

6 April 2020

Dear Principal Investigators and Department/Unit Heads

Re: Updated Alfred Health Contingency Plan for COVID19 Interruption to Clinical Trials and Other Research

The previously released Alfred Health Contingency Plan for COVID-19 Interruption to Clinical Trials aligns with the recently issued *COVID-19: Guidance on Clinical Trials for Institutions, HRECs, Researchers and Sponsors* prepared by the Clinical Trials Project Reference Group, State and Territory Departments of Health, NHMRC and TGA.¹ The purpose of this update is to provide more specific guidance on the measures to be taken in relation to clinical trials and other research.

The safety of trial participants, other hospital patients, their families and staff remains the priority. Whilst it is essential for critical clinical trials to continue, the potential for research to divert critical hospital resources and the possible redeployment of research staff to clinical services, need to be taken into consideration. Therefore, a rationalisation and prioritisation of clinical trials and other research is required.

To that end, the following position has been adopted:

1. COVID-19-Related Clinical Trials and Research:

New applications for COVID-19-related clinical trials and other research will have expedited human research ethics review by the Alfred Hospital Ethics Committee and site authorisation by Alfred Health. The details of the process can be accessed at: <https://www.alfredhealth.org.au/research/ethics-research-governance/research-updates/>

2. Non-COVID-19 Clinical Trials: Approved and Authorised – Open to Recruitment:

These trials will be assessed for continuation on a case-by-case basis. It is thought that this would be best managed at the Unit/Department level. Principal Investigators, in consultation with the sponsor and Head of Department, are asked to review each clinical trial with respect to:

- whether the trial is critical
- the associated risks and benefits of continuing the trial
- the potential burden on hospital resources such as Pathology, Radiology, in-patient and ICU admissions and;
- the likelihood of staff deployment.

The decision for each trial, as well as any contingency plans to be adopted (eg, telehealth/telephone follow-up; local collection of pathology samples; local imaging; changes to drug dispensing arrangements, etc), are to be included in a report to be submitted to the Program Director for approval and the Ethics & Research Governance Office (ERGO) for notification. Undoubtedly, many Units have already undertaken these assessments but the central collection of this information will assist in future planning. A number of sponsors have already communicated their decisions to researchers and ERGO.

3. Non-COVID-19 Clinical Trials: Approved and Authorised - Recruitment not Commenced:

These trials will be assessed on a case-by-case basis using the criteria and process outlined above for trials open to accrual.

4. Non-COVID-19 Research Other than Clinical Trials:

This requirement is in line with Commonwealth and State Government directives that only essential Alfred Health staff should be on the premises at this point in time. There is also currently a huge burden on staff and resources.

Therefore research other than critical clinical trials undertaken at Alfred Health that involves the following research activities is deferred indefinitely. These principally include:

- Studies involving staff as participants
- Studies requiring nursing services (excluding research nurses and research co-ordinators)
- Studies requiring face-to-face contact (if there is no option to make alternative arrangements)
- external personnel who need to be on-site to conduct their research (including researchers/students with an Alfred Health honorary appointment solely for the purposes of research)

With the exception of audits and opt-out registries and those excluded above, researchers are asked to review the remaining projects, in consultation with the Unit Head and sponsor/lead institution, with respect to:

- the justification for the continuation or commencement of the study
- the associated risks and benefits
- the potential burden on hospital resources such as Pathology, Radiology, etc and;
- the likelihood of staff deployment.

For studies conducted across multiple departments, the assessments should be made in conjunction with these Units. Just as for clinical trials, the decision for each project, as well as any amendments proposed, are to be included in a report to be submitted to the Program Director for approval and the Ethics & Research Governance Office (ERGO) for notification. A sample report format accompanies this update. Any amendments proposed will require a formal amendment application.

5. 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 explored. Site initiation visits and site selection processes may continue by tele- or video-conferencing.

6. Other Affiliations and Funding

Researchers affiliated with other institutions or education providers should refer to directives issued by these organisations. Investigators are also encouraged to liaise with funding bodies in regards to the impact of the delays on the funding arrangement.

7. Alfred Hospital Ethics Committee Review and Alfred Health RGO/Site Authorisation:

The ethics and research governance functions will continue albeit predominantly remotely. Whilst every effort will be made by ERGO to respond to inquiries in a timely manner, we thank you for your patience for any delays due to the challenges of working remotely.

New Applications Submitted:

Ethics and governance applications will continue to be accepted with study commencement to be determined by institutional guidelines and intra-Unit review.

Amendments:

In line with the recently issued guidance¹, the Alfred Hospital Ethics Committee has agreed to provide 'pre-approval' for certain categories of amendments that do not pose potential safety risks to participants enrolled in **critical clinical trials**. These include changes that involve:

- Follow-up of participants via telephone or telehealth
- Changes to visit schedule and visit activities
- Collection of pathology samples at a local centre
- Imaging at a local centre
- Alterations to drug dispensing arrangements (with approval from Alfred Clinical Trials Pharmacy)

- Change of site to a location outside of the hospital (on a case by case basis with prior consultation with ERGO)

Approval from the Sponsor is required prior to the implementation of these amendments. Researchers are reminded of the importance of maintaining communication with participants as well as the need to document discussions as well as the participants' continued consent with respect to study changes. As outlined in the previous guidance, these 'pre-approved' amendments are to be included in the post COVID-19 report to be submitted to ERGO.

Amendments other than those listed above, are to be submitted for ethics and/or governance/site authorisation review.

For **studies other than critical clinical trials**, amendments are to be submitted as per usual.

Legal Documents:

A process for the electronic signing of legal documents is currently being explored. The details will be provided once finalised. In the interim, legally acceptable forms of signatures, such as scanned or photographed signatures, will be adopted. Separate guidance will be issued shortly on this matter.

We thank you for your co-operation in these challenging circumstances. Further updates will be provided in response to newly issued government and Hospital directives. Please share this guidance with your colleagues, collaborators and sponsors. If you have any questions, please contact the Ethics & Research Governance Office.

Yours sincerely

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Director of Research
Alfred Health

Professor John J McNeil
Chair
Alfred Hospital Ethics Committee

1. *COVID-19: Guidance on Clinical Trials for Institutions, HRECs, Researchers and Sponsors*. Clinical Trials Project Reference Group, State and Territory Departments of Health, NHMRC and TGA (<https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials>).