CHICKEN SOUP FOR THE BUSY COORDINATOR

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STUDY AMENDMENTS – GETTING APPROVALS AND ENSURING UPDATED STUDY DOCUMENTS ARE USED

Scenario:

Dr ABC, made some major changes to the clinical research protocol, consent documents and questionnaires that are used in his research study. He approached the clinical research coordinator (CRC) for assistance on the ethics approval and submission process for the amended study documents.

Below are some of the pointers mentioned by the CRC:

Ethics Submissions

- Any anticipated protocol amendments, regardless of its significance - minor, major or administrative, these amendments should be submitted to NHG DSRB (or relevant approving IRB).

Prior to Implementation of Protocol Amendments

- Obtain written approval from the NHG DSRB / IRB **prior** to the implementation of the amendment (except where necessary to eliminate apparent immediate hazard(s) to the research participants).
- Provide adequate training for all study team members on the changes made to the protocol and other documents (and all trainings should be recorded on the Training Record Form).

***Note**:* For Clinical Trials regulated by the Health Sciences Authority (HSA); ^substantial amendments (e.g. protocol amendments) must be submitted and approved by HSA prior to its implementation. Please refer to the Guidance on Determining Whether an Amendment to a Clinical Trial is a Substantial Amendment for further details. *(^Substantial amendments to a clinical trial have the potential to affect the benefit-risk assessment of the trial, they should be subjected to a review process similar to the initial clinical trial application and must not be implemented before approval or acceptance of notification by HSA, unless it is an urgent safety measure.)*

Best Practices to Ensure Updated and Approved Study Documents Are Used

- All protocol, ICFs and other study documents submitted should be version-tracked. Use a tracking log to track amended protocol/ICF versions to avoid discrepancies.
- Supersede old versions of the protocol and ICF with the most current approved versions.
- Print all protocol amendments and ICFs after receiving DSRB / HSA (if applicable) approval.

References:

1) NHG Investigator's Manual 3rd Edition, Chapter 4.5: Study Amendments
2) NHG PCR SOP (501-B04): Interactions with Domain Specific Review Board

Addition reading:

1) ICH Guideline for Good Clinical Practice E6R2 (8.2: Before the Clinical Phase of the Trial Commences)
2) Health Sciences Authority Frequently Asked Questions

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