



Western Health

**Western Health
Contingency Plan for COVID-19 Interruption to Research and Clinical Trials**

Date: 13 July 2020

Due to the current resurgence of COVID-19 cases through community transmission, we are required to implement the initial contingencies that were introduced during the first wave of the pandemic dated [23 March 2020](#).

As a result all trial activities must either be re-assessed and/or undertaken through alternate means that abide by the social distancing requirements, PPE requirements and restrictions on visitors attending WH campuses.

As a result all monitoring of trials should be undertaken remotely. Site Initiation Visits (SIV) should be postponed until a more appropriate time. If for whatever reason a SIV or onsite monitoring needs to proceed onsite during the current lockdown phase, please advise the Office for Research as to the reasons why the SIV/Monitoring must proceed and what contingencies will be put in place to ensure the safety of staff, patients and the broader community. These activities may only proceed if the Office for Research approves the request. It is incumbent on the Principal Investigator (PI) and trial team to ensure that any such requests are a last resort and absolutely necessary and that all efforts were made to avoid trial visitors attending WH during this period.

Recruitment of WH patients into a trial must have a risk assessment by the relevant department to confirm that it is safe to do so. Even when departmental approval is granted, PIs constantly must exert their discretion in proceeding/continuing with any trial involving patients, as the situation evolves, on the premise that:

- it is safe to do so for the patient, staff and broader community,
- it is essential that this study proceeds under the current circumstances,
- there are no other viable alternatives in how trial activities can be conducted, and;
- that all appropriate measures will be implemented as per the COVID-19 contingencies to mitigate any risks.

Potential trial participants that would only be require to attend WH for the purpose of a trial, and not also as part of their clinical care, are not permitted to be recruited and attend trial visits during this period until further notice.

All research team members must familiarise themselves with the WH COVID-19 contingencies for research, see our webpage for information: [WH COVID-19 Contingencies](#)

If you have any queries, please do not hesitate to contact me or any member of the Office for Research Team.

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

Yours sincerely,

Bill Karanatsios
Research Program Director
Western Health