COVID-19 REMOTE SUBJECT CONSENTING

Purpose: To implement and standardize the manner in which site staff will consent or reconsent a subject who is in isolation or unable to return to the site due to the COVID-19 pandemic in lieu of sponsor provided directives.

I. Overview

The FDA requires that the informed consent of a subject be documented on an IRB approved Informed Consent Form (ICF) and signed and dated by the subject or subject's LAR. Due to the COVID-19 pandemic, in person consenting may not be an option due to subject isolation or site precautions, therefore the below procedures would satisfy the documentation of this requirement if the subject is in COVID-19 isolation.

II. Process

A. If technology is available, electronic methods of consenting should be considered if the FDA requirements for electronic signatures on the informed consent are Sponsor and IRB approved in accordance with 21 CRF parts 11, 50, and 56.

1. The information presented to the subject, the processes used for obtaining Informed Consent, and documentation of electronic informed consent must meet the requirements of the regulations listed above.
2. Ensure to also obtain written approval from the Sponsor via email and when applicable, IRB approval prior.
3. The subject must first be contacted via the telephone to confirm their email address and to seek approval prior to sending the ICF electronically.
4. The unsigned ICF is to be sent to the subject via secure email.
5. If the subject does not have email access, then the subject must be contacted to confirm their mailing address.
6. Once the mailing address is confirmed, the ICF is to be mailed to the subject via a FedEx mailer. Obtain approval from your supervisor or senior management prior to sending via FedEx.
7. Once approval has been received, utilize a blank FedEx label to enter in the site information, the subject's name and address, and the site FedEx account number. Keep the original FedEx label as per FedEx label instructions.
8. Include a return FedEx label and FedEx envelope with your information as the recipient so that the subject can mail back the signed ICF via FedEx.
9. You must schedule a time with the subject to conduct a 3-way phone call or video conference with the subject, an impartial witness, and/or additional participants as requested by the subject i.e. a caregiver or family member. If feasible, an Investigator delegated to consent, should also be made available.
10. You must review the ICF with the subject via telephone or video conference. If done via video conference, then this must include witnessing the subject's signature on the ICF.

11. You must document the method of consenting, who was on the call/video conference, time and date consented, and all applicable site-specific consent requirements.
12. The subject would be asked to email the signed ICF back to the site staff and once received, the site will sign the ***copy*** of the ICF.
13. The subject will also be asked to mail out the original ICF, if possible. Once the original ICF is received, then the person that completed the ICF process via teleconference/video conference, would then also sign the original ICF with a late entry date to reflect the date of original consent.
14. If the subject is unable to email the signed consent to the site, the subject can take pictures of the signed consent and send to the site staff. The site staff can then sign a separate ICF form as the person obtaining consent.
15. A note to file (NTF) or progress note should be created to document the process that was used to consent. Ensure that the NTF or progress note clearly documents that this was completed due to COVID-19 isolation by the subject and their inability to return to the site.
16. The NTF or progress note, the copy of the subject's signed ICF with your signature, and the wet ink original of the ICF should all be filed together in the subject source along with the Sponsor's written approval. Any applicable site-specific consenting forms will also be utilized and filed accordingly.

B. General Reminders:

1. All attempts to bring the subject back to the site should be documented accordingly in the subject's source.
2. If the subject is unable to return due to COVID-19 isolation, this should also be clearly documented in the subject's source.
3. The PI is to be informed of this immediately along with the Sponsor, via email.
4. Approval to consent or reconsent electronically should be requested via email and the copy of the approval email or any related communication should be placed in the subject's chart and a copy should be provided to regulatory for the filing in the ISF.
5. Remember to clearly document the exact method in which you consented along with the names and titles, if applicable, of all participants of the call or videoconference.

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