

MH COVID-19 Advice for Clinical Trials and other Clinical Research studies

Effective date: Wednesday 13 May 2020

This document outlines the current Melbourne Health (MH) advice in relation to clinical trials and other clinical research activity.

MH's response to the COVID-19 emergency is based on and guided by the advice provided by the Victorian Government's Department of Health and Human Services:
<https://www.dhhs.vic.gov.au/victorian-public-coronavirus-disease-covid-19>.

MH remains committed to the ongoing support, safety and wellbeing of our patients, staff, research partners and the wider community.

MH believes it is now in the best interests of all our stakeholders, patients and staff in particular, that we move towards a resumption of normal levels of clinical research, on the understanding that we do so in parallel with the evolving COVID-19 situation and in full compliance with government and institutional guidelines and policies.

The challenges arising in relation to Coronavirus are ongoing and we ask for patience, flexibility and creativity as we work together through this rapidly evolving healthcare crisis.

Clinical trials and other clinical research activity may return to regular levels effective from Wednesday 13 May 2020.

This includes both ongoing studies, where activities/recruitment have been reduced or suspended, and new studies which have all necessary ethics and governance approvals in place to commence.

- Management of individual studies is at the discretion of, and should be coordinated by, the respective principal investigators (PIs) in consultation with their research teams and heads of department/clinical service.
- Within each department/clinical service, consideration should be given to a gradual resumption of normal clinical research activity beginning with studies offering the greatest potential benefit to participants compared with standard of care/alternative treatments. The gradual re-escalation of research activity will be influenced by a number of factors including the COVID-19 pandemic situation and associated Victorian government advisories in place at any given time as well as clinical trial space.
- Special consideration needs to be given to the relative risks of the conduct of early phase studies and studies involving aerosol generating procedures such as pulmonary function tests. The particular risks of these studies to participants and staff should be discussed with sponsors prior to study recommencement. The Respiratory Function Laboratory will advise on suitable precautions for pulmonary function tests.

- Researchers are strongly encouraged to implement/continue using measures such as telehealth, hospital in the home, study coordinator phone calls, use of local community pathology services, etc., in study protocols as far as possible – these should become an ongoing and integral component of as many clinical research protocols as possible. PIs and research teams should liaise with clinical trial sponsors and other research collaborators to formally incorporate such measures as standard procedures in current and new research protocols in the future.
- Researchers and their teams are asked to develop emergency management/contingency plans appropriate for each of their particular studies to enable a safe and rapid response to changed circumstances as may be required in the event of a rapid spike in COVID-19 infections and new urgent government advisories.
- Research staff should also familiarise themselves with current MH “*COVID-19 Practice Guidelines*” on the MH intranet site, which include detailed guidance about the use of PPE and are updated regularly.
- For study visits requiring attendance at the hospital, research nurses and coordinators should contact participants no later than a day before a scheduled visit to ascertain whether it is safe and appropriate for a participant to attend the hospital for that study visit. Questions to ask should include whether:
 - The participant has been in contact with a person who has a confirmed case of COVID-19.
 - The participant is experiencing any cold/flu symptoms.
 - The participant has returned from overseas since 16 March 2020.
 - If the participant answers “Yes” to any of the above questions, the visit should be rescheduled following appropriate action, including screening for COVID-19, a period of home isolation, etc., where required.

RMH Clinical Trials Centre - Facilities for Clinical Trials Visits

- The temporary relocation of the RMH CTC, to accommodate the Patient Transit Lounge in the CTC space in 2 south west is ongoing at this time. Limited alternative facilities for clinical trials activities are available and can be booked through the CTC administrator via email: CTC@mh.org.au
- **Please note:** The currently available CT facilities (without access to the RMH CTC) are limited, providing capacity for only 25 – 30% of the CTC capacity. The use of telehealth, hospital in the home and similar measures may assist with CT capacity.
- Available facilities include:
 - 2 South West (Procedure Room 1 only)
 - 1 South East
 - 1 Centre
 - 2 East
 - Royal Park Campus

- 4 West
- 5 West Day Medical

Monitoring of clinical trials

- Limited facilities for monitoring visits are available, including the Monitor's Room in 2 south west and the Research Tutorial Room in 2 south east. Bookings can be made through the CTC administrator via email: CTC@mh.org.au.

Research ethics and governance

- The Office for Research is open for business. (Some) Staff members are working from home on a rolling basis – all team members can be contacted by email and there are staff in the office every day, Monday – Friday.
- The MH HREC is meeting regularly and reviewing new research projects, amendments, QA projects and other correspondence in accordance with established guidelines and schedules. In order to expedite review of COVID-19 and other urgent research, additional extraordinary meetings of the HREC are held as required.

Information for all members of our community is available on MH's website at: <https://www.thermh.org.au/news/covid-19-rolling-updates-our-community#comingtohospital> and, for staff, detailed COVID-19 Clinical Practice Guidelines are available on the MH intranet site including guidelines for correct PPE and procedures. This advice is under constant review and may need to change rapidly in response to the evolving COVID-19 situation and changes in community/hospital infections.

Please bring this advice to the attention of all members of your research teams, colleagues, research partners and sponsors ASAP.

The Office for Research will provide further information and updates as these become available.