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AlfredHealth

22 May 2020

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

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

The easing of some Commonwealth and State Government COVID-19 restrictions has allowed Alfred Health to reassess its position on clinical trials and other research which were previously detailed in the COVID-19 Guidance issued on 06 April 2020.

The revised position is aimed at returning clinical trial and other research activity to pre-COVID-19 levels but in compliance with government directives, Hospital policy and other relevant guidance. In order to achieve this, the following changes have been adopted:

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

In consultation with, and support of, the Department/Unit Head and/or Program Director, as well as the approval of the sponsor, Principal Investigators can initiate, continue or re-commence clinical trials on the condition that the trial complies with government directives and Hospital guidance. Consideration should be given to the potential risks and benefits; the availability of staff and hospital resources; feasibility in the current circumstances and; the impact of reverting to more stringent restrictions should this occur.

Researchers are encouraged to retain the current contingency strategies such as: telephone or telehealth follow-up; use of local pathology and imaging centres and; alterations to drug dispensing arrangements. However, if there are no alternative options, on-site patient visits can be undertaken within COVID-19 protocols.

Given the level of uncertainty surrounding the pandemic , it is advisable, where possible, for current and future clinical trial protocols to make provision for COVID-19 contingency plans should they require implementation. In the interim, please continue to record non-serious breaches to be included in the post COVID-19 report and/or submit amendment applications to the Ethics & Research Governance Office (ERGO).

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:**

In line with current Commonwealth and State Government directives that allow only essential Alfred Health staff (with some exemptions) to be on the premises at this point in time, the conditions regarding specific research activities outlined in the previous guidance remain in effect.

4. **External Personnel**

Since monitors are covered by an exemption in the current State Government directive, they are allowed on-site on the condition that they are accommodated in a controlled area away from patient care domains under strict social distancing rules with supervised access and agree to the Alfred Health screening procedures. All monitors will be required to comply with the Alfred Health Entry Point Screening Station for Staff and Visitors guide and complete the attached Pre Visit Screening checklist prior to on-site visits. One monitor per trial visit will be permitted and these visits must be logged in at the centralised non clinical monitoring area on arrival. Further information about the arrangements for a centralised area for monitor access will be provided once the details have been finalised.

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.

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

The ethics and research governance functions continue as per the 'new norm', namely, virtual Ethics Committee meetings and ERGO staff working remotely. Effective this week, there will be staff in the office every business day but all staff remain contactable by telephone and email.

In terms of the signing of legal documents, unfortunately, we have not been able to create a single and consistent e-signing process due to the differing requirements of sponsors. We hope to explore this option in the future but in the interim, request that hard copies of legal documents and the research contract checklist be sent to ERGO once they have been reviewed and approved for signing.

We thank you again for your continued support and perseverance in this ever-evolving landscape. 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

Professor Stephen M Jane
Director of Research
Alfred Health

Yours sincerely

[Contact Name, use No Spacing and Strong style]
[Position Title]