55 Commercial Road
Melbourne, VIC 3004
ABN 27 318 956 319

T +61 3 9076 2000
F +61 3 9076 2222
alfredhealth.org.au

Office of Ethics and
Research Governance

T +61 3 9076 8825
E research@alfred.org.au

AlfredHealth

10 July 2020

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

Re: Updated Alfred Health COVID19 Guidance on Clinical Trials and Other Research

In keeping with Alfred Health's commitment to prioritise the safety of trial participants, other hospital patients, their families and staff, the return to Stage 3 restrictions announced by the Victorian State Government will result in a reinstatement of the conditions outlined in the *Alfred Health Contingency Plan for COVID-19 Interruption to Clinical Trials and Other Research* guidance issued on 06 April 2020.

We respect the clinical decisions made by researchers based on the balance between the risks associated with COVID-19 infection versus those of disease activity. Therefore, the management of the clinical trial and research program, within the current government directives and Hospital guidance, will be at the discretion of the Principal Investigator, in consultation with, and approval from, the Head of Department/Unit, Program Director and the sponsor.

Researchers are asked to make the following considerations when reviewing their research program:

1. **Non-COVID-19 Clinical Trials: Approved and Authorised – Open to Recruitment as well as Approved and Authorised Clinical Trials not Commenced:**

Trials are to be assessed on a case-by-case basis. Consideration should be given to: whether the trial is critical; the potential risks and benefits of commencing or continuing the study; the availability of staff; the potential burden on hospital resources such as Pathology, Radiology, in-patient and ICU admissions and; feasibility in the current circumstances.

Where possible, patients are to be managed remotely, thereby reverting to, or continuing with, contingency strategies such as: telephone or telehealth follow-up; use of local pathology and imaging centres and; alterations to drug dispensing arrangements. These non-serious breaches should continue to be included in the post COVID-19 report or submitted as an amendment application, if required.

If on-site patient visits are essential, patients are to undergo COVID-19 screening via telephone on the day prior to the scheduled visit, as per the current government and Hospital policies and guidelines.

2. **COVID-19-Related Clinical Trials and Research:**

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.

3. **Non-COVID-19 Research Other than Clinical Trials:**

The conditions regarding specific research activities outlined in the previous guidance remain in effect. Therefore, studies requiring: staff as participants; nursing services; face-to-face contact and; external personnel, continue to be deferred indefinitely. The remaining studies, with the exception of audits and opt-out registries, are to be reviewed on a case by case basis using the same criteria as for non-COVID-19 clinical trials above.

4. **External Personnel**

On-site monitoring visits by sponsors are to be deferred. Alternative options such as sponsor-supported 'work-arounds' involving Unit staff should be reverted to. Similarly, site initiation visits and site selection processes may only proceed via tele- or video-conferencing. Any ramifications of the deferral of on-site visits should be referred to the Director of Research, Professor Stephen Jane

5. Other Affiliations and Funding

Researchers affiliated with other institutions or education providers should refer to directives issued by these organisations.

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 the Ethics & Research Governance Office.

Yours sincerely

Professor Stephen M Jane
Director of Research
Alfred Health