



## Western Health

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## Contingency Update for COVID-19 Interruption to Research and Clinical Trials

Date: 25 May 2020

We would like to thank everyone who has followed the initial COVID-19 research contingencies dated 23 March 2020 that was issued earlier. These contingencies still apply and we urge Principal Investigators (PIs) to still use caution and their discretion in the conduct of their research involving human participants during the COVID pandemic. However, we provide the following update in lieu of current Federal and State Government social distancing/lockdown announcements.

### Research and Clinical Trials

Whereby research involving patients of the health service has not been formally suspended at WH, the COVID-19 contingencies stipulate that such trials may continue or commence with caution and due appreciation of the potential risks that may be posed to either the patients or staff whilst undertaking such research.

As such we strongly encourage all departments to:

1. Carefully consider which research can be undertaken safely without jeopardising the safety of staff and participants. This should be determined by the respective PI and their Head of Department.
2. Acknowledge that the management and responsibility of individual studies is at the discretion of, and should be coordinated by, the respective PIs in consultation with their research teams and heads of department/clinical service.
3. Each research team should carefully continue to pursue aspects of the research that can still be conducted remotely or via safer avenues, such as telehealth etc.
4. Only allow existing patients of WH to be considered for recruitment into a trial, as research that involves non WH patients is still not able to resume as of this date. Only by exception can any research not involving WH patients resume on WH campuses. PIs of such studies must make a formal request to Bill Karanatsios on the below details for such an exemption clearly stipulating the reasons why the research should resume and contingencies that will be implemented to safeguard WH/research staff, our patients and the participants themselves. This request will be considered in accordance with current WH regulations governing permission of external visitors on WH premises.

### Monitoring of Research

If sponsors are requesting on site monitoring of clinical trials, this can be permitted if the following can be accommodated:

1. A dedicated room can be provided for monitoring purposes that is away from patient areas.
2. Monitors are limited in number and scheduled for multiple trials in accordance with what space can be made available to accommodate the social distancing requirements.
3. Monitors are to be contacted and pre-screened the day before to ascertain that they are not exhibiting COVID-19 symptoms or have been in contact with anyone diagnosed or suspected to have COVID-19 or where in a position in last two weeks that may have placed them at risk of exposure.



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4. Monitors are to be signed in with confirmation that they are COVID-19 free to the best of their knowledge and their temperature is to be taken and recorded.
5. Working space allocated to the monitors should be wiped down prior to their arrival and again at the end of the day using appropriate disinfectants.

Where monitoring requests can be accommodated remotely this should still be encouraged.

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

Yours sincerely,

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### Relevant links:

- DHHS Coronavirus Information: <https://www.dhhs.vic.gov.au/victorian-public-coronavirus-disease-covid-19>
- Australian Governance – Department of Health. Coronavirus (COVID-19) news & media: <https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-news-and-media>
- Western Health Novel Corona Virus Information: <https://coronavirus.wh.org.au/>
- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic>