

07 September 2017

Dr Irene Braithwaite
Medical Research Institute of New Zealand
Private Bag 7902
Wellington 6242

Dear Dr Braithwaite

Re: Ethics ref:	17/STH/177
Study title:	A randomised, open-label, two arm, parallel group controlled trial of the efficacy of rhinotherapy delivered by nasal high flow therapy (rNHF) in the treatment of influenza.

I confirm receipt of this application for HDEC review, which was submitted on 04 September 2017.

Arrangements for HDEC review

Your application has been assigned for HDEC review by the HDEC-Expedited Review pathway.

As this pathway involves a subcommittee of the Chair plus up to two other members, this application will not be assigned to the agenda of a meeting of the full HDEC. A member of the subcommittee may contact you by telephone to discuss this application before a decision is taken.

Timeline for giving a final opinion

The 15-day clock for giving a final opinion on this application starts on 07 September 2017. This clock may stop once only, where the HDEC requires further information from you in order to make a final decision. You would then have up to 90 days to provide this further information, at which point the review clock would be re-activated.

No amendments to be made before HDEC approval

No amendments can be made to your application before it is approved, except where requested by the HDEC as a condition of approval. If you think you may need to amend your application during this time, we advise you to withdraw and re-submit it at a later date.

Please don't hesitate to contact us for further information.

Yours sincerely,



Kirsten Forrest
Advisor
Health and Disability Ethics Committees
hdec@mh.govt.nz

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI: Braithwaite CV	1	29 August 2017
CVs for other Investigators: CV For Prof R Beasley	1	29 August 2017
CV for CI: CV for Dr Fingleton	1	29 August 2017
Evidence of CI indemnity	1	01 December 2016
Evidence of scientific review: Scientific Review: Dr Davies	1	08 August 2017
Evidence of sponsor insurance	1	25 August 2017
PIS/CF: PIS / CF Rhinotherapy in Influenza Study	1	29 August 2017
PIS/CF: PIS/CF for common screening process to both the common cold and Influenza rhinotherapy studies.	1	29 August 2017
Protocol: Version 1 protocol	1	29 August 2017
Survey/questionnaire: Rhinotherapy tolerability questionnaire	1	30 August 2017
Survey/questionnaire: Influenza symptom diary	1	29 August 2017
Device User Manual for participants to have at home	1	27 August 2017
Social Media: possible line feeds	Version	29 August 2017
Poster / advertising: Flu study	1	29 August 2017
Facebook / social media advertising	1	29 August 2017
Summary of device instructions for participants	1	29 August 2017
Covering Letter: Cover letter for ethics application	1	29 August 2017
Investigator's Brochure	1.0	31 August 2017
Application		

Appendix B Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1) (c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2018
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Devonie Waaka	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

<http://www.ethics.health.govt.nz>