HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

APPROVAL TO CONDUCT HUMAN RESEARCH

To Chief Investigator or Project Supervisor:	**Associate Professor Sally Hewat**
Cc Co-investigators / Research Students:	**Doctor Gwendalyn Webb** **Miss Hollie-Ann Shortland** **Conjoint Associate Professor Anne Vertigan**
Re Protocol:	**Myofunctional device use in oral care and swallowing in an aged care population: A pilot feasibility study**
Date:	**30-Sep-2021**
Reference No:	**H-2021-0250**

Thank you for your recent application to the University of Newcastle Human Research Ethics Committee (HREC) for approval of the protocol identified above.

Details of previous approvals for Initial, Renewal and Variation applications are available upon request.

A *Certificate of Approval* is enclosed.

THE *CERTIFICATE* AND THIS ADVICE ARE TO BE RETAINED
THEY ARE IMPORTANT DOCUMENTS

- Note any comments related to the approval.
- **Where the HREC is the lead or primary HREC, if the research requires the use of an Information Statement, ensure the Reference No. is inserted into the complaints paragraph in the approved document(s) prior to distribution to potential participants.**
- Where the research is the project of a higher degree candidate, it is the responsibility of the project supervisor to ensure that the candidate receives this approval advice.

Conditions of Approval

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as detailed below.

PLEASE NOTE:
In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's HREC.

- ***Monitoring of Progress***

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. The *Certificate of Approval* identifies the period for which approval is granted and your progress report schedule. A progress report is required on an annual basis, you will be advised when a report is due.

- ***Reporting of Adverse Events***

1. It is the responsibility of the person **first named on the Certificate** to report adverse events.

2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.

3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Certificate to the (HREC) by way of the Adverse Event Report form within 72 hours of the occurrence of the event or the investigator receiving advice of the event.

4. Serious adverse events are defined as:
    - Causing death, life threatening or serious disability.
    - Causing or prolonging hospitalisation.
    - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
    - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
    - Any other event which might affect the continued ethical acceptability of the project.

5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.

6. Adverse events which do not fall within the definition of serious, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- ***Variations to approved protocol***

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research*. Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which

case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

With best wishes for a successful project.

Associate Professor Ami Eidels
Chair, Human Research Ethics Committee

For communications and enquiries:
Human Research Ethics Administration

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RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref

HUMAN RESEARCH ETHICS COMMITTEE
Certificate of Approval

Applicant: (first named in application)	Associate Professor Sally Hewat
Co-Investigators / Research Students:	Doctor Gwendalyn Webb Miss Hollie-Ann Shortland Conjoint Associate Professor Anne Vertigan
Protocol:	Myofunctional device use in oral care and swallowing in an aged care population: A pilot feasibility study

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the *National Statement on Ethical Conduct in Human Research, 2007*, and the requirements within this University relating to human research.

Note: Approval is granted subject to the requirements set out in the accompanying document ***Approval to Conduct Human Research***, and any additional comments or conditions noted below.

Details of Approval

HREC Approval No: H-2021-0250	**Date of Initial Approval:** 18-Aug-2021

Approval

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.

Progress reports due: Annually.

If the approval of an External HREC has been "noted", the reporting period is as determined by that HREC.

Approval Details

Initial Application

Approved

Authorised Certificate held in Research & Innovation Services

Human Research Ethics Committee