EMHS Research Hub

REMOTE MONITORING FOR CLINICAL TRIALS

Background

COVID-19-related hospital access and border restrictions have limited the ability of Contract Research Organisations (CRO) and sponsors to send staff to WA Health sites to conduct clinical trial monitoring.

In order to ensure EMHS patients can continue to access high quality clinical trials, remote monitoring may be required. This statement provides guidance on remote monitoring at EMHS sites.

In line with the Australian Clinical Trials Project Reference Group COVID-19 guidance, EMHS encourages remote monitoring where necessary.

Key Requirements

Sponsors/CROs should ensure that remote monitoring processes are efficient and workable for sites, fully costed in trial budgets and avoid undue burden on hospital resources. These arrangements must protect participant privacy and adhere to the patient confidentiality protocols already in place for the trial.

Access to patient records must be in line with trial contracts/agreements:

- Any access to identifiable records for monitoring purposes should be disclosed in the Participant Information Sheet and Consent Form (PICF).
- Any change to remote monitoring practices **must not** result in confidential patient information being sent to the sponsor/CRO unless this has already been addressed in the PICF and agreement.

Remote source data verification may be done electronically, provided appropriate security arrangements are in place:

- Patient medical records can be scanned and sent to the sponsor after redacting any identifiable information using AdobePro or similar.
- Email transmission is not permitted.
- Alternatively, monitoring visits can be conducted via MS Teams or Avaya. Screen sharing of records for source verification is permitted in line with the requirements outlined above.

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- The EMHS Site Principal Investigator must maintain a log of all instances in which information is shared for monitoring purposes in the trial source records. This ensures compliance with Section 5.4.1 of the Department of Health Information Access, Use and Disclosure Policy Compendium).

Sponsors should have guidelines or standard operating procedures which outline their processes for remote monitoring and include information about confidentiality and security. This includes that site staff should retain control over screen sharing and outline limitations on storage, sharing and screenshots. These should be provided to the site upon request.

Contact

For more information, please contact the **EMHS Research Hub** at EMHS.REG@health.wa.gov.au or (08) 9224 3799.