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Remote Source Document Verification (SDV) Requirements

Case scenario

Sponsor A had to postpone on-site monitoring visits due to visit restrictions imposed by the trial site arising from the COVID-19 situation. As an interim database lock was soon approaching, sponsor A decided to conduct remote monitoring visits instead to verify the data that had been transcribed from the source documents to the case report forms (CRFs). Thus, monitor B requested for the Clinical Research Coordinator (CRC) to share the source documents for the required trial participants remotely via a video call.

What should the CRC do to prepare for the remote SDV?

Checklist for remote SDV

	✓ Ensure that the sponsor has obtained written agreement from the trial site for remote SDV. ✓ The written agreement may be in the form of an addendum to the clinical trial agreement or via email.
	✓ Check that the sponsor has notified the Health Sciences Authority (HSA) about the remote SDV plans prior to implementation. ✓ The notification may be submitted to HSA at HSA_CT@hsa.gov.sg. ✓ File a copy of the notification in the Investigator Site Files.
	✓ Ensure that the required source documents have been redacted by replacing the identifiable information (e.g. name, address, contact details etc.) with the trial participant ID. ✓ Retain copies of the redacted source documents on file for documentation purposes.
	✓ Request another study staff to verify that all identifiable information has been removed from the redacted source documents prior to the remote SDV. ✓ The verification should be documented and maintained on file.
	✓ Ensure that the redacted source documents are shared via the video call in a secured manner (e.g. disable screen recording and prohibit screen shots).

Reference:

1. Guidance on Conduct of Clinical Trials in relation to the COVID-19 situation – version dated 29 Jul 2020

Additional Reading Material:

2. NHG Proper Conduct of Research SOP: 501-B07 Study Conduct - Monitoring

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