ST VINCENT'S
HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

# Guidance for Remote Source Data Monitoring

The following guidelines are recommended for remote monitoring of source documents by external sponsors / monitors of clinical trials at SVHM during the Covid-19 pandemic.

## Sending Redacted Source Documents

**Sending redacted participant source documents via email to the Monitor is not permissible at SVHM.**

## Remote Monitoring via MRO

Remote source data monitoring should be undertaken via the Monitor accessing the participant source data uploaded onto MRO remotely, the following actions should be undertaken to enable the Monitor to so:

1) Establish the Monitor as a contingent worker

- Provide the following documents to the Monitor for review and signature:
    - Confidentiality Agreement
    - SVHA ICT Information Systems Acceptable User policy
    - SVHA Security Induction

  Email confirmation the Monitor has reviewed and agreed to the SVHA ICT Information Systems Acceptable User Policy and SVHA Security Induction is acceptable.
- Receive a copy of the Monitor's current Police Check.
- Send the signed Confidentiality Agreement, email acknowledgment as mentioned above, and copy of their Police Check to your departmental HR advisory, along with the following information to establish the Monitor as a Contingent Worker and a Workday Account (for documentation storage purposes)
    - Full Name
    - Email Address
    - DOB
    - Supervisory Organisation that they will be hired under
    - Associated Cost Centre (Workday requires this field to be completed – no fees associated with process of contingent worker establishment)

2) Gaining Remote Access

- Contact IT (it.servicedesk@svha.org.au) for the Monitor to be given remote multifactor authentication access, allowing for the Monitor to use their work device to access the SVHM network.

3) Gaining MRO access

- Contact Medical Records Online (MRO) Support (mro.support@svha.org.au) for the CRA to be granted limited read-only access to MRO. Provide the Monitor's SVHM email address, and a list of the participants' UR numbers on the study. This access expires after 3 months.
- Provide the Monitor the MRO User Guide that is located at: http://intranet/Departments/medicalrecordonline/Pages/Resources.aspx.
- Further information on MRO and how to use it can be found at: http://intranet/Departments/HealthInformationServices/Pages/MRO-Information.aspx

Screensharing via MS Teams

It is permissible for a Study Team member to screenshare using MS Teams to allow Monitors to view source documents for verification. The following must be adhered to:

- Only MS Teams as SVHM's approved platform is allowed.
- Sharing documents via MS Teams or email is not permitted.
- The meeting cannot be recorded.
- The study team must notify the HREC prior to the IMV that this is the method of remote monitoring they intend to use.