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 3619
E research@alfred.org.au

AlfredHealth

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Alfred Health
Contingency Plan for COVID19 Interruption to Clinical Trials

Units conducting clinical trials will continue to perform business as usual until such time that the Unit is required to change practice based on direction from the Alfred Health Executive team. Alfred Health will be guided by the Department of Health in all decisions relating to patient care and working capabilities of staff.

The COVID19 situation is unprecedented and we do appreciate the support of our sponsors of our clinical trials ensuring that patients remain on treatment and all safety activities are completed. We ask for patience as we work through the situation, including reducing email traffic and expectation of immediate responses from study staff and plans that we cannot predict.

The safety of our clinical trial participants and staff will be our priority in the event that COVID19 affects our normal operations. If Alfred Health directives affect a clinical trial, sponsors will be contacted and the following may need to be implemented to ensure that enrolled patients are prioritized to receive care in a safe environment. Investigators will work with sponsors to ensure continuity of approved protocols; however expanded patient visit windows, prioritizing of clinical trial activities and changes in proposed ways to conduct visits will need to be planned. Alfred Health expects a proactive response from sponsors and will inform RGO and HREC of planned changes resulting in COVID19 affecting normal business.

Currently, all work related overseas travel by staff is cancelled.

In the event that visitors are banned from Alfred Health, the following will be affected:

- Site Selection Visits will be performed via phone in combination with information provided electronically
- Monitoring visits postponed. Remote monitoring visits may be possible on an as need basis. If site staff numbers are reduced, then the focus will be on patient care, not providing data for data monitoring.
- Site Initiation Visits (SIV's) will be postponed or completed via teleconference
- Audits will be postponed

In the event that non-essential visits (i.e. non treatment visits) are banned from Alfred Health, the following strategies may be implemented as approved and discussed with sponsors and RGO:

- Patients will be contacted by telephone by RN's, PI's or SI's to conduct AE and concomitant medication assessments
- Patients will have pathology samples (e.g. bloods/urine) and ECGs testing taken at local pathology collection centres close to their home
- Central laboratory blood collection may need to be suspended on non-dosing days
- Enrolment of patients to dose escalating studies will need to be discussed with sponsors on a case by case basis due to long PK days and the protocol requirement of multiple visits
- *Access to oral drugs for patients will be discussed with sponsors on a case by case basis including dispensing of drugs via courier or increasing the amount of drug dispensed.
- Safety investigations will be prioritized, however longer visit windows for all other activity needs to be discussed with sponsors
- Patients requiring essential imaging may need to attend a local imaging centre

In the event that a clinical trial patient has a suspicious or confirmed COVID19 infection:

- Unless requiring admission, patients will not be allowed access to Alfred health site and won't attend any scheduled visits
- Investigators will maintain contact with the patient by phone during the period of isolation by a RN/PI or SI, particularly with respect to safety and treatment interruption

- Patients will not be allowed to visit local pathology centres, imaging centres or GPs, therefore local and central pathology will be curtailed during this period
- Efficacy visits will be delayed until the patient has recovered

In the event that a clinical trial patient refuses to come to site due to fear of contracting COVID19 or is unable to physically attend the site:

- AE and concomitant medication assessments may take place over the telephone by a RN, PI or SI of study
- have safety pathology completed in a local pathology collection centre
- ensure patients contact the site with any safety concerns
- *Access to oral drugs for patients will be discussed with sponsors on a case by case basis including dispensing of drugs via courier or increasing the amount of drug dispensed
- Patients requiring essential imaging may need to attend a local imaging centre
- In exceptional circumstances, and will approval of the sponsor, a visit may be arranged at another site or facility.

***Clinical Trials involving drugs:**

- Oral drugs may be able to be couriered to patients depending on the drug and temperature requirements. This must be discussed with the sponsor first and then Clinical Trials Pharmacy. cc Clinical Trials Pharmacy with the sponsor confirmation. Units will need to arrange courier services.
- Investigators should contact the sponsor to check availability of drug as drug manufacture and supply may be impacted.
- Clinical Trials Pharmacy has some limited additional storage for extra stock if required.
- Investigators considering provision of an increased amount of dispensed drug should contact the sponsor first and then Clinical Trials Pharmacy. cc Clinical Trials Pharmacy with the sponsor confirmation.
- Clinical staff assisting trial staff in dispensing trial drugs must be on the delegation log even if it is not signed by the PI, if the PI is unavailable.
- Investigators will need to consider contingency plans for the possibility that Clinical Trials Pharmacy staff are redeployed to other pharmacy services or are unable to provide a service.

In the event that clinical trial staff have suspicious or confirmed COVID19 and are unable to come to work:

- Trial activity during the period of absences will need to be reduced.
- The remaining staff priority will be to ensure that enrolled patients are reviewed and treated.

The following may also be initiated, depending upon the number of trial staff affected:

- All data entry reduced – priority will be given to essential SAE and AE reporting
- All protocol amendments (unless directly related to patient safety) may be suspended
- All administrative tasks will be prioritized based on staff's ability to perform such activities
- RGO and HREC submissions for new trials may be delayed
- Data lock timelines not able to be adhered to

Alfred Health also acknowledges that sponsors may be affected by COVID19 and would appreciate information that will affect operations at site. This includes, but is not exclusive to:

- an interruption in the supply of trial drugs or devices, central kits, study supplies and support to any trial specific portals
- planned teleconferences
- monitoring
- SIV completion

For Alfred Health sponsored trials, coordinating site staff should implement contingency plans in respect to the above information and their obligations for safety monitoring.

Reporting to the Alfred Hospital Ethics Committee and Alfred Health RGO:
As this situation is unprecedented, it is acknowledged that protocol and GCP breaches are inevitable. There is no suitable guidance covering reporting currently available.

As safety in clinical trials is the priority, all significant safety issues, urgent safety measures and serious breaches impacting on patient safety and rights should be reported.

With respect to non-serious breaches, in lieu of reporting individual events, a post COVID-19 deviation report should be submitted after the situation has resolved.

The report will require summary information on:

- number of patients impacted,
- changes to medication dispensing,
- dose interruptions,
- changes to visit schedule and visit activities
- use of external services (e.g. pathology, imaging, visit sites)
- missing data

We thank you for your support of the Alfred Health contingency plan.

Professor Stephen M. Jane
Director of Research
Alfred Health