

17 April 2018

Human Research Ethics Committee

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Dr Francesco Piccolo
Head of Respiratory & Sleep Medicine
SJG Midland Public & Private Hospitals, PO Box 1254
MIDLAND WA 6936

Dear Dr Piccolo,

Re: (NORAD) Expired Nitrous Oxide Predicting ReADmission: A prospective cohort study to evaluate fractional exhaled nitric oxide levels in hospitalised patients with acute exacerbations of chronic obstructive lung disease and the risk of hospital readmission
(Our ref: 1370)

Thank you for forwarding the above study for review by the St John of God Health Care (SJGHC) Human Research Ethics Committee (“the Committee”) and for your response to a query from the SJGHC HREC dated 13 April 2018.

I am pleased to advise that the Committee has granted ethical approval of your study as satisfying the ethical requirements under the National Health and Medical Research Council’s *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) (“the National Statement”). This ethical approval is inclusive of the documents included in your submission letter dated 26 March 2018.

The HREC approval period is from 17 April 2018 to 1 April 2020. Should an extension of this timeframe be required, you must seek continued approval from the Committee before the expiry of this time period.

In accordance with NHMRC guidelines, the Participating Site/ Principal Investigator is responsible for:

1. Notification to the HREC of any adverse events or unexpected outcomes that may affect the continuing ethical acceptability of the study;
2. The submission of any proposed amendments to the study or previously-approved documents;
3. The submission of an annual progress report for the duration of the study which is due on the anniversary of HREC approval;
4. Reporting of all protocol deviations to the sponsor (if applicable) and all serious breaches reported to the HREC (preferably via the sponsor), together with details of the procedure(s) put in place to ensure the deviation or serious breach does not recur;

Core Members

Clin Prof Dr Simon Dimmitt
BMedSc (Hons) MBBS FRACP FCSANZ
Chair

Ms Tracey Piani
RN BA (Hons)
Member with current experience
in the professional care of humans

Fr Joe Parkinson
STL PhD
Member who performs a pastoral care role

Mr Eric Heenan
BLaws (Hons) The Honorable Q.C.
Member who is a lawyer that is
not engaged to advise the institution

Dr Janie Brown
BNurs Med PhD
Member with current relevant
research experience

Sr Leonie O’Brien
BEd MPS
Laywoman with no affiliation
to the institution

Dr Ben Carnley
MBBS FRACP FRCPA
Member with current relevant
research experience

Mr Hamish Milne
BA (Hons) MPhil MBA GAICD FAIM
Layman with no affiliation to the institution

Other Members

Prof Sally Sandover
BSc MPH
Community member
Expert knowledge in medical education

Mr Patrick O’Connor
MPsych (Clinical) MBA
Community member with expert
knowledge in clinical psychology

Mr Colin Keogh
BSW MAPP GCLCC
Hospital Representative
Expert knowledge in Mission and culture

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5. Notification and reason for ceasing the study prior to its expected date of completion (if applicable);
6. The submission of a final report and translation of results (including publications) upon completion of the study.

The following documents have been reviewed and approved:

Title	Version	Date
Study Protocol	1.2	Mar 2018
PIS and Consent	1	Mar 2018
GP Letter	1	Mar 2018
CRF 1 - Day 1	2	Mar 2018
CRF 2 - Early Post-Discharge		Nov 2017
CRF 3 - 6 week follow up		Oct 2017
CRF 4 - 3 month follow up		Oct 2017
CRF 5 - 6 month follow up		Oct 2017
CRF 6 - 9 month follow up		Oct 2017
CRF 7 - 12 month follow up		Oct 2017
MDA National Insurance Certificate for David Manners expiring 30 June 2018		25/01/2018
ANFIUWP Professional Indemnity Insurance Certificate expiring 20 February 2018		

You are reminded that this letter constitutes ethical approval only. You must not commence this research at SJGHC until separate authorisation in writing has been obtained.

Final approval for this study to be conducted at SJG Midland is subject to receipt of a completed Participating Site Operational Approval form (PSOA). Once this has been received by the SJGHC Ethics Office, you will be advised of final study approval in writing.

I wish you well with your research.

Yours sincerely,



Clinical Professor Dr Simon Dimmitt
Chairman
St John of God Health Care Human Research Ethics Committee

cc. Robyn Lewis, SJG Midland Hospital (via email)