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Site Guidance: Remote Monitoring During the COVID-19 Pandemic

Dear AFT Investigators and Study Staff,

The **AFT Guidance for Remote Monitoring During the COVID-19 Pandemic** has been developed to provide guidance for sites that participate in remote monitoring activities during the COVID-19 pandemic, when on-site visits are limited or restricted, to protect the safety of study participants and study staff.

The AFT Guidance document can be accessed by [clicking on this link](#).

If you have any questions regarding this document, please contact the *AFT Director of Quality Management and Compliance*, Majagamy Ramos-Bordonaro, MSRA, CCRP at quality@alliancefoundationtrials.org.

Thank you,

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Alliance Foundation Trials (AFT)

Site Guidance: Remote Monitoring

During the COVID-19 Pandemic

1. Summary

1.1. Clinical study monitoring is a necessary component to protect the safety of the subjects and the integrity of the study data. Monitoring is conducted on a regular schedule as defined in the clinical monitoring plan (CMP) and is commonly conducted in person with the monitor visiting the site to conduct the monitoring visit.

When circumstances arise where in person visits are not feasible, a mechanism for remote monitoring should be implemented. An important factor in remote monitoring is the ability to view the subject's health record. Ideally, remote monitoring can be conducted by granting the monitor access to the subject's electronic health record (EHR) or electronic medical record (EMR). When this approach is not possible (for any reason), copies of the subject's health record will need to be redacted, certified and sent to the study monitor via a secured method.

2. Purpose

2.1 The purpose of this document is to provide guidance for sites that participate in remote monitoring activities during the COVID-19 pandemic, when on-site visits are limited or restricted to protect the safety of study participants and study staff.

3. Procedures

3.1 Guidance for Essential Documents Review

Whenever possible, essential regulatory documents should be reviewed during the remote monitoring visit. Focus should be placed on the following documents and changes at the site to include:

- The Form 1572 (*for IND studies*), to include changes to the site PI, sub investigators, research locations, laboratories, etc.
- Updates to site staff, documented on the Delegation of Authority Log (DOA).
- Training documentation for the latest protocol (amendments).
- Other documents identified as time sensitive (that should not wait until the next on-site visit), for example, approval of the latest protocol amendment.
- A comprehensive review of the ISF must be prioritized during the next on-site visit.

3.2 Guidance when the Institution has a Policy for Direct Access to EHR/EMR

When the institution has a remote monitoring policy and/or procedure that allows for monitor access to the subject's EHR/EMR, after being prompted by the AFT Study Team or study monitor, the site staff should follow the following process:

- Provide the institution's policy/procedure, including copies of any required legally binding agreements.
- Once acceptance of the policy is confirmed the study monitor may move forward with their visit as planned.

3.3 Guidance when the Institution Does Not have a Policy for Direct Access to EHR/EMR (Alternative to Direct Access to EHR/EMR)

When the institution does not allow direct access to the subject's EHR/EMR, or if the mechanism in place to allow direct access is not feasible for AFT, the following procedures for certified and redacted copies should be followed along with determining one method from the following options for providing source documentation.

4. Certified Copies

4.1 Guidance when the institution has a policy for certified copies

When the institution has a certified copies policy, after being prompted by the AFT Study Team or the study monitor, the site staff should follow the following process:

- Provide the institution's policy/procedure.
- Once acceptance of the policy is confirmed the study monitor may move forward with their visit as planned.

4.2 Guidance when the institution does not have a policy for certified copies

When the institution does not have a policy for certified copies, AFT will accept the following procedures for certifying copies:

- The person who certifies the copy ensures that it is an accurate and complete representation of the original, having all the same attributes and information as the original.
- The person who certifies the copy should be the person who actually made the copy.
- The copy should include the following (can be hand-written on the document or automated from the EHR/EMR system);
 - Name or at least Initials or signature of person certifying copy on every page when printed
 - Date of printing / certification
 - Alternative, completion of certification form for electronic copies created from EHR/EMR

5. Redaction of Certified Copies

5.1 Information that is considered private health information (PHI), **and** which is not necessary for the monitor to complete the source verification activities, must be redacted from each page prior to uploading source documents into RAVE or providing documents to the study monitor via secure methods (i.e. secure email, eFax).

