26 November 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 easing of restrictions and Victoria moving into the Last Step stage announced by the Victorian State Government, will result in a reinstatement of the conditions outlined in the Updated Alfred Health Contingency Plan for COVID19 Interruption to Clinical Trials and Other Research guidance issued on 21 May 2020.

As was the case in the past, 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; 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. However, given that the non-serious breaches will continue to be collected for some time, it is recommended that the contingency plans are formalised in a revised or supplemented Protocol and submitted as an amendment application to the Reviewing Ethics Committee and subsequently for authorisation by Alfred Health.

   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:**
   - Most of the conditions regarding specific research activities outlined in the previous guidance remain in effect. Studies requiring 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**
   - 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 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.

A central registration of all monitors will be established on the Teams portal to capture and monitor the total numbers of monitors attending Alfred Health at any one time. Oversight of this registration point will be the responsibility of Anne Woollett.

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 Rebecca Keast, Project Officer and EA, TrialHub (r.keast@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.

Further details are detailed in the attached COVID-19 Normal Return to Workplace Team Plan – External Clinical Trial Monitors document which has been approved by Alfred Health. Please refer any queries related to monitoring to Anne Woollett, Clinical Trials Director, TrialHub (a.woollett@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.

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