

Thursday 21st May 2020

### Revised Guidelines during COVID-19 for Clinical Trials and Other Clinical Research at Austin Health

Austin Health is committed to the ongoing support of its patients, employees, and community. Access to clinical trials is an essential part of the care we provide.

We are now moving from a very threatening environment in which we anticipated widespread community transmission of COVID-19 with massive strain on our hospital, to a new low -prevalence but unstable situation. While the risk is now much reduced, the consequences of allowing COVID-19 into Austin Health remain potentially devastating.

As the situation continues to change, contingencies will be implemented and reviewed regularly. We must carefully manage the safety of patients, employees, the community and our partners.

During re-opening and while operating in the COVID-19 era the onus rests with trial Principal Investigators to adhere to the following:

1. You must comply with Victorian Government health regulations (which are subject to frequent change) and you must keep up to date with these.
2. A weekly Austin Health Situation Report is circulated on Friday afternoon to keep managers abreast of new or emerging requirements relating to the COVID-19 situation, and provides information on relevant policies and guidelines. The COVID-19 Sharepoint Folder in MS Teams is the simplest source of local updates.
3. Subscribe to the Victorian Government Coronavirus COVID-19 Daily Update <https://www.dhhs.vic.gov.au/coronavirus-covid-19-daily-update>
4. You, your team and any visitors are strongly encouraged to download and activate the COVIDSafeApp <https://bit.ly/2LHhf7G>
5. Recruitment may resume with approval from each relevant Head of Department. Recruitment must be *gradual* and your capacity to manage the workload constantly monitored.
6. You have responsibilities to protect your staff, your patients, Austin Health and essential visitors from COVID-19 (including research study monitors). **Working from home where possible is still official Victorian Government Policy.** Commercial/collaborative group representatives are very strongly discouraged from coming on site but instead should conduct their roles by teleconferencing. You must provide a safe workplace. Wherever possible staff who can work from home should continue to do this. If working on site:
  - Stay at home if you are sick (get tested).
  - Avoid physical contact when greeting each other.
  - Keep your distance – stay 1.5 metres away from others
  - Practise good hand hygiene
  - Attend to regular surface and contact-point cleaning
  - 4 square metres or more is required per work station
  - Sharing food is not permitted.
  - Face to face meetings of greater than 20 people are not permitted.

7. Refer to the COVID-19 Exposure in the Workplace Procedure and complete the workspace risk assessment.
8. Familiarise yourself with Austin Health's Visitor Policy <https://www.austin.org.au/inpatients>
9. You must have robust systems to ensure that no one (staff, patient, study monitor, other) with SYMPTOMS enters Austin Health premises including offsite testing facilities, without being first diverted and tested for COVID-19. For patients this is best done by a completing a Risk Assessment for COVID-19 by telephone 24-hours prior to any visit and again at the commencement of the visit. See Appendix A. Please liaise with Infection Control (COVID Registrar) to discuss any queries or concerns.
10. The Office for Research strongly supports remote Site Initiation Visits (SIVs). If this cannot be undertaken remotely, then only **one** monitor is allowed on site. A risk assessment (Appendix A) must be completed for the monitor. The workstation for the monitor must be located in a non-patient area and you must ensure that you comply with the requirements in POINT 6 above.
11. The Office for Research strongly supports Remote Monitoring Visits. If this cannot be undertaken remotely, then a monitor is allowed on site. A risk assessment (Appendix A) must be completed for the monitor. The workstation for the monitor must be located in a non-patient area and you must ensure that you comply with the requirements in POINT 6 above.
12. Efforts to keep participants off site must remain in place where possible. This includes continuing measures such as Telehealth, courier or drive through delivery of medications, and utilising alternative pathology and imaging arrangements.
13. Principal Investigators must be prepared to provide the Office for Research with a contingency plan within 24 hours of a major change in public health policy (e.g. return to full level 3 restrictions).

Please acknowledge by reply email to [research@austin.org.au](mailto:research@austin.org.au) to indicate that you have read and understood the requirements, and copy in the relevant Head of Department. Once you have completed this, you may commence patient recruitment.

**Additional support from Office for Research:**

If you need further advice, please contact either:

**Mrs Lisa Pedro, Manager Ethics and Research Governance**

E: [lisa.pedro@austin.org.au](mailto:lisa.pedro@austin.org.au), Mobile 0418 342 209

**Dr Sianna Panagiotopoulos, Manager, Office for Research**

E: [research@austin.org.au](mailto:research@austin.org.au), Mobile 0419 884 715

Website: [https://www.austin.org.au/Office\\_for\\_Research\\_COVID-19/](https://www.austin.org.au/Office_for_Research_COVID-19/)

### Participant Study visits and Risk Assessment for COVID-19

- It is important that you perform a risk assessment **24 hours before** a participant/monitor attends for a planned visit to determine if it is safe for participants to attend for that visit.
- It is important that you repeat a risk assessment **at the start of the planned** visit.
- A carer for research participants must only attend the planned visit when absolutely necessary. A risk assessment should also be performed for the carer.
- If the participant/monitor/ carer answers YES to any of the questions, it will be necessary to reschedule the visit until the person/s is/are cleared. Please follow the directions below:

**a) If the participant/monitor/ carer is already at our precinct:**

- STOP,
- offer the patient a surgical mask,
- offer the patient a seat away from others,
- phone the Austin Health coronavirus hotline, 9496 6606 (8am-8pm 7 days).
- Hotline staff will speak to the patient and provide further guidance

**b) If the participant/monitor/ carer is at home:** refer the patient for COVID-19 testing (a list of testing locations can be found on the [Getting tested for coronavirus \(COVID-19\)](#) page)

1. Do you have any of the following symptoms?	Tick box	Date first noticed
Fever or chills (in the absence of an alternative diagnosis that explains the clinical presentation)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Cough	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Shortness of breath	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Sore throat	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Runny nose	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Anosmia	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Additional questions for healthcare or aged care workers:</b>		
<b>Additional questions for close contacts of a confirmed COVID-19 case:</b>		
Stuffy nose	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Headache	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Myalgia	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Nausea	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Vomiting	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Diarrhoea	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Testing is recommended for people with new onset of other clinical symptoms consistent with COVID-19 AND who are close contacts of a confirmed case of COVID-19; who have returned from overseas in the past 14 days; or who are healthcare or aged care workers.		

<b>2. Risk assessment completed by:</b>		
Name:		Date:
Contact (phone or email):		