ALLIANCE FOUNDATION TRIALS, LLC

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Alliance Foundation Trials (AFT)

Guidance for Remote Re-consent During the COVID-19 Pandemic

Purpose

The purpose of this document is to provide guidance for investigative sites that do not have a policy in place for remote re-consent of subjects. AFT developed this guidance as part of the Mitigation and Response Plan for the COVID-19 pandemic. Unless extended, this guidance is only **valid until 01-Sep-2020.**

Procedure when the institution <u>has</u> a remote re-consenting policy

- Email the institution's policy to your study contact
- AFT Quality Management and Compliance (QMC) must review and approve the policy
- Upon receipt of QMC approval, follow the institution's policy for re-consent of subjects

Guidance when the institution <u>does not</u> have a policy for remote re-consenting

1) Re-consent documents should be sent to the subject or the legally authorized representative by mail or email:
    - for mail, include a self-addressed stamped envelope for return of the document
    - for email, use secure methods to transmit information according to the institution's data security policies
    - fax is also acceptable

2) To initiate the re-consent process, study staff should:
    - call the subject to let them know that they will be receiving a re-consent form
    - schedule a time to call them again to go over the re-consent form
    - ask what the best method to send the information is
    - mail/email/fax the re-consent form with instructions to contact study staff when the re-consent form is received
    - document the version number/date of the re-consent form and the date it was sent to the subject in the subject's study chart/records
    - ensure that the subject has enough time after receiving the re-consent form to read it before the scheduled phone call

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3) To conduct the re-consent, the person obtaining re-consent should:
    - review the re-consent changes with the subject, asking open-ended questions to gauge comprehension, and answering subject's questions and concerns
    - instruct the subject where to sign and date the re-consent form
    - instruct the subject to return the signed document by mail, email, or fax
    - for mailed documents, the subject should place a signed copy of the re-consent form into the self-addressed stamped envelope and mail back to the site
    - if concerns exist about having subjects mail potentially contaminated document, the investigator may accept the use of a photographic image of the signed consent form transmitted through electronic means
    - for emailed documents, the subject should email back a scanned copy. The original signed document may be returned during the next visit or mailed using the self-addressed stamped envelope
    - for faxed documents, the subject should fax back the signed re-consent. The original signed document may be returned during the next visit using the self-addressed stamped envelope
    - contact the subject if the signed copy is not returned; preferably, two attempts by phone and/or email and a registered letter. All attempts should be documented in the subject's study chart.

4) Following the re-consent phone call, the person obtaining consent should:
    - upon receipt of the signed re-consent from the subject (received via mail, email or fax)
        - sign the signature page as the “Signature of person obtaining the consent”
        - date using the current date. <u>Do not back date to the date that subject signed or any other date.</u> The date when the site receives the consent and executes a signature is the date when the subject is considered to be fully consented.
    - ensure that the subject receives a copy of the fully signed consent by either scanning a copy and emailing, mailing, or giving to the subject at the next study visit
    - document the re-consent process in the subject's study chart
    - file the signed re-consent in the subject's study chart

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For non-English speaking subjects

- Follow the steps outlined above using a translator per your institution's policy for non-English speaking research participants.

Institutional Review Board Notification/Approval

- Institutional Review Boards (IRBs), local or central, may require notification of any changes to the consenting process including implementation of remote re-consenting practices. The overseeing IRB must review and approve the planned informed consent process. It is the site's responsibility to follow their IRB reporting requirements.