

Institutional ethical approval and governance authorisation



Dr Helen Cass
Senior Registrar
Richmond Intensive Care Unit
Epworth HealthCare

Jun 26, 2020

Dear Dr Cass

Project: The adequacy of user seal checking for N95 mask use compared to formal fit testing. A retrospective, multicentre observational study

Reference Number: EH2020-580

The above mentioned proposal satisfies the conditions set out in section 5.1.18 of the NHMRC National Statement on Ethical Conduct in Human Research (2007) and has been ethically reviewed at an institutional level.

I am pleased to advise that the above project has been considered by the Research Development and Governance Unit (RDGU) and has demonstrated no apparent risk beyond minor inconvenience to participants. **The project is therefore authorised to commence.**

The following conditions apply to the research project at this site.

1. The Principal Investigator (PI) will ensure that the research project is conducted in line with the Epworth Research Policy the Epworth Research Handbook and all applicable Standard Operating Procedures.
2. The PI will immediately report anything to the Epworth RDGU that might warrant review of authorisation of the project in the specified format.
3. The Epworth RDGU will be notified if the project is discontinued at this site before completion, and why.
4. The Epworth RDGU will be notified if the PI leaves Epworth.
5. The Epworth RDGU will be notified of any amendments to the project.
6. The Principal Investigator will provide progress reports to the Epworth RDGU, in the specified format, and provide a comprehensive final report at the completion of the project.
7. The RDGU may undertake an internal audit of the research activity at Epworth. The PI must accommodate these activities and allow time to meet with the auditor, where required.

If you have any questions regarding this letter, please contact the Research Development and Governance Officer: (03) 9936 8058, Research@Epworth.org.au

Yours sincerely,

A handwritten signature in black ink, appearing to read "Nik Zeps".

Nikofajp Zepi (Jun 26, 2020 08:54 GMT+10)

Prof Nik Zeps
Group Director of Research and Development

Research Development and Governance Unit
Epworth HealthCare