Monash Health is committed to the ongoing support of its patients, staff, and community.

In the current environment of responding to the COVID-19, Monash Health will continue to offer care to all clinical trials participants. However, as the situation develops, contingencies will be implemented and reviewed regularly in order to manage the safety of patients, staff and the community.

Monash Health’s priority for clinical trials is the safety of participants currently enrolled in an essential clinical trial. Other trial activities, such as feasibility, start-up visits and non-essential monitoring, whilst important, will require further consideration and may be placed on hold to best manage the health service’s broader priorities and the capacity of its staff.

All study treatment decisions must remain with the Principal Investigator, but will be subject to approval by the Monash Health executive and the Clinical Trials Governance Group put in place to support priority decision making.

Supporting Safe and Continued Care at the Monash Health Clinical Trial Centre

All essential trials will continue until otherwise advised, but with patient management amended to best minimise exposure risk as outlined below:

- Participant recruitment for all new trials will be suspended from today, Thursday 19 March 2020. Exceptions may be considered by the Clinical Trials Governance Group and approved by the Monash Health Executive.
- Participant recruitment to existing trials may continue, but will be reassessed in response to changing circumstance. This will include studies that have both Ethics and Governance approval and have completed study start up activities.
- Those participants who have already provided informed consent and are undergoing screening, are permitted to continue screening for essential trials, as long as the Principal Investigator believes this is imperative to the participant’s care.
- Other research studies which involve retrospective chart review, data linkage, remotely completed questionnaires, etc. only and which do not require patients to visit the hospital, may commence or continue in accordance with existing approvals.
- Research Coordinators will make contact with participants no later than the day before a scheduled visit, to enquire whether:
  - the participant has knowingly been in contact with a person who has a confirmed case of COVID-19;
  - the participant is experiencing any cold/flu/fever symptoms;
  - the participant has recently travelled through or to Iran, mainland China (excluding Hong Kong SAR, Macau and Taiwan) Italy or South Korea;
  - the participant has returned from overseas since 12:00am on Monday 16 March 2020;
- If the participant advises that they are experiencing any cold/flu/fever symptoms, they will be required to undergo testing. As soon as they have confirmation that they do not have COVID-19, they may reschedule their visit.
- If a participant has been in contact with an infected person or has recently travelled internationally, they will not be permitted to attend the study visit. Study visits may be rescheduled to occur no less than 14 days after returning to Australia.
- If site access is deemed a risk, dispensing procedures will be amended for all self-administered drugs. Subject to approval by sponsors, Principal Investigators, and the site pharmacy, this may

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1 As assessed by the Clinical Trials Governance Panel, an essential clinical trial is one in which the potential therapeutic benefit outweighs the potential risk of infection by attending the Clinical Trials Centre.
include ensuring that participants have the drug couriered to them directly or are provided with sufficient drug to tide them over until other arrangements have been made.

- Research participants not able to self-administer will continue to attend appointments as planned, but may be asked to undergo different access procedures.
- Monitoring and non-essential treatments will be reviewed by the Primary Investigators and assessed in terms of suspension.
- Research participants will be advised about necessary arrangements for study visits, including pathology and imaging. Arrangements may include attending local providers (i.e. local i-MED or Melbourne Pathology) or maintaining appointments as previously planned (i.e. Moorabbin imaging).
- In the event that the study visit does not require trial medication/pathology samples or other clinical procedures, other avenues, such as telephone or TeleHealth tools, may be utilised.
- In the event that a participant presents to the trials centre with cold/flu or fever, they will be asked to attend the fever clinic and will need to reschedule the study visit. All research participants can also check the COVID-19 Information page on the Monash Health website frequently as new information is becoming available daily: https://monashhealth.org/patients-visitors/coronavirus/

**Research teams**

- Principal Investigators and their teams may be impacted and must self-isolate if they have COVID-19, have been in contact with an infected person, are suspected of having COVID-19, or have recently returned from overseas.
- Research teams are required to prepare over the next two weeks:
  - A written evaluation of which trials they deem to be essential for ensuring participant’s continuity of care and the trials that they deem to be non-essential and may be put on an interim hold;
  - A written contingency or business continuity plan that may be enacted in the event that the Principal Investigator or their team are impacted. This includes, prioritisation of the most critical participants and the preferred course of action to be followed.
- It is proposed that the written evaluation or contingency plan be submitted to the Director of Clinical Research by Tuesday 31 March, so that a Clinical Trials Governance Group Chaired by the Director of Clinical Research and involving Principal Investigators, may review and provide an overall contingency plan for Clinical Trials. This group will also review on a regular basis, Monash Health’s position with regard to maintaining safety and continuity for clinical trials over the coming months.

**Visitors and trial support teams**

- All on-site monitoring, site selection, study start-up and site initiation visits will be put on hold, effective from Thursday 19 March 2020.
- Monitoring activities will be restricted to remote monitoring and to satisfy study milestone events within resource limitations. This will be subject to review, as the priority will be to ensure there are sufficient resources to support participant’s trial continuity.
- All routine and non-essential monitoring will be put on hold until further notice.
- All audits will be postponed.
- Carers for research participant must only attend the trial site when absolutely necessary for the participant’s safety and to provide transportation. It is strongly requested that only one carer per participant accompanies the participant to study visits.

**Research Ethics and Governance**

- In terms of Human Research Ethics and Governance, it is expected that there will be protocol deviations enacted as a result of participants being unable to attend visits or research personnel being unable to attend work. These are to be documented and provided in a summary report form when the research team are able to complete this function.
• Whilst applications for Ethics and Governance may be submitted for review and approval, new studies will not be permitted to commence until further notice.
• Only under extraordinary circumstances, such as for a therapeutic trial for COVID-19 which has been granted both Ethics and Governance approval, will exceptions be granted to commence a new trial. Such exceptions must be recommended by the Clinical Trials Governance Group for approval by the Monash Health Executive.
• Post-approval amendments for Ethics and Governance will continue as usual, to ensure safety and continuity of the studies currently underway.

Clinical Trials Governance Group
The Clinical Trials Governance Group will be convened immediately to oversee the appropriate management of Monash Health’s clinical trials activities.

The group will be chaired by the Monash Health Director, Clinical Research with membership comprising leadership of units actively involved in clinical trials, such as:

1. Gastroenterology & Hepatology
2. Haematology
3. Oncology
4. Monash Heart
5. Nephrology
6. Respiratory & Sleep Medicine
7. Rheumatology
8. Paediatric Trials Lead
9. Pharmacy
10. Diagnostic Imaging
11. Monash Pathology
12. Clinical Trials Business Development Manager
13. Human Research Ethics and Research Support Services Manager (ex officio)
14. Clinical Trials Centre Manager (ex officio)
15. Research Governance Manager (ex officio)

Further Updates
Information is becoming available on a rapid basis. Therefore, further updates will follow as required, including operational procedures to support the guidelines