

May 27, 2020

MEMO

CLINICAL TRIALS – REMOTE MONITORING AND STUDY STATUS UPDATES DURING THE COVID 19 PANDEMIC

The COVID-19 situation continues evolving and impacting the University's clinical trial activities. We provide the following guidance to investigators and study staff and encourage you to direct questions to linda.longpre@ucalgary.ca

Monitoring

Given travel restrictions and public health requests for social distancing, sponsors are transitioning from on-site monitoring of their trials to remote monitoring.

All participants sign consent forms prior to study enrolment, which allow the sponsors to access personal health records that are relevant to study conduct. When remote monitoring is performed, the sponsor requires the access to the same health records. As you know, AHS is unable to grant monitors limited access to participant health records at this time. Following consultation with AHS, we have created two options for remote monitoring visits.

Option 1 – De-identified certified copies

When providing certified records, please ensure that:

- You ask the sponsor what they require (avoid sending more information than is required)
- The certified copies are properly de-identified, i.e. ALL IDENTIFIERS (names, initials, MRNs, AHS numbers, etc.) have been removed. This requires the careful review of the entire document before sending.
- The study ID is written on the top of each page.

This option is less optimal than option 2 as sponsors will still need to review the data once the pandemic restrictions have been lifted.

Option 2 – Screen sharing participant records

To allow monitors access to the true source documents that they would require, AHS has agreed to allow screen sharing between the site and the monitor, as long as it is done using a secure platform approved for the sharing of level 4 health data.

The University has indicated that Microsoft Teams (MS Teams) is the required platform for all meetings that involve Level 4 data. This includes health information that can be linked to an individual, including health status and diagnostic, treatment or care information. For more information about Level 4 data, please see UCalgary's [Information Security Classification Standard](#).

If you are using AHS systems, they have a secure Zoom license allowing for screen sharing of health information. Please contact AHS for more information about accessing their licensed version of Zoom.

Please note that whichever platform you choose to utilize, the monitoring must be set up using either the University or AHS licenses. You may NOT use these platforms under a sponsor/monitor license. Doing so will be a breach in privacy and considered a breach of the AHS research agreement.