NHG RESEARCH EDUCATION

Qualité

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Common Observations from Monitoring visits: Documentation of Informed Consent

The NHG Monitoring Framework for HBR

The NHG Monitoring Programme for HBR Full Board studies had been implemented since 02 April 2018. This is a collaborative programme between the NHG Institutions and NHG Research and Development Office. The monitoring programme comprises of on-site monitoring and remote monitoring.

Scope of Monitoring

The scope of an on-site monitoring visit may include but is not limited to the review of: signed informed consent forms and documentation of consent, eligibility of newly enrolled patients, source documentation (e.g. medical records, data capture forms), verification of case report forms/database, study team training and qualification and investigator files.

Remote monitoring is carried out by the institutional monitor and has the same scope as an on-site visit. The difference lies in that it does not require the institutional monitor to physically review the files and source documents, but rather perform a remote evaluation and discussion with the study team members.

Common Errors

Two common errors associated with the informed consent process are highlighted below:

Signed Informed Consent Form (ICF) discrepancies

Example 1: Different signatures were used by the subject on the English ICF and the translated short consent form.
The PI or study team member delegated to take consent should ensure that the signature provided by the subject is consistent throughout the ICF.

Example 2: The date signed by the impartial witness (i.e. 13Jul2018) on the ICF was different from the date signed by the illiterate subject and investigator (i.e. 12Jul2018).
The purpose of an impartial witness is to attend the informed consent process if the subject or subject's legal representative is illiterate. Their role is to ascertain that the study is explained to the patient accurately and that the subject understands the information that was given. The impartial witness should personally sign and date the consent form at the same time and day when the consent process was being conducted.

Example 3: The subject was consented using the ICF appended with the Chinese Short Consent Form. However, only the Chinese short consent form was signed and dated by the subject. The English ICF was not completed.

The investigator or delegated study team member conducting the consent should ensure that the subject signs both the DSRB-approved English language ICF and the translated short consent form.

Documentation of the informed consent process was not done

Example: The informed consent process was not documented in the medical records or other source documents.

The study team member who conducted the informed consent discussion must minimally record the protocol reference, date of informed consent, informed consent process (i.e. use of impartial witness/translator, verification of the appropriate legal representative for consent), as well as the fact that a copy was given to the subject in the subject's medical record.

Informed consent must be obtained from research subjects before study participation. It is imperative that the consent from the subject is clearly documented in the ICF and the informed consent process is documented in the medical records, without discrepancies, to demonstrate that appropriate consent was obtained. It is the PI's responsibility to read and understand the consent taking requirements from the PCR SOPs and Human Biomedical Research Act 2015 documents.

References

1. Human Biomedical Research Act 2015
2. *RQM SOP 301-B02: NHG Monitoring Programme for Human Biomedical Research Studies*
3. NHG Proper Conduct of Research Standard Operating Procedures
- *PCR SOP 501-C01: Informed Consent Form and Process*

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