

## Epworth Research COVID-19 Guidelines Update– March, 2021

When implementing our COVID-19 response measures, at all times the safety of our patients and staff are our highest priority. The following COVID-19 response measures apply to clinical trials conducted at Epworth HealthCare.

### CLINICAL RESEARCH AT EPWORTH

All currently approved clinical trials and other research studies may continue unless otherwise advised, with patient management aimed at minimising exposure risks as outlined below.

All projects, investigators and study staff must follow the most recent Epworth COVID-19 guidelines for visitors, physical distancing and face mask measures.

Where appropriate, efforts to minimise participant visits to Epworth sites are encouraged.

Prior to participants attending any Epworth sites they must be contacted no later than the day before a scheduled visit, to enquire whether:

- the participant has knowingly been in contact with a person who has a confirmed case of COVID-19;
- the participant is experiencing any cold/flu/fever symptoms and;
- the participant has returned from overseas since Monday 16 March 2020.

If a participant advises that they are experiencing any symptoms (cold/sore throat/cough/fever), they will not be permitted to attend a study visit and will be required to undergo testing. As soon as they have confirmation that they do not have COVID-19, they may reschedule their visit.

If a participant has been in contact with COVID-19 cases or has recently travelled internationally, they will not be permitted to attend the study visit. Study visits may be rescheduled to occur no less than 14 days after returning to Australia or the potential exposure.

Research participants will be advised about necessary arrangements for study visits, including pathology and imaging. Arrangements may include attending local providers (eg. Melbourne Pathology) or maintaining appointments as previously planned (eg. Epworth Imaging).

In the event that an impacted study visit does not require trial medication/pathology samples or other clinical procedures, other avenues, such as telephone or TeleHealth tools, may be utilised.

In the event that a participant presents to any Epworth site for a study visit with cold/flu or fever, they will not be permitted to attend and be asked to contact their GP clinic by telephone, and to reschedule their study visit.

## RESEARCH STAFF

Principal Investigators and their teams must self-isolate in accordance with Epworth HealthCare policy if they have tested positive for COVID-19, if they have been in contact with an infected person, are suspected of having COVID-19, or have recently returned from overseas.

Principal Investigators/study teams are encouraged to prepare a COVID-19 contingency plan to be implemented as required. This may be in response to government or health service restrictions or in the event the Principal Investigator or study team are impacted.

## MONITORING and SITE VISITS

Monitoring activities and site visits may be conducted onsite (where COVID-safe measures can be maintained) or by remote monitoring. Remote clinical trial monitoring visits are encouraged and may be conducted using SiteDocs in accordance with SOP-TM-09: Management of Remote and Onsite Monitoring Visits.

## STUDY PARTICIPANTS WITH SUSPECTED OR CONFIRMED COVID-19 INFECTION

Clinical trial participants with suspected or confirmed COVID-19 infection will be managed according to the standard Epworth HealthCare COVID-19 patient management protocol. Clinical trial participants with COVID-19 will not be treated differently to non-clinical trial patients with suspected or confirmed COVID-19 infection.

## PROTOCOL DEVIATIONS DUE TO COVID-19

Instances of participants not attending a scheduled clinical trial visit due to being:

- in isolation at home with suspected or confirmed COVID-19 infection;
- treated in hospital for suspected or confirmed COVID-19 infection or;
- considered at-risk by attending for a clinical trial visit.

will be recorded as COVID-19-related Adverse Events and managed accordingly.

## TRAVEL ADVICE AND EXPOSURE SITES

Any staff member who has returned to Australia from overseas travel, must self-isolate until 14 days have passed. For all those involved in clinical trials, Epworth strongly advises against personal travel overseas or interstate unless this is necessary under exceptional circumstances.

Anyone who has visited any exposure site listed on the Department of Health website (<https://www.dhhs.vic.gov.au/case-locations-and-outbreaks-covid-19>) during the times indicated should get tested and isolate for 14 days, regardless of the results.

## REPORTING TO THE EPWORTH RESEARCH GOVERNANCE OFFICE

COVID-19 Adverse Events should be reported to the RGO in accordance with Epworth Research 'Management and Reporting of Safety Events' Standard Operating Procedure SOP-TM-06. There are currently no additional requirements for reporting clinical trial COVID-19 events to the RGO. However, our RGO reporting requirements may change as further information and guidance becomes available.