



Sir Charles Gairdner and Osborne Park
Health Care Group Human Research Ethics Committee
Hospital Avenue
NEDLANDS WA 6009

18 December 2017

Dr Ed Fysh
Intensive Care Unit
Sir Charles Gairdner Hospital
Nedlands WA 6009

Dear Dr Fysh

PRN: RGS0000000699
Project Title: Efficacy and Safety Outcomes of Drainage of Intensive Care Pleural Effusions

Thank you for submitting the above research project for ethical review. This project was considered by the Sir Charles Gairdner and Osborne Park Health Care Group Human Research Ethics Committee at its meeting held on 22 March 2018.

I am pleased to advise you that, as this study meets the requirements of the *National Statement on Ethical Conduct in Human Research*, the Sir Charles Gairdner and Osborne Park Health Care Group Human Research Ethics Committee has granted ethical approval of this research project.

The nominated participating site(s) in this project is/are:

Sir Charles Gairdner Hospital

[Note: If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the Human Research Ethics Committee (HREC). Notification of withdrawn sites should also be provided to the HREC in a timely fashion.]

The approved documents include:

Document	Version	Version Date
Protocol	2.1	00/11/2017
Participant Information Sheet and Consent Form	2.1	12/02/2018
Participant Information Sheet and Consent Form – Person Responsible	2.0	12/02/2018
Participant Information Sheet - Bedside	2.0	02/02/2018

The SCGOPHCG HREC has approved this study, including the inclusion of third party consent. There is, at present, no specific reference to the capacity to utilise next of kin or third party consent within the Guardianship and Administration Act (1990) for research and this frequently prevents the approval of research predicated upon the inclusion of participants under consent provided by third party decision makers.

In this instance the HREC were satisfied that, as this research involves an assessment of existing treatment modalities and a patient will receive one of these two treatments regardless, the procedures in this study can be considered 'treatment'. As such the HREC were of the opinion that in this instance, the Guardianship and Administration Act may apply and next of kin consent could be used. Any process utilised to include patients unable to consent for themselves must comply with the precepts of the Act. However, the HREC require that, for the purposes of this research, no member of the patient's medical team act as third party decision maker in the event that other individuals higher on the third party consent hierarchy are unavailable. Any patient unable to consent for themselves and who do not have next of kin available should be treated in accordance with standard clinical practice.

Please note that while the HREC have thoroughly reviewed this research and have agreed that it is ethical and is in compliance with the *National Statement on Ethical Conduct in Human Research*, this is not a legal opinion.

Ethical approval of this project from Sir Charles Gairdner and Osborne Park Health Care Group Human Research Ethics Committee is valid from 22 March 2018 to 22 March 2023 subject to compliance with the 'Conditions of Ethics Approval for a Research Project' (Appendix A).

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate site authorisation has been obtained from the Chief Executive or Delegate of the site under whose auspices the research will be conducted at that site.

Should you have any queries about the Sir Charles Gairdner and Osborne Park Health Care Group Human Research Ethics Committee's consideration of your project, please contact the Ethics Office at HREC.SCGH@health.wa.gov.au or on 08 6457 2999. The HREC's Terms of Reference, Standard Operating Procedures and membership are available from the Ethics Office or from <http://www.scgh.health.wa.gov.au/Research/>.

The HREC wishes you every success in your research.

Yours sincerely



Sean Howarth
Delegate of the Chair
Sir Charles Gairdner and Osborne Park Health Care Group
Human Research Ethics Committee
12/12/2017 16:01