

March 19, 2020

MEMO

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

The COVID-19 situation is rapidly 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 but instead of reviewing shadow charts or electronic health records, access is given to certified copies of the health records.

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.

Study Status

Sponsors have started to notify research teams about changes to the status of a clinical trial including:

- Halted/Suspended recruitment
- Suspended study visits
- Premature study closure
- Study cancellation

It is important that UC and AHS research administration are aware of these notifications and requests. Therefore, please forward them also to linda.longpre@ucalgary.ca.