Epworth Research COVID-19 Contingency Plan Update– July 8, 2020

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

CLINICAL TRIALS CURRENTLY OPEN TO RECRUITMENT

All clinical trials currently open to recruitment will continue until otherwise advised, but with patient management aimed at minimising exposure risk as outlined below:

Participant recruitment for all ***pending*** trials (not yet open to recruitment) may commence if approved by the Group Director of Research and Development in addition to all other mandatory approvals.

Participant recruitment to ***existing*** trials may continue, but will be reassessed in response to changing circumstance. This will include studies that have both Ethics and Governance approval and have completed study start up activities.

Those participants who have already provided informed consent and are undergoing screening, are permitted to continue screening for ***essential*** trials, as long as the Principal Investigator believes this is imperative to the participant's care.

Other research studies which involve retrospective chart review, data linkage, remotely completed questionnaires, etc. *and* do not require patients to visit the hospital, may commence or continue in accordance with existing approvals.

Research Coordinators will make contact with participants 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;
- the participant has returned from overseas since Monday 16 March 2020;

If the participant advises that they are experiencing any cold/flu/fever symptoms, they 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 an infected person 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 the 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 the trials centre with cold/flu or fever, they will 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.

MONITORING VISITS

Onsite clinical trial monitoring visits are not permitted until further notice.

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;
- considered at-risk by attending for a clinical trial visit;

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

TRAVEL ADVICE

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.

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.