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When Is Re-consenting of Research Subjects Needed?

Scenario

Principal Investigator, Dr. Liam, has recruited 40 subjects for his Clinical Research. He plans to extend the study with additional 4 study visits. He has amended the study Protocol and Informed Consent Form (ICF). However, he is unsure if re-consenting is needed. He consulted DSRB and was advised on the following:

Investigators must inform subjects of any important new information that may affect their willingness to continue participation. The DSRB must approve the method of notification prior to implementation. The method may include, but is not limited to any of the following,

a. Information Letter
b. Addendum to previously signed consent form to be signed by subject
c. Revised consent form to be signed by subject

Fresh consent from the subject would be required if existing personal data collected is to be used for a different purpose after July 2014. DSRB approval on the revised consent document needs to be obtained prior to that re-consenting.

Therefore, Dr. Liam should put up a study amendment to inform DSRB of the Protocol & ICF changes.

DSRB Study Amendment Form

In the DSRB Study Amendment Cover Note section, he should state the following:

Will the enrolled study participants be informed of these changes?

- Yes

Will the enrolled study participants be re-consented?

- Yes, enrolled study participants will be informed of the changes in the ICF and will be re-consented using the revised ICF (after approval of DSRB and HSA) on their next visit prior to implementation.

As a general rule, any change in the risk/benefit profile that would significantly impact the participant's willingness to participate in the study will require re-consent.

However, not all changes to the informed consent document requires re-consenting of participants. Changes such as correcting grammatical or typographical errors generally do not require re-consent.

NB: Informed consent is not a one-time single event prior to enrolling research subjects, but must be a continuous ongoing process.

References

1. NHG investigator manual 3rd Edition Sept 2017 Page 26
2. NHG PCR SOP 501-C01 Informed Consent Form and Process Page 7

Additional References for Clinical Trial

1. ICH GCP E6 (R2) 4.8.2 Informed Consent of Trial Subjects
2. https://www.hsa.gov.sg/clinical-trials/conducting/informed-consent

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