Government of Western Australia
North Metropolitan Health Service

NMHS Position Statement on Remote Monitoring in Clinical Trials

The concept of remote trial monitoring has been around since 2013 following research showing that on-site monitoring does not increase data accuracy. It is also an economic decision for commercial companies and Contract Research Organisations (CRO) as monitoring is a significant expense. COVID-19 has expedited the blanket adoption of remote monitoring as a response to lockdowns and border closures and this approach is likely to be the new norm. The position statement outlines how remote monitoring can be facilitated in NMHS whilst ensuring data standards and participant data security through following all relevant local and national guidelines.

WA Health is a signatory to, COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors, compiled by the Clinical Trials Project Reference Group (CTPRG). This guidance outlines the approach to remote monitoring management and states, '*Remote source data verification may be done electronically as long as appropriate security arrangements either are or can be put in place.'* In addition, '*Remote monitoring visits are encouraged as the first option in all cases and sponsors and institutions should ensure that these are facilitated, taking into account the need to avoid undue burden on hospital or institutional resources. These arrangements must adhere to patient confidentiality protocols already in place. Remote source data verification may be done electronically as long as appropriate security arrangements either are or can be put in place.'*

Participants and Transparency

Participants need to be made aware of any access to their identifiable records for monitoring purposes through 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 unless this has already been addressed in the PICF and contract agreement. Remote source data verification can be undertaken electronically if appropriate security arrangements are in place.

IT Considerations

Consider requesting the following software via the HFN 30 IT request form.

- **Adobe Pro** – for redaction of identifiable data in the patient medical records before being printed and sent to the CRO/sponsor (please be aware that HSS requires the Department to pay the licensing fee for this program).
- **My File eXchange (MyFX) account** and/or **My File Transfer (MyFT) account** - for sending redacted records to the CRO/sponsor as sending via email is not permitted.

Monitoring visits

- These can be conducted via MS Teams or Avaya. Screen sharing of redacted records for source verification is acceptable in line with the requirements outlined above.
- Screen-sharing must be managed by the site being monitored.
- A Disclosure Register needs to be maintained for all instances in which information is shared, this is in line with the current requirements for monitors having temporary access

to records which are onsite (Section 5.4.1, Information Access, Use and Disclosure Policy Compendium).

- Remote access to record systems is not permitted.
- Sponsors should have Standard Operating Procedures available to the site. These should outline their remote monitoring process outlining the security of participant confidentiality and define the limitations on data storage, data sharing and screenshots.

For more information please contact SCGH.RGO@health.wa.gov.au or (08) 6457 4531.

This document can be made available in alternative formats on request.

© North Metropolitan Health Service 2020