

Dear Laura

Application Number: 403/10

Title: **Use of a Novel Technique to Assess Swallowing Function in Healthy Older Adults**

Chief investigator: **Dr. Charles Cock**

The Issue: The Southern Adelaide Health Service / Flinders University Human Research Ethics Committee (SAFUHREC) have reviewed and approved the above application. Your project may now commence. The approval extends to the following documents:

- Study Protocol
- Participant Information Sheet Amended 13 December 2010
- Consent Form
- Study Advertisement
- Confirmation of insurance arrangements from SA Health

Approval Period: 15 December 2010 to 15 December 2013

Please retain a copy of this approval for your records.

TERMS AND CONDITIONS OF ETHICAL APPROVAL

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. Compliance with the *National Statement on Ethical Conduct in Human Research (2007)* & the *Australian Code for the Responsible Conduct of Research (2007)*
2. To immediately report to FCREC anything that may change the ethical or scientific integrity of the project.
3. To regularly review the FCREC website and comply with all submission requirements as they change from time to time.
4. Submit an annual report on each anniversary of the date of final approval and in the correct template from the FCREC website
5. Confidentiality of research participants **MUST** be maintained at all times.
6. A copy of the signed consent form must be given to the participant unless the project is an audit
7. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
8. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
9. The researchers agree to use electronic format for all correspondence with this department.
10. All requests for access to medical records at any SAHS site must be accompanied by this approval email.

Kind regards

BEV

**Bev Stewart-Campbell
A/Executive Officer
Human Research Ethics Committee**

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Flinders Medical Centre, Bedford Park SA 5042

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This is a formal correspondence from the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee. This committee was renamed to reflect the regional nature of the committee and the fact that the committee is jointly hosted by the Flinders University. This committee used to be known as the Flinders Clinical Research Ethics Committee. Whilst this official title of the committee has changed the committee is still properly constituted under AHEC requirements with the registration number EC00188. This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." This department only uses email correspondence for all documents unless prior arrangements have been made with the manager. No hard copy correspondence will be issued.



07 January 2014

Dear Dr Cock

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC). Whilst this official title of the committee has changed the committee is still properly constituted under AHEC requirements with the registration number EC00188. This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." This department only uses email correspondence for all documents unless prior arrangements have been made with the manager. No hard copy correspondence will be issued.

Application Number: 403.10

Title: Use of a novel technique to assess swallowing function in healthy older adults

Chief investigator: Dr Charles Cock

The Issue: The Southern Adelaide Clinical Human Research Ethics Committee (SACHREC) has issued a further approval for the above project under our expedited review program recognising that there have been neither amendments to the project nor any other changes that require fresh ethical scrutiny.

- Annual review and extension request dated 06 January 2014

Approval Period: 07 January 2014 to 07 January 2015

Please read the terms and conditions of ethical approval below, as researchers have a significant responsibility to comply with reporting requirements and the other stated conditions.

For example, the implications of not providing annual reports and requesting an extension for research prior to approval expiring could lead to the suspension of the research, and has further serious consequences.

Please retain a copy of this approval for your records.

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Centre*

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TERMS AND CONDITIONS OF ETHICAL APPROVAL

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions.

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below.

Researchers have a significant responsibility to comply with the *National Statement 5.5* in providing the SAC HREC with the required information and reporting as detailed below:

1. **Compliance** with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
2. To **immediately report to SAC HREC** anything that may change the ethical or scientific integrity of the project.
3. **It is the policy of the SAC HREC not to provide signed hardcopy or signed electronic approval letters**, as our office is moving to electronic documentation. The SAC HREC office provides an unsigned electronic PDF version of the study approval letter to the Chief Investigator/Study Manager via email. These email approvals are generated via the email address research.ethics@health.sa.gov.au which can be linked back to the SAC HREC.
4. **Report Significant Adverse events (SAE's)** as per SAE requirements available at our website.
5. **Submit an annual report on each anniversary of the date of final approval** and in the correct template from the SAC HREC website.
6. **Confidentiality** of research participants **MUST** be maintained at all times.
7. A copy of the **signed consent form** must be given to the participant unless the project is an audit.
8. Any **reports or publications derived from the research** should be submitted to the Committee at the completion of the project.
9. All requests for **access to medical records** at any SAHS site must be accompanied by this approval email.
10. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
11. The researchers agree to use **electronic format** for all correspondence with this department.
12. Researchers are reminded that **all advertisements/flyers** need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contract should be coordinated through the FMC media unit.

Kind regards
Rhiannon Kitik
Administration Officer
SAC HREC