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**AlfredHealth**

28 February 2022

Dear Principal Investigators, Department/Unit Heads and Research Co-ordinators

**Re: Updated Alfred Health COVID19 Guidance re Resumption of Onsite Monitoring for Clinical Trials - Revised**

Based on the advice of Victoria's Chief Health Officer, I am pleased to announce that monitors for clinical trials can return onsite effective immediately.

Monitors will be allowed onsite on the condition that they are able to show proof they have received, at a minimum, two doses, *but preferably three doses*, of a COVID-19 vaccination (digital or printed). Monitors will also need to be accommodated in a controlled area away from patient care domains under strict social distancing rules with supervised access and agree to and abide by the Alfred Health [conditions of entry](#).

Monitors will be required to access public retail spaces rather than Alfred Health staff tea rooms.

A shared calendar for the Alfred Health Lane monitoring room which accommodates two people has been set up. Researchers can apply for access to the shared calendar by contacting Anne Woollett, Clinical Trials Director, TrialHub ([a.woollett@alfred.org.au](mailto:a.woollett@alfred.org.au)), after which time researchers will be able to make bookings themselves. There is cleaning equipment available in the room. Areas previously approved in clinical trial units for the purposes of monitoring can be used once again under the same conditions.

Please also refer any queries related to monitoring to Anne Woollett ([a.woollett@alfred.org.au](mailto:a.woollett@alfred.org.au)) or Angela Henjak, Senior Manager Office of Ethics & Research Governance ([a.henjak@alfred.org.au](mailto:a.henjak@alfred.org.au)).

Remote access to the electronic medical record (EMR) is another option for the monitoring of clinical trials. Information about the process and the associated documents are attached for your information. There is CERNER training available for Alfred Health staff. CERNER training for monitors is being finalised and will be accessible shortly.

Site initiation visits (SIV) can also be conducted with one representative from the sponsor on site. However, the SIV meeting will need to remain via teleconference. Site selection processes may go ahead if suitable, but with only one representative from the sponsor on site, adhering to Alfred Health Screening procedures. Tele- or video-conferencing may be used as an alternative.

We acknowledge the challenges imposed in the current circumstances but greatly appreciate your continued support, perseverance and patience. Further updates will be issued as required. Please share this guidance with your colleagues, collaborators and sponsors. If you have any questions, please contact Anne Woollett or the Ethics & Research Governance Office.

Yours sincerely

DocuSigned by:

*Stephen Jane*

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Professor Stephen M Jane  
Director of Research  
Alfred Health