5.2 Methods for redaction

- If printed from EHR/EMR:
 - Obscure items using permanent black marker
 - Ensure all patient data is redacted, as described above in section 5.1
 - Scan document to make available for the study monitor (via upload in RAVE, secure email, or eFax)
- If saving an electronic version from EHR/EMR directly to PDF:
 - The document should be saved as a PDF file
 - Use of AdobePro or other similar tool to redact all required elements
 - Make available for the study monitor (via upload in RAVE, secure email, or eFax)

5.3 Sending certified redacted copies

- Documents should include the assigned subject ID number. This can be hand-written on the top or bottom margins of the document.
- When sending electronic versions of the clinical source documents the file name should be named to include sufficient information to easily identify the information provided, to include the following:
 - The AFT study #
 - The study's assigned subject ID
 - A word identifying the specific source document (e.g. "Labs", "Progress Note")
 - The date the source document was obtained or completed
 - **File naming example:** AFT-01_123001001_Labs_04APR2021

5.4 Uploading Source Documents in RAVE EDC

Redacted and certified source documents can be uploaded in the RAVE database, for studies where capability is established, via the ***"Supporting Documentation: Remote Source Verification"*** form.

- For AFT-38, the *"Supporting Documentation: Remote Source Verification form"* is rolled out by answering yes to the question *'Did the assigned monitor for your site request the submission of supporting documents for this cycle to facilitate Remote Source Verification?'* which is found on the Visit Form.
- For all other studies, the *"Supporting Documentation: Remote Source Verification"* form can be added via the *'Add Event'* drop down list on the Subject page.
- Take the following steps when uploading documents directly into RAVE
 - Complete the *'Cycle'*, *'Assessment'*, *'Report Type'* fields and the *'Attachment'*. These are all required fields.
 - If the appropriate *'Report Type'* is not available, *'Other, specify'* should be selected and

the field for *'Specify report type'* should be completed.

- To attach redacted supporting documentation, click the *'Browse...'* button in the *'Attachment'* column to search for the file to be uploaded.
- Only one document can be uploaded per log line. To add additional log lines, click the *'Add a new log line'* button on the bottom left of the table.
- If a log line is inadvertently added and needs to be removed:
 - Delete the document uploaded to the logline by clicking on the pencil next to the log line that needs to be deactivated, checking the box next to *'Remove'*, and saving the form.
 - After the document is deleted, inactivate the logline by clicking the *'Inactivate'* link on bottom left of the table, selecting the logline number that needs to be deactivated from the drop-down menu, and clicking *'Inactivate'*.

5.5 Sending Documents via Email

- Redacted and certified source documents may be sent via email. Follow institutional email security policies to ensure working within best practices for cybersecurity and encryption, and within all applicable regulations.

5.6 Sending Documents via eFax

- AFT has provided an eFax solution for sites where secure email messaging or upload capabilities in the RAVE EDC for redacted and certified source documents is not possible during a remote monitoring visit.
- eFax, or online fax, is the use of the internet and internet protocols to send a fax, rather than using a standard telephone connection. Unlike email, it is possible with eFax to exchange fax messages with a traditional telephone-based fax machine.
- To use eFax, the documentation may be sent via a fax machine to the fax number provided by the study monitor.
- The study monitor will receive the document in their email as an attachment.

6. Questions

- For issues/questions related to uploading documents in RAVE, the site should contact their study data manager (DM).
- For technical issues with eFAX system, contact AFT techsupport at techsupport@alliancefoundationtrials.org. **Note to NEVER send documents with PHI directly to AFT.**
- All other questions should be addressed to the study team or the study monitor as applicable for the study.