CHICKEN SOUP FOR THE BUSY COORDINATOR

APRIL 2020

WHAT SHOULD BE DONE IF STUDY PROCEDURE(S) ARE NOT CONDUCTED IN ACCORDANCE TO IRB APPROVED PROTOCOL

Dr Ken is the Principal investigator (PI) for Study XYZ, which is his inaugural research study. The study protocol had been approved by the DSRB for the required the collection of subjects' height, weight and blood pressure. Further on in the study, Dr Ken realized that he also required additional data (glucose readings for comparison). Hence, he performed finger prick tests for all the subjects to collect their blood glucose levels for this study.

At a monitoring visit, the study monitor noticed the additional finger prick test which had not been approved by the DSRB. The study monitor recommended Dr Ken to submit a Non-Compliance/Study Deviation report for the additional finger prick test as well a study amendment to include it as an additional study procedure (as he required the additional data).

How could Susie the Clinical Research Coordinator (CRC) assist Dr Ken in fulfilling the recommendations?

❖ **Assist Dr Ken in submitting a Non-Compliance/ Study Deviation Report via ROAM**

The Non-Compliance/ Study Deviation report should be submitted to the DSRB as soon as possible, but not later than 14 calendar days after first knowledge by the investigator.

Definition: NON-COMPLIANCE is a failure by an investigator or any study team member to abide by the DSRB policies and procedures, GCP guidelines or applicable regulations governing the protection of human subject research.

❖ **Assist Dr Ken in submitting a Study Amendment via ROAM**

The study amendment submission must include (but is not limited to) the following:

- A duly completed ROAM Study Amendment Cover Note (including summary and rationale of amendments);
- Amended documents (both tracked and clean versions);
- Any other documentation that the DSRB may specifically request; and
- Any other relevant documentation to be given to subjects when, in the judgment of the DSRB, the additional information would add meaningfully to the protection of the rights, safety and/ or well-being of the subject.

NB: Collection of additional data or implementation of new procedures can only start after obtaining DSRB (IRB) approval.

What other areas could Susie help Dr Ken with?

- ✓ **Investigator File –** Document and file all study submissions, approvals and relevant correspondence.
- ✓ **Informing and Training of additional study procedure to study team –** After approval had been received from DSRB, Dr Ken should inform his study team on the additional study requirement and ensure that training would be provided to study team members delegated with the task (finger prick).
- ✓ **Study Responsibility / Delegation log –** Update the log for study team member delegated to carry out the finger prick test.

REMINDER: The PI should not implement any deviation from or changes to the protocol without agreement by the sponsor and prior review and documented approval from the DSRB, except where necessary to eliminate an immediate hazard(s) to subjects.

Reference:

- NHG Investigator's Manual 3rd edition, Chapter 3.3.5 – Compliance with the Protocol, Chapter 4.5 – Study Amendments, Chapter 4.8 – Non-Compliances / Study Deviations
- NHG Addendum to Investigator's Manual 3rd edition, Chapter 4.8 – Non-Compliances / Study Deviations

Additional Reading:

- ICH GCP E6 R2 Guidelines, 2016
- NHG Proper Conduct of Research SOP, 501-A02: Responsibilities of Research Team, 501-A03: Training and Education, 501-B04: Interactions with DSRB

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

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