Health Research South

Remote Monitoring Guidelines for Clinical trials

The COVID-19 pandemic, lockdown and general restrictions have prevented on-site monitoring of clinical trials. Remote monitoring has now increasingly become a necessity for the required source data verification (SDV). While CRO and sponsors have different expectations and recommended pathways to conduct remote SDV, there are guidelines that the site should be aware of in order to comply with the GCP guidelines and the Privacy Act 2020.

Recommended Guidelines:

Participants' privacy and confidentiality must be protected:

- The patient's name and signature on the ICF **must** be redacted. The date (which as per GCP must be completed by the patient themselves) and the investigator's name/signature/date should not be redacted. This should show a difference in the writing (of the dates) to show that the patient has consented.
- Direct and indirect identifiers must be redacted on all clinical documents:
    - NHI, name, street address, phone number, online identity (e.g., email, twitter name), identification numbers (e.g., community services card, driver's licence), date of birth, identification of relatives, identification of employers, clinical notes and any other direct or indirect identifiers that carry significant risk of re-identification. This includes names/signatures of third parties, e.g., radiologists.
- It is recommended that one staff member redacts and self-checks, followed by a second staff member, who checks for redaction before a document is sent/shared.
- Approved redacting software can also be used but check that all identifiers have been redacted and that identifiers cannot be read after being redacted, scanned and zoomed in.
- CRAs/CROs/sponsors should not expect a full SDV with remote monitoring, as it is challenging and time consuming to ensure complete redaction.

Sharing of redacted documents:

- Any approved and validated platform/portal can be used to share **redacted** data with CRA/CRO/sponsor. Make sure the validated portal includes audit trails.
- Alternatively, data which are photocopied/photocopy redacted/scanned can be sent via email. This leaves an email trail, and the redacted photocopy is available at site for audit purposes.

What is not recommended:

- Using teams/zoom for remote SDV:
    - non-redacted ICFs/other data should not be held up to the camera (even if requested for a brief period), as sites cannot be guaranteed that a screen shot has not been taken and who else is viewing the documents.
    - holding documents up to the camera (even if redacted) leaves no audit trail and evidence would be much more difficult to provide to an auditor.
- Using a portal's inbuilt redaction system because it cannot be guaranteed that all identifiable data will be redacted.