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

All Translated Documents No Longer Required To Be Submitted To DSRB

With effect from **19 Oct 2020**, all translated documents (such as posters, flyers, brochures, patient diaries/cards, questionnaires, assessments, etc.) will not need to be submitted to DSRB for acknowledgement. The study team may track the use of translated study documents using PCR Template 509-018 Study Documents Translated Tracking Log.

Click here for the website announcement.

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

If you are a Principal Investigator (PI) or part of a study team planning a HBR, you will need to assess whether there may be IFs arising from the intended research. Develop an IF management plan that is aligned with your institution's IF policy and submit this plan as part of your DSRB application for review. If you need help on what to include, refer to the NHG Guidance Document on Management of Incidental Findings. To expedite the review process, please ensure that an adequate management plan is presented to the DSRB.

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

Reminder: Reporting Multiple Non-Compliance Events/Study Deviations in a Single Non-Compliance/Study Deviation Report (NCR) Form

If you have multiple non-compliance events and/or study deviations to report to DSRB, do consolidate and submit it in a single Non-Compliance/Study Deviation Report (NCR) Form. This will save time in reporting.

RQM Updates

Updates to PCR SOPs

The following PCR SOPs have been updated and effective from 22 October 2020:
- PCR SOP 501-B08: Data Collection and Handling

Click here to download the documents.

Education & Training

Chicken Soup For The Busy Coordinator

- ❑ **Jun 2020 - Performing Subject Eligibility Assessment & Documentation**
- ❑ **Jul 2020 - Ensuring Data Integrity With Principles Of Good Documentation**
- ❑ **Aug 2020 - Study Submission & Interaction with DSRB. How to Reduce The Number of Queries?**
- ❑ **Sep 2020 - Remote Source Document Verification (SDV) Requirements**
- ❑ **Oct 2020 - Should CRCs keep (maintain) identifiers of patients who did not consent to study participations?**

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

Proper Conduct of Research (PCR) SOP Reminder #1

Study Documentation - Who's signature is this?

Study documentation must be attributable to allow accurate reporting, interpretation and verification of study information. As such, part of the function of a Study Responsibility/ Delegation Log is to document the signatures of study team members so that study procedures and/or documentations completed by specific study team member may be verified. If different signatures (e.g. long and short signatures) are used interchangeably by an individual, it is strongly recommended to include the different signatures in the Study Responsibility/ Delegation Log.

Reference: PCR SOP 501-B03 (Study Initiation)

Proper Conduct of Research (PCR) SOP Reminder #2

Subject Eligibility Assessment - What should you document?

Eligibility assessment documentation is important as it records the study team's effort in ensuring that a potential subject meets the study eligibility criteria. Generally, documentation should be able to clearly identify the following:

a. Who conducted the eligibility assessment
b. When the eligibility assessment was completed
c. Whether subject met all the eligibility criteria (as stated in the current approved protocol)
d. The diagnostic test(s) (type / date of tests / results) used to assess the subject's eligibility – if any.

Study teams can consider using an Eligibility Checklist (PCR template 504-008) to complete the eligibility assessment documentation.

Reference: PCR SOP 501-B05 (Documentation)

Upcoming Proper Conduct of Research (PCR) Courses
Blended Learning: Monthly Online Courses + Workshop

Virtual Workshop Dates	Course Title
Monthly Online Course *Register by 15th of the Month* *(FY21 Workshop Date TBA)*	**[PCR100] Study Start-Up: Budgeting, Case Report Form Design, Database Design**
Monthly Online Course *Register by 15th of the Month* *(FY21 Workshop Date TBA)*	**[PCR200] Study Conduct I: Subject Recruitment & Informed Consent**
23 Feb 2020 ***Registration closes 15 Dec 2020***	**(PCR 300) Study Conduct II: Documentation, Safety Reporting & Investigational Products***
7 Jan 2021 ***Registration closes 15 Nov 2020***	**(PCR 400) Monitoring, Audits and Inspections***

**Virtual Classrooms may be converted back to Physical Classroom Workshop if the Covid-19 situation & HR policies allow.*

*For course registration and more details, please click **HERE**.*