



21 March 2108

Dr Adelaide Charlton
Intensive Care Unit
John Hunter Hospital

Dear Dr Charlton

Re: DCD 1010 (PILOT STUDY): Validation Of A Spontaneous Breathing Test To Better Predict Time To Circulatory Death In Organ Donation Candidates (Safety And Feasibility Study) (1703/15/4.02)

HNEHREC Reference No: 17/03/15/4.02

NSW HREC Reference No: HREC/17/HNE/85

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Hunter New England Human Research Ethics Committee. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has determined the variation meets the requirements of the National Statement on Ethical Conduct in Human Research and has granted ethical approval for the following amendment requests:

Document	Version	Date
Protocol	5	9 March 2018
Master Person Responsible Information Sheet and Consent Form	6	9 March 2018

- For the addition of The Tweed Hospital and The Cairns Hospital as study sites;
- For the addition of Dr Michael Lindley as Principal Investigator at The Tweed Hospital;
- For the addition of Ms Mary Campbell as co-investigator at The Tweed Hospital;
- For the addition of Dr Angus Carter as Principal Investigator at The Cairns Hospital;
- For the addition of Ms Loren Ginders as co-investigator at The Cairns Hospital; and
- For the additional role for Dr Adelaide Charlton as co-investigator at The Cairns Hospital

Approval has been granted for this study to take place at the following sites:

- **John Hunter Hospital, NSW**
- **Royal North Shore Hospital, NSW**
- **Royal Prince Alfred Hospital, NSW**
- **The Cairns Hospital, QLD**

Hunter New England Research Ethics & Governance Office

Locked Bag No 1

New Lambton NSW 2305

Telephone: (02) 49214950

Email: HNELHD-HREC@hnehealth.nsw.gov.au

<http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx>

- Royal Brisbane & Women's Hospital, QLD
- The Tweed Hospital, QLD
- Flinders Medical Centre, SA
- Royal Adelaide Hospital, SA
- Lyell McEwan Hospital, SA
- Royal Melbourne Hospital, VIC

The *National Statement on Ethical Conduct in Human Research (2007)*, which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. Ethics Approval will be ongoing subject to the following conditions:

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals. A proforma for the annual report will be sent at the beginning of the month of the anniversary of approval. Your review date is **April 2018**.
- All variations or amendments to this protocol must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*
https://www.nhmrc.gov.au/files/nhmrc/publications/attachments/e112_nhmrc_position_statement_monitoring_reporting_safety_clinical_trials.pdf
 - Unforeseen events that might affect continued ethical acceptability of the project.
- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

The Hunter New England Human Research Ethics Committee also has delegated authority to approve the commencement of this research on behalf of the Hunter New England Local Health District. This research may therefore commence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per the contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Hunter New England Local Health District website.

Please quote **17/03/15/4.02** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

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