CHICKEN SOUP FOR THE BUSY COORDINATOR

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Informed Consent Process During Covid-19 Period

Scenario

A Principal Investigator (PI), Dr Chan, wanted to do a clinical research study on COVID-19 patients who are in isolation or quarantined . Due to fear of contamination, documents would not be brought out of isolation rooms /quarantine area. As such, the PI was unsure how he could obtain and document consent from COVID-19 patients. He consulted his Clinical Research Coordinator (CRC) and his CRC advised the PI as below.

Approval for Alternative Consent Process

PI could consider alternative informed consent methods in special circumstances such as the recruitment of individuals who are in isolation, quarantined or received a stay home notice due to COVID-19.

Prior to implementation, a detailed plan on the alternative informed consent process should be submitted to and approved by the IRB and regulatory authorizes (where applicable). The PI should ensure that the:

- Rights, safety, well-being and privacy of subjects are safeguarded;
- Data security, confidentiality, reliability, integrity and quality are assured;
- Basic principles of informed consent (i.e. information, comprehension and voluntariness) are assured.

Alternative Consent Process

The PI may consider conducting informed consent discussion with the subjects / LR via face to face discussion or remote consent via audio/ video calls. Either way, the PI must ensure a signed copy of the Informed Consent Form (ICF) is maintained in the study investigator file and provide the entire signed ICF to the subject / LR.

During the consent process, all relevant parties (i.e. subject/LR, witness and person obtaining consent) would be required to personally sign and date on the ICF (where possible).

If a hardcopy of the ICF is signed, the PI/ study team member involved in the consent-taking could take a photo of the entire ICF signature page (including signatures and ICF version no.), print a copy of the photograph and certify it as a true copy. The certified true copy of the signature page could be combined with an uncontaminated copy of the corresponding ICF for filing at site and provision to the subject / LR. Alternatively, the signed ICF may be saved electronically in a manner that has secure and limited access and prevents unauthorised editing.

If an electronic version of the signed ICF / signature page needs to be transmitted to another study team member for verification / printing etc., the study team should use secure platforms such as corporate email or TigerConnect* to send the information. Emails containing personal data must be encrypted and confidential files must be protected with strong passwords (i.e. 12 characters, mix of number, symbols, upper/lower case letters, no personal information).

**TigerConnect is a secure messaging platform (encrypted end to end) used by healthcare workers. As part of the security feature, messages on TigerConnect are automatically deleted after a specific period of time.*

Documentation of Informed Consent Process

The PI/ study team member who conducted the informed consent discussion must also minimally record the protocol reference, date informed consent was obtained, informed consent process (e.g. presence of and reasons for engaging witness / translators), as well as the fact that a signed copy was given to the subject / LR in the source documents (e.g. medical records, informed consent process documentation template/checklist).

References:

1. NHG PCR SOP 501- B05 Documentation
2. NHG PCR SOP 501- C01 Informed Consent Form and Process
3. HSA Guidance On The Conduct of Clinical Trials in Relation to The COVID-19 Situation

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