NHG RESEARCH EDUCATION

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Issue 35: May 2020

Obtaining Remote Consent for your Research

Background

In the recent situation where physical isolation (e.g. warded or quarantined patients) or social distancing are being applied across the nation during the COVID-19 outbreak period, the need for remote consenting becomes a necessity for important research to continue.

Allowance for Remote Consenting: SOP & Guidances

Based on MOH's Guidance Document *(Ref item 1.)* and the latest NHG Proper Conduct of Research (PCR) SOP on Informed Consent, alternative methods to carry out informed consent process other than physical face to face interactions such as verbal / video consent-taking are allowed if the condition necessitates so.

Excerpt from *NHG PCR SOP: 501-C01 Informed Consent and Process, Item 5.5.e:*

"Informed consent discussion should take place in person. ***Where it is not practicable for the researcher to obtain consent through a physical face-to-face interaction with the research subject, the researcher may consider obtaining consent remotely, including phone calls, email correspondence and e-Consent"***

Points to Consider Before Embarking on Remote Consent

i. The study risk and suitability of remote consent on the target population pool (e.g. elderly)
ii. Whether study team has the technical knowledge and systems to support the remote consent process (e.g. secure and reliable platforms to convey and discuss study information, collect and store written consent obtained).
iii. Whether the identity of the potential subject can be accurately verified during the remote consent process
iv. Ensure that remote consent process continues to comply with applicable regulations and institutional policies / SOPs in areas such as (and not limited to):
   - Data security
   - Protection of confidentiality and privacy
   - Research data integrity (e.g. ensuring electronic consent is retained in a format which can represent accurately the information received)
   - Engagement of required parties to be present during consent (e.g. translator and witness to attend live chats or video conference as needed)

NB: IRB's approval will need to be sought before implementing any changes to the consent process.

Case Example: Conducting Remote Consent

Below is an example of a remote consent process approved by DSRB for a questionnaire study:

- Study invitation email is sent to potential subject
- If potential subject is interested, a PDF copy of the ICF is emailed to subject for consideration
- A video conference is conducted via a secure platform (e.g. Zoom system with appropriate security setting) to discuss the study details and obtain signed consent (via e-signatures)
- Subject emails signed ICF to study team for signing
- Both the subject and study team taking consent would share their computer screens when signing the consent so that the other party can witness the signing process
- A complete copy of the ICF containing all required signatures would be emailed to the subject
- Subject would be requested to acknowledge the receipt of the final document via email reply (a written confirmation)
- The signed ICF & email acknowledgement from the subject will be filed in a secure & validated platform
- The whole process would be clearly documented.

The following **guidance documents** are currently available on NHG SharePoint for NHG researchers:

Guidance Document on Electronic Informed Consent Process
Guidance Document on Electronic Filing of Essential Documents

For non-NHG researchers, please contact your respective Institution Research Office for a copy.

NB: For **HSA regulated trials,** researchers are advised to get in touch with HSA for consult on the electronic informed consent process before proceeding.

References:

1. *MOH's Guidance on the Requirement of Appropriate Consent for the Conduct of Human Biomedical Research and Handling of Human Tissue (17 May 2019)*
2. *NHG PCR SOP: 501-C01 Informed Consent and Process*

'Hang on a sec...I don't remember this being scheduled as a **video** conference call.'

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