Coronavirus (COVID-19) – Monash Health Research Support Services & Clinical Trials Centre Guidelines – Revised 12 May 2020

Monash Health is committed to the ongoing support of its patients, employees, and community. In the current environment of responding to 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, employees, the community and our partners.

These guidelines are an update to the previous guidelines of 19 March 2020. Further updates will be made in response to any major directives from the Victorian Government or in response to further developments in respect to the pandemic.

Supporting Safe and Continued Care of Tier 1 and Tier 2 Trials at the Monash Health Clinical Trial Centre

All Principal Investigators who have submitted a completed contingency plan by 30 March 2020 and 23 April 2020 to indicate that the study is Tier 1 (an essential trial) or Tier 2 (non-essential) are permitted to continue on the study as long as it aligns with the following provisions:

- Physical distancing measures and efforts to keep participants off site must remain in place where possible. This includes continuing measures such as Tele Health, courier or drive through delivery of medications, and utilising alternative pathology and imaging arrangements, if possible.
- Prior to a participant attending the Clinical Trials Centre or any other Monash Health site they must be contacted by telephone the day before to ensure they are well and aware of the measures in place to ensure participant and staff safety such as; temperature screening of all patients, visitors and employees. During this call participants must be:
    - asked if they are displaying any COVID-19-like symptoms which would prevent them from attending Monash Health;
    - informed that any accompanying carers may be asked to wait off site or in the car until the study visit is completed;
    - offered support as appropriate for any anxiety about attending the hospital for vital care and informed of what measures are in place to ensure their safety while receiving care at Monash Health.
- Recruitment may resume on the basis that the Head of Department has approved resuming recruitment. Recruitment must be gradual and the Head of Department must limit recruitment to a select number of trials at any one time in a prioritised order. Capacity of the trials centre will be monitored closely and study resumption will be slowed if capacity is exceeded.
- Principal Investigators must be prepared to provide an updated contingency plan, within a one to two week time frame, if the need arises due to government or health service restrictions. Failure to do so may result in revocation of both Human Research Ethics and Governance Approval of the trial.
- 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. The Remote Monitoring Procedure on PROMPT must be followed.
- No on-site site initiation is permitted. No commercial/collaborative group representatives are permitted on site.

Supporting Safe and Continued Care of Clinical Research at Monash Health

With necessary approvals by the Head of Department and physical distancing measures observed, research studies may continue with the following measures:

- Current studies that have approval for activities that do not require attendance at a Monash Health site may continue. Examples may include retrospective chart review, data linkage, remotely completed questionnaires, interviews by video conferencing/telephone, or sample collection at a local pathology service.
- If the current study approval ***does not*** include: retrospective chart review, data linkage, remotely completed questionnaires, interviews by video conferencing/telephone, sample collection at a local pathology and the study ***can be*** done via remote mechanisms, then a post-approval amendment must be submitted to research@monashealth.org for review and approval.
    - The study cannot resume without the post-approval amendment being approved.
    - The researcher needs to ensure that the relevant protocol/project description and Participant information and Consent Forms are updated and submitted with the post-approval amendment request. This includes providing the full study title and Monash Health reference in the request. Incomplete documents will delay review and approval.
    - Researchers should allow up to two weeks for review and approval of amendments.
- If the study cannot be done with physical distancing measures and must be done at a site of Monash Health, the Principal Investigator will need to apply for an exemption, detailing the rationale for needing to conduct the study on site at Monash Health.
    - The exemption request is to be submitted to research@monashhealth.org
    - The exemption request must include written approval from the Head of Department at Monash Health.
    - Researchers should allow up to two weeks for a response.
    - The research may not resume without approval in writing from Research Support Services.

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 maintain a written contingency plan for each study that may be enacted in the event that the Principal Investigator or their team are impacted.

Research Ethics and Governance

- Applications for COVID-19 related research are to be submitted by no later than 12noon each Monday, in order to be expedited for a response within a week.
- Research related to COVID-19 must also be registered via central repository: https://docs.google.com/forms/d/e/1FAIpQLSeksnID_laubCJZzWdMtsM_xNyVnC2STVZTolT1v6jA4CZIRQ/viewform
- Applications for Ethics and Governance of new studies may be submitted for review and approval.
- Post-approval amendments for Ethics and Governance will continue as usual and researchers should allow up to two weeks for a response. Urgent amendments for a clinical trial are expedited.

Further Updates

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