

# CHICKEN SOUP FOR THE BUSY COORDINATOR

Sep 2018

## ENSURING TIMELY SUBMISSION OF STUDY STATUS REPORT TO THE IRB FOR STUDY RENEWAL

### Scenario:

Dr B is the Principal Investigator (PI) for an investigator initiated study. At a weekly meeting with the clinical research coordinator (CRC) for the investigator initiated study, the PI realised that the study's approval period has lapsed. The study status report was not submitted to the NHG DSRB for the continuing review of the study. The study was in the "Enrolment Closed, Subjects Follow-up" phase. Although there were no further study activities performed after the expiry date of the study, the CRC highlighted the importance of timely submission and approval of renewal from the DSRB for all on-going studies. Therefore, the study status report should be submitted to the DSRB as soon as possible.

### When is a Continuing Review required?

Continuing review is required as long as individually identifiable follow-up data are collected from subjects enrolled. The DSRB/IRB will conduct continuing review of ongoing research at intervals appropriate to the degree of risk, but not less than once per year.

### Who should submit the study status report and when should it be submitted?

The PI or qualified designees are required to submit a completed NHG DSRB Study Status Report Form at least 4 to 6 weeks before the study approval period ends.

### What happens when the study has expired or there has been a lapse in ethics approval?

If the study approval expires, no research activities, including screening, enrolment, interventions, interactions and collection of identifiable data can occur after the expiry date, until the continuing review application has been approved by the DSRB/IRB, or unless the PI determines that it is in the subjects' best interest to continue their participation in the research study and specific permission for this had been granted by the DSRB. If study activities were performed past the expiry date of the study's approval period, a non-compliance report must be submitted to the DSRB.

### Here are some tips for CRCs to assist their PIs in the timely submission of the study status report

- Set 2 reminders in the outlook calendar and the mobile phone calendar, at the 8<sup>th</sup> week and 6<sup>th</sup> week prior to the study's expiry date. This will allow time for the PI to review the study status report (drafted by the CRC) before submitting it to the DSRB.
- Look out for the reminder email sent by the NHG ROAM system for the submission of the study status report form for the related study.
- When the reminder email is received, immediately start drafting the status report and inform the PI to review the draft for submission.

**Note: Changes to Continuing Review Requirements for Studies at Data Analysis Stage – For Studies Submitting to NHG DSRB** [\[OHRPP Post-Its, Issue 11, Aug 2018\]](#)

With effect from 15 Aug 2018, unless otherwise determined by the DSRB, studies that have submitted a Status Report Form indicating the study status as "Ongoing, Last Participant, Last Visit Over & Only Data Analysis Ongoing" can enjoy a waiver from continuing review. The study team will only need to submit the study Status Report Form when the study is completed. The PI must continue to report non-compliances, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSTOs) and study amendments to the DSRB.

### Reference:

- NHG Investigator's Manual 3<sup>rd</sup> Edition Chapter 4.6 : Continuing, Chapter & 4.9: Changes in Study Status
- NHG Proper Conduct of Research Standard Operating Procedures: 501-B04 interaction with Domain Specific Review Board

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*\*Disclaimer: Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. IRB practices or requirements for continuing review may differ between different clusters/ institutions. Readers are encouraged to follow their approving IRB's policies/guidelines relating to the above scenario/ case study.*