As per the directives outlined in the **Epworth Research Coronavirus (COVID-19) Contingency Plan – 19 March 2020** all clinical trials currently open to recruitment may continue until otherwise advised with patient management amended to best minimise exposure risk. **However pendingclinicaltrials (not yet open to recruitment) are currently suspended.**

## Research studies which involve retrospective chart review, data linkage or remotely completed questionnaires may continue to be registered and authorised in accordance with existing policies and procedures only if:

## Direct researcher/patient contact is not required;

## Participants are not being asked to visit the hospital/research centre for the sole purpose of participating in the study;

## Researchers are not accessing wards or patient populated areas of the hospital unnecessarily to conduct research.

The registration of new research projects with the Research Development and Governance Unit (RDGU) can still occur and is encouraged. Development and governance activities will still be undertaken, however projects will only receive governance authorisation if deemed appropriate/necessary as per the stipulations above.

There may however be clinical trials that warrant **exemption from the COVID-19 research restrictions** such as those involving treatments for acute or life threatening health condition. If you wish to request an exemption from the current COVID-19 research restrictions please complete the attached form and submit with your registration request.

The RDGU and all of the Victorian NMA accredited HRECs are prioritising COVID-19 research projects**. Completion of this form is not necessary for the registration and authorisation of COVID-19 research projects.**

## **Project details**

**Study Name:**

**Principal Investigator:**

**HREC number (if applicable):**

## **Essential project information**

* Provide a brief description as to why this project should be granted governance authorisation during the COVID-19 pandemic restrictions.
* Is this research:

Commercially sponsored

Collaborative Group

Investigator Initiated

* How many patients do you intend to enrol in the study?
* Are there contingencies in place should the designated research staff become unavailable?

No

Yes, please discuss:

* Where will essential research visits occur?
* Have arrangements been made for the study to be conducted remotely (including telehealth, phone, etc.) wherever possible?

No

Yes, please discuss:

* Can you confirm that clinical trial supplies will not be affected by the COVID-19 pandemic, including trial drugs or devices, study supplies, central labs, specimen shipping abroad etc.?

No

Yes

* Is a suitably qualified and trained clinician researcher available to take over as Principal Investigator should she/he become incapacitated?

No

Yes

* Is there any other information that you see as essential for the RDGU to know about your study?

## Once complete, please submit this form with your research project registration request to [**research@epworth.org.au**](mailto:research@epworth.org.au)