CHICKEN SOUP FOR THE BUSY COORDINATOR

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Tips to Prevent Informed Consent Non-Compliances

Scenario:
Principal Investigator (PI), Dr X's, study was selected for audit. During the audit, the following findings were noted by the auditors upon reviewing the informed consent forms (ICFs) of the recruited subjects:

1) One of the study team members acted as the impartial witness for Non-English speaking subjects when translated Short Consent Forms (SCF) appended to English ICF were used.
2) The Legal Representative (LR) acted as the impartial witness.
3) Superseded versions of ICFs were used.

What Are The Correct Informed Consent Procedures?

1) The auditor reminded the PI that the impartial witness should not be a member from the study team. If a translator is being used, this person can also serve as a witness.
2) The LR who is providing consent on behalf of the subject should not concurrently be an impartial witness as the role of the witness is to independently assess and ensure that consent is appropriately obtained from the subject or LR.
3) The most current approved ICFs should be used when obtaining consent.

Tips to Prevent Informed Consent Non-Compliances:

1) Using an Informed Consent Checklist
   The PI and study team may develop an informed consent checklist to be used during consent-taking to check if the consent process complies with Proper Conduct of Research (PCR) requirements such as:
   - An impartial witness must be present during the informed consent process for Non-English speaking subjects if a fully translated ICF (in the language understandable to the subject) is not available.
   - The impartial witness should be fluent in both English and the language that the subject understands.
   - Impartial witness should not be a member of the study team.
   - If the LR had provided consent, the LR should also not be acting as the impartial witness in the consent taking process.

2) Using an ICF Tracking Log
   The PI and study team could use the ICF tracking log template found in the NHG Research website to track all versions of the ICF in use. Information in the log include:
   a) Version No.
   b) Version Date
   c) Date of IRB approval

The PI and study team need to regularly update the log and check to ensure that the latest version of the informed consent form is used for consent taking. Superseded version(s) of blank consent forms should be removed, except for a copy to be filed in the Investigator File for record-keeping purpose, to prevent using the wrong version of ICFs.

Note: PCR SOPs and templates are available in NHG SharePoint accessible to NHG Institutions only

References:

1) NHG Investigator's Manual 4rd Edition October 2022
2) NHG PCR SOP 501-C01 Informed Consent Form and Process
3) PCR Log 509-017 ICF Tracking Log

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