Corporate Policy: Remote Monitoring Visits Conducted During COVID-19 Pandemic

Scope:

This policy applies to all Remote Monitoring Visits (RMVs) or remote audits being facilitated and managed during the COVID-19 pandemic at Evolution Research Group (ERG) portfolio companies.

Purpose:

The purpose of this policy is to express ERGs desire to facilitate ongoing RMVs while during the COVID-19 pandemic. Due to the high demand in requests in conjunction with staggered and limited resources and scheduling of staff, ERG will mandate this process be followed to ensure consistency and to maintain adequate control of our records in accordance with regulations and guidelines. This policy is the expected process to be followed for all RMVs unless extenuating circumstances are expressed from a Sponsor/CRO, which will be further discussed and approved on a study basis with the Site Director, Chief Operations Officer (COO) and Chief Information Officer (CIO) for ERG.

Procedure:

1. **RMV Request**
    a. Written requests are to be sent to the sites with at least a 5-business day (more may be needed if the volume of documents to be redacted and scanned are significant) window to allow for appropriate staging, scheduling, and scanning preparations. If there are circumstances that may prevent accommodating the timelines proposed, the site will offer availability at the next possible time.
    b. Remote visits will be scheduled and placed on the site's clinic calendar under the same guidelines as an onsite monitoring visit would, to ensure adequate resources and support is available.
    c. The written confirmation letter or email from the CRA must include detail surrounding what the RMV will entail with a comprehensive list of what is expected to be uploaded for review (eg. temperature logs, subject visit source, scheduling of interviews with staff, query response time with CRC, etc). This will ensure an expedited and fluid approach.

2. **Folder Creation for Upload**
    a. A SharePoint online file folder (HIPAA compliant and in alignment with 21 CFR Part 11) will be created by the site for the specific project with oversight from ERG IT department. Restricted access controls will be applied to ensure view access is only for the CRA(s) and the study site teams. The access will be controlled and turned off upon completion of the scheduled visit. Scheduled visits will not be permitted to exceed the agreed upon timelines unless approval is obtained by ERG management.

i. Note: ERG IT department will be responsible for any troubleshooting or issues with access to file folders. If a CRA has issues, they should be instructed to contact IT directly via Techsupport@ergclinical.com.

b. While ERG prefers that this be the only method for file share used, there may be circumstances that prevent this approach, and must be further discussed and approved by the Site Director, COO, and CIO.

c. Although redaction of PHI is not required in accordance with the authorization that has been provided by the participants, as well as the HIPAA compliant environment in which the transmission of documents will be shared, the site will make every effort to remain cognizant of what information is being scanned and to redact prominent identifiers such as full names, addresses, or phone numbers.

i. Note: If an Informed Consent Document is requested to be scanned, then the full name apart from the first, middle, and last initial will be redacted (eg: C---- M--- S---).

d. The scanned and uploaded documents must then be certified in accordance with ERG policy for Certified Copies.

3. Facilitation of RMV

a. Interviews must be scheduled on calendar for study staff (such as PI, Site Director, or Pharmacist). A one-hour time block may be applied for interviews with staff and CRA and increase frequency as available.

b. The Lead CRC/Designee is responsible for facilitating the visit like an onsite monitoring visits by way of scheduled periodic check ins, query resolution, and phone calls.

c. If the CRA requests additional documents just prior to or during the RMV, every effort will be made to accommodate these requests; however, the staff may not be available or onsite to assist with this in real time. In those instances, the requests must be documented as action items and sent at the next available opportunity (if post RMV, then an encrypted file may be sent prior to next RMV in accordance with section 2 of this policy).

d. Lead CRC/designee is responsible to either sign Monitor Sign-In Log denoting the visit is remote and filing this policy that captures this activity during the COVID-19 pandemic, or sending the monitor a copy to sign and scan as a certified copy. All correspondence during the visit is to be filed in the Investigator Site File (ISF).

e. Any queries that are unable to be resolved or confirmed as resolved will be required to be added to the CRAs Follow Up letter for proper resolution post RMV.

4. Subject Consenting Requirements for RMVs

i. Unless the study consent form contained specific information about monitoring that is no longer correct, additional consent should not be required to move to remote monitoring.
ii. If sponsor requests an amended consent be issued, site must contact VP Quality Assurance on further consideration and management of the request.

5. Unblinded RMV

a. The same process will be completed for unblinded RMVs. Visits may need to occur on separately scheduled dates and times to ensure the unblinded staff can be made available given the reduction in staff that is unblinded to a trial.

END POLICY