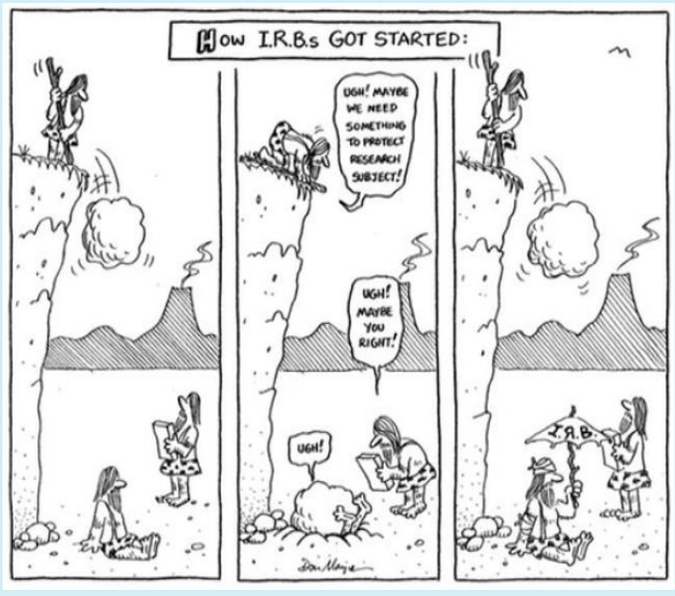
Reference: 501-B09 Study Completion Activities

Responsible Conduct of Research (RCR)

Protection of Human Subjects

The protection of human research subjects require that the evaluation of research applications involving human subjects, take into consideration the risk to subjects, the adequacy of protections against risk, potential benefits of the research to subjects and others, and the importance of the knowledge to be gained. The protection of human research subjects is a collective effort of the researchers, IRB(s) and institutions where research is conducted.

To find out more about RCR, Click Here.



Cartoon by Don Mayne www.researchcartoons.com (ahrecs.com/latestnews/friday-afternoons-funny-research-ethics-committees-got-started/)

Education & Training

Chicken Soup For The Busy Coordinator

- ❑ **Jun 2021 - Pre-screening/ Screening Process: Documentation and the Use of Subject's Identifiers**
- ❑ **Jul 2021 - Minimum Training Requirements for PI and Study Team Conducting Human Biomedical Research (HBR)**
- ❑ **Aug 2021 - Impartial Witness & Witness In Informed Consent-Taking For HBR Studies**
- ❑ **Sep 2021 - How to conduct and document E-SIV**

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