Wales Research Ethics Committee 5
Bangor

Mailing address:
Health and Care Research Wales
Castlebridge 4
15-19 Cowbridge Road East
Cardiff, CF11 9AB

telephone: 07970 422139
email: Wales.REC5@wales.nhs.uk
website: ww.hra.nhs.uk

22 May 2020

Dr Thomas Daniels
Consultant respiratory physician
University Hospital Southampton NHS Trust
Southampton General Hospital
SGH, Tremona Rd
Southampton
SO16 6YD

Dear Dr Daniels

Study title:	**GOOD Nasal Irrigation and Gargling to Halt Transmission of COvid-19 to care-home-based Vulnerable InDividuals**
REC reference:	**20/WA/0162**
Protocol number:	**ERGO56353**
IRAS project ID:	**282814**

The Research Ethics Committee reviewed the above application at the meeting held on 21 May 2020. Thank you for attending to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Recommendation

Number	Condition
1	The Committee strongly considered that the use of the Residents poster has the potential to needlessly alarm the care home residents as such it was recommended that this not be used at this stage of the study

This is a recommendation only and not condition of favourable ethical opinion.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Intervention CH - poster]	1	29 April 2020
Copies of advertisement materials for research participants [Residents poster - all CH]	1	29 April 2020
Covering letter on headed paper [Cover letter]	1	07 May 2020
Instructions for use of medical device [Rinsing instructions]	1	05 May 2020
Interview schedules or topic guides for participants [Interview schedule]	1	22 April 2020
Letter from funder [Funder letter]	1	06 May 2020
Letter from sponsor [Sponsor letter]	1	05 May 2020
Letter from statistician [Statistician letter]	1	06 May 2020
Non-validated questionnaire [Baseline]	1	29 April 2020
Non-validated questionnaire [Manager - weekly]	1	29 April 2020
Non-validated questionnaire [Staff - intervention]	1	29 April 2020
Non-validated questionnaire [Champion - weekly]	1	29 April 2020
Non-validated questionnaire [Staff - control]	1	29 April 2020
Participant consent form [Interview consent form]	1	28 April 2020
Participant information sheet (PIS) [Site IS]	1	22 April 2020
Participant information sheet (PIS) [Care worker IS]	1	28 April 2020
Participant information sheet (PIS) [Interview IS]	1	28 April 2020
REC Application Form [REC_Form_07052020]		07 May 2020
Research protocol or project proposal [protocol]	1	27 April 2020
Summary CV for Chief Investigator (CI) [CI CV]	1	30 April 2020
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study flow diagram]	1	05 May 2020

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

No declarations of interest have been made in relation to this application

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 282814	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Jason Donal Walker, MB BCh BAO, FRCA
Consultant Anaesthetist
Chairman Wales REC 5

E-mail: WalesREC5@wales.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

Wales Research Ethics Committee 5

Attendance at Committee meeting on 21 may 2020

Committee Members

Name	*Profession*	*Capacity*	*Present*
Dr Swapna Alexander	Consultant Physician	Expert	Yes
Mr David Rhys Jones	Retired Teacher	Lay +	Yes
Mr Eliezer Lichtenstein	Manual Therapist	Lay +	Yes
Dr Pamela A Martin-Forbes	Clinical Studies Officer	Expert	Yes
Dr Paul G Mullins	Reader, Senior MRI Physicist (Vice-Chair)	Lay +	Yes
Mr Vishwanath Puranik	Consultant ENT Surgeon	Expert	Yes
Mrs Lynn C Roberts	Matron, Emergency Department	Expert	Yes
Dr Judith L Roberts	Lecturer, Clinical Psychologist	Expert	Yes
Dr Giovanni d'Avossa	Consultant Neurologist	Expert	Yes
Dr Jason D Walker	Consultant Anaesthetist (Chairman)	Expert	Yes

In attendance

Name	*Position (or reason for attending)*
Mr Norbert Leon Ciumageanu	Research Approvals Officer
Mr Gurmel Bhachu	Research Approvals Specialist
Dr Sumayya Mushtaq	Observer