CHICKEN SOUP FOR THE BUSY COORDINATOR

August 2016

Tips on how a CRC can help ensure that protocol and ICF amendments are implemented after DSRB approval

During the course of the research study, protocol amendments may be made to protect the safety and welfare of the research subjects, and/or improve the scientific validity of the study.

Scenario

For trial XYZ, a protocol and informed consent form (ICF) amendment was submitted to DSRB on 10 May 2016 to include a major amendment, which involved the drawing of an additional blood sample for a biochemistry test. The amendment was approved on 06 July 2016. However on 22 June 2016, a trial participant Mr Tan returned for his follow up visit. Mr Tan was re-consented using the amended ICF, and an additional blood sample was drawn from him. As the amended ICF and additional study procedures had not yet been approved by DSRB at the time of the study visit, this resulted in a protocol non-compliance.

What could the CRC have done to prevent this non-compliance?

- Print all protocol amendments and ICFs only after receiving DSRB approval.
- Replace all old versions of the protocol and ICF in the working file with the most current DSRB-approved versions.
- Carefully review and understand the changes in the amendments submitted to, and approved by DSRB.
- Provide adequate training for all study team members on the revised protocol and ICF. All trainings should be recorded in training logs.
- All protocol and ICFs should be version-tracked and entered into a 'Protocol and ICF version tracking log'.

References

ICH Guideline for Good Clinical Practice E6R(1)
NHG Investigator's Manual (2nd Edition) & Addendum

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