CHICKEN SOUP FOR THE BUSY COORDINATOR

Aug 2022

Subject Management During Covid-19 – The use of e-Informed Consent

Scenario

PI, Dr V, clinical research studies were affected by Covid-19 as some of his subjects were unable to return for follow-up visits due to COVID restrictions. Thus, Dr V consulted his Clinical Research Coordinator (CRC) on ways to overcome the difficulties of Covid-19.

The CRC suggested conducting the research virtually wherever possible. For example, questionnaires studies could be conducted remotely via phone calls or video call. The CRC also advised Dr V to conduct remote consent to facilitate research. Some of the pointers highlighted by the CRC are as below:

Electronic Informed consent (e-IC) process

- Electronic consent, if the technology is available (e.g. video conference with potential subject & electronic signatures) are obtained to document consent).
- The e-IC must contain all elements of informed consent required by regulatory/ethics review bodies [e.g. Health Science Authority (HSA), Ministry of Health (MOH) and Institutional Review Board (IRB)] and comply with applicable regulations (e.g. Human Biomedical Research Act, PDPA on the collection, use and disclosure of personal data).
- The e-IC process should also be clearly stated in the IRB application form and approved by the IRB.
- If any or all of the consent process takes place remotely and is not personally witnessed by the study personnel, the e-IC process must include a method to ensure that the person signing the informed consent is the subject who will be participating in the research or the subject's LR. Study personnel may consider verifying identity by using information from official identification, such as NRIC, birth certificate, driver's licence and passport.
- After the ICF is personally signed and dated by all required parties, a signed copy of the complete ICF should be provided to the subject / LR, either in hardcopy or softcopy. If a soft copy of the signed e-ICF is provided to the subject / LR, the researcher should consider sending it in a file format that allows limited and secure access (e.g. via encrypted email, confirming with subject/LR's that his/her email account is not a shared account) and prevents unauthorised editing of the signed e-ICF.
- An original copy of the complete signed ICF should also be retained at site (e.g. filed in the investigator file or stored in a validated electronic platform).
- The consent process should be documented in the source document (e.g. medical records or informed consent process template).

Considerations for use of Electronic mode

1) Additional costs, resources and time required to set up the e-IC process
2) Subject/LR's reluctance to use electronic mode due to limited experience and / or comfort level with the use of technology (e.g. elderly, poor eyesight, impaired motor skills)
3) The need to plan for backup process / system in case of system failure and during maintenance periods
4) Technical issues/ limitations (e.g. requirement to use a specific operating system or device type)
5) Additional considerations to ensure that the e-IC process and consent form storage complies with local Regulations and other applicable requirements / guidelines [e.g. Personal Data Protection Act (PDPA), Singapore Electronic Transactions Act 2010]

Reference:

1. NHG PCR 599-005 Guidance Document on Electronic Informed Consent Process (Effective 08-Jun-2021)

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