CHICKEN SOUP FOR THE BUSY COORDINATOR

AUGUST 2020

Study Submission & Interaction with DSRB – How to Reduce The Number of Queries?

Scenario:

Due to the COVID-19 situation in Singapore, Dr Charlie, the Principal Investigator (PI), would like to change the mode of reimbursement to study participants from physical vouchers to electronic payment. After discussion with the necessary departments, he managed to obtain approval from his institution for electronic reimbursement (payment mode) to research participants. Dr Charlie would now need to submit a study amendment to amend the DRSB application form, study protocol and informed consent forms.

However, due to the nature of his study and tight study timeline, Dr Charlie was unable to halt study recruitment. Hence, Dr Charlie used the current approved informed consent form for recruitment. During consent-taking; he would inform participants regarding the change in payment mode and amended the payment mode under the "*Costs & Payments if Participating in the Study*" section of the informed consent form with his initials and date, before the informed consent forms were signed by him and the participants. Dr Charlie's study Clinical Research Coordinator (CRC) found out that he was amending consent forms and informed him that it was incorrect for him to do so. The CRC advised Dr Charlie to submit a non-compliance report and submit an amended informed consent form to the DSRB for approval before using them.

How could the CRC assist Dr Charlie (PI) in submitting the DSRB Study Amendment and Non-Compliance Report with minimal queries from the DSRB?

Tips to Speed Up the DSRB (Study Amendment) Approval Process

- To assist PI with amending the DSRB application form, study protocol and informed consent forms accordingly, then submit to DSRB for approval as soon as possible:
  - Ensure that the version number and date of the amended documents are correct
  - Ensure the tracked and clean versions of the amended documents are submitted
- To explain clearly how the new mode of reimbursement works in the DSRB application form
  - As approved by the relevant departments in the institution
- Ensure that all required elements of the ICF is included in the PIS (Participant Information Sheet).
- To state the rationale for all amendments made in the cover note of the amendment application form.
- *Optional: To upload an amendment summary to summarize the changes made in documents and application form for easy checking by DSRB.*
- If necessary, the CRC could arrange for a discussion between DSRB and the PI to clarify queries so as to expedite the review process.

Tips for Reporting Non-Compliance to DSRB and Corrective Actions

- To assist with drafting of the non-compliance report for PI to submit to DSRB at the soonest, no more than 14 calendar days after first knowledge by the PI.
- To clearly explain the situation for the need of immediate subject recruitment and the informed consent process of informing the patients of the amendments.
- Re-consent patients with the updated informed consent form when patients come back for follow-up visits.
- Proper documentation of the recruitment process.

Reminder:

- The PI should adhere to the approved protocol unless the change is necessary to eliminate an immediate hazard to the research participants.
- All study amendments must be approved by the DSRB. The PI may implement these changes only after written approval from DSRB has been obtained.

References:

1. *NHG Investigator's Manual, 3rd Edition; Chapter 4.5 Study Amendments and Process*
2. *NHG Addendum to Investigator's Manual, 3rd Edition*
3. *NHG PCR 501-B04 Interactions with Domain Specific Review Board*

Additional References:

1. *NHG PCR 501-CO1 Informed Consent Form*

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