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AlfredHealth

21 March 2023

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

Re: Updated Alfred Health COVID-19 Guidance on Clinical Trials and Other Research

With the easing of COVID-19 restrictions, we are pleased to announce the resumption of all research activities at Alfred Health with all previous restrictions to clinical trials and other research lifted; effective immediately.

Researchers are required to continue to comply with the relevant COVID Alfred Health policies and guidelines and are responsible for ensuring adherence to the guidelines and policies by sponsor representatives and external researchers in their Departments.

It is recommended that studies continue to include COVID-19 contingencies in the protocols and project plans submitted for ethics review and/or site specific authorisation (governance approval).

Expedited human research ethics review by the Alfred Hospital Ethics Committee and/or site authorisation by Alfred Health continues to be available for new COVID-19-related applications.

Monitors, sponsor representatives and authorised external researchers are 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) and wear an appropriate mask, as directed by staff. Sponsor representatives and external researchers will also need to be accommodated in a controlled area away from patient care domains under social distancing rules with supervised access and agree to and abide by the Alfred Health [conditions of entry](#). External personnel will also be required to access public retail spaces rather than Alfred Health staff tea rooms.

Remote access to the electronic medical record (EMR) continues to be another option for the monitoring of clinical trials.

Site selection processes, site initiation visits (SIV) and SIV meetings can be conducted with sponsor representatives onsite in adherence to Alfred Health [conditions of entry](#) and Alfred Health COVID-19 policies and guidelines.

We thank you again for your support, resolve and patience throughout the pandemic. Please share this guidance with your colleagues, collaborators and sponsors. If you have any questions, please contact the Office of Ethics & Research Governance Office or TrialHub.

Yours sincerely

DocuSigned by:

Stephen Jane

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Professor Stephen M Jane
Director of Research
Alfred Health

