CHICKEN SOUP FOR THE BUSY COORDINATOR

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Pointers for Electronic Consent (e-Consent)

Scenario

A new study adopted the use of e-consent and this is the first time the PI, Dr Steven, is conducting a study using e-consent. Dr Steven consulted the CRC, Jasmine, on the use of e-consent and she advised on the following:

Overview of informed consent requirements

Informed consent is defined by the International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines as a process in which "a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate." The consent process is a legal and ethical requirement regardless if it is paper or e-consent.

Requirements of e-consent & how it should be conducted

1. The e-consent form must contain all elements of informed consent required by regulatory / ethic 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). E-consent process should also meet the applicable regulatory requirements and be approved by ethics review board (DSRB) before implementation.
2. The e-consent should be appropriate for the intended subjects, taking into consideration the subject / Legal Representative (LR)'s age, language and comprehension level. For example, subjects may have difficulties navigating or using electronic systems due to lack of familiarity with electronic system, poor eyesight, or impaired motor skills. In such cases, e-consent process may not be appropriate for these subjects.
3. Remote e-consent process should be conducted via face to face interface such as via Zoom or other secured video conference platform approved by the Institution/IHiS. Phone calls and email correspondences may be considered if it is not practicable for the researcher to obtain consent through a physical face to face interaction. E-Consent process should be conducted in a private location in order to ensure privacy and confidentiality.
4. E-consenting systems need to meet local (a) technical security (b) legal requirements and (c) personal data protection requirements.
5. The documentation of consent should be appropriately stored and archived in accordance to applicable regulations and requirements (e.g. comply with PDPA, institution research data policies, research SOPs).
6. All study personnel should be adequately trained (and training documented) on the electronic systems and informed consent process.

What are the platforms that e-IC can be conducted?

There are many vendors who can provide e-IC platform for research purpose. When feasible, researchers are recommended to consult with institution IT department to assess whether the e-IC platform is compliant with institutional IT security and research data policies.

What is an electronic signature?

E-consent should be electronically signed or the parties agree to use wet ink signatures that are scanned and transmitted electronically by e-mail or other electronic transmission in portable document format (PDF) document or other mutually agreeable secured document format shall be binding as if they were original signatures.

The platforms or systems must meet the requirements of Singapore Electronic Transactions Act (ETA).

NB: Any electronic systems used to obtain and document informed consent should generally be a validated system with functions to capture electronic signatures and date of consent, have access control (e.g. to ensure confidentiality) and be able to protect the data (e.g. audit trail function to track activities within the system). Electronic documentation should also be easily retrieved for verification purposes.

For Clinical Trials regulated by HSA, please refer to the latest Guidance on Electronic Consent available on HSA website.

References, guidance documents & SOPs:

1. MOH's Guidance on the Requirement of Appropriate Consent for the Conduct of Human Biomedical Research and Handling of Human Tissue dated 17 May 2019
2. Electronic Transaction Act, 2010
3. NHG's Guidance Document on Electronic Informed Consent Process
4. NHG's Guidance Document on Electronic Filling of Essential Documents
5. NHG PCR SOP: 501-C01 Informed Consent and Process
6. NHG Research Data Policy

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