Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

24 May 2016

Dr James Johnston
Department of Surgery
University of Auckland
Private Bag 92019
Auckland Mail Centre 1142

Dear Dr Johnston

Re:	**Ethics ref:**	**16/STH/53**
	Study title:	The nature of microbial involvement in the development of adenotonsillar hyperplasia.

I am pleased to advise that this application has been *approved* by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of Study

1. The Committee thanked the Secretariat and the Researcher for their work prior to the meeting following up on Māori consultation as this provided further required information prior to the meeting.
2. This study involves collecting, with consent, adenoids and tonsils that are being removed as part of standard care from paediatric patients at Starship and testing these to investigate the microbiomes that are causing disease processes.
3. Matched control participants will also be recruited that do not have any problems with their tonsils or adenoids to compare the microbiomes present between these groups. Control participants will have their adenoids and tonsils swabbed while under anaesthetic for another procedure.
4. The research will also involve comparing the microbiomes present for participants requiring the removal of their adenoids and tonsils, compared to those only having their adenoids removed.
5. It is hoped that this research will provide more information on why some children require their adenoids and/or tonsils to be removed and give more information about what is going on in terms of microbiomes present in this area for this group.
6. The committee appreciated that the independent peer review and noted that it was good that the researchers had adjusted their protocol in response to this peer review.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

7. The Committee questioned the eligibility criteria for control participants as although the protocol included eligibility criteria for case participants it was not included for control participants. The Committee also questioned whether the

control participants would be matched in any way to case participants. The Researcher explained that control participants would be matched to case participants but this was not formalised in the protocol.

8. The Committee questioned how controls and cases would be matched. The Researcher stated that they intend to match controls with cases by age, ethnicity, and gender. The Committee stated that it is important that the inclusion criteria and matching information is detailed in the study protocol. As the control group would not be recruited until the bulk of the case group had been enrolled into the study, it was suggested that and amended protocol could be submitted before recruitment of control participants commenced; this amendment would include details about the matching and inclusion criteria for control participants in the protocol.
9. The Committee noted that the study protocol states that in all cases the participant's adenoids and tonsils will be removed, however, some case participants will only be having their adenoids removed as part of standard care. The Researcher confirmed that some participants will only have their adenoids removed and stated that they have more data about the microbiomes found on tonsils for this group from a related study, the information from this related study means that not being able to collect tonsils from all participants is not expected to negatively impact their results to a significant degree.
10. The Committee noted that the question in the application form regarding new information being found that could influence participant's willingness to be in the study, such as new safety information, seemed to be answered incorrectly. The Researcher stated that in the case of any such information being discovered that participants, or their parents in the case that the informed consent was provided by the participant's parents, would be informed as soon as possible.
11. The Committee questioned who would initially approach potential participants about the study. The Researcher stated that the treating clinician would be informed about the study and would ask participants, or their parents, if they would like to find out more about this study. Interested participants would then be contacted by the researcher to complete the informed consent process. The committee noted that this is a suitable consent process and it is appropriate for participants to initially hear about the study from someone involved in their care.
12. The Committee noted the importance of Māori consultation for this study as it involves the head and neck as well as collection of tissue. They stated that this had been covered well by the Secretariat in emails with the Researcher prior to the meeting.
13. The Committee noted that some older participants are likely to be competent to provide their own informed consent. The Committee stated that this is a judgement call that must be made by the person collecting consent, if an older participant (for example a 15 year old) was deemed competent to provide informed consent they must provide their own informed consent. The Committee also noted that all participants aged 16 years or older must provide their own informed consent. The Researcher confirmed that they were comfortable to do this for the study.
14. The Committee questioned who would be taking the swabs of control participant's throats. The Researcher stated that he hoped to take these swabs himself as he hoped to be present for all surgeries of participants in this study.

Summary of ethical issues (outstanding)

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

15. Please remove the reference to age of consent in the Participant Information Sheet, there is no legal age of consent for research in New Zealand and all competent participants, including every participant aged 16 years or older, must provide their own informed consent. Participants deemed not competent to

provide informed consent, aged under 16 years, should provide assent and consent will be provided by their parent or legal guardian.

16. Please alter the statement in the Participant Information Sheet that says that a swab will be taken to reflect that each participant will have 6 swabs taken.
17. The Participant Information Sheet for 7-12 year olds includes information about standard care that is not study specific. However, the Participant Information Sheet should only include information on study specific procedures and does not need details such as that the participant's adenoids and tonsils will be removed through their mouth. Please remove information from the Participant Information Sheet regarding procedures that will occur as part of standard care.
18. Please ensure that the Participant Information Sheet states that the study was approved by the Southern HDEC, rather than Northern A.
19. The control Participant Information Sheet states that the swabs will be taken while the participant is under general anaesthetic, however, this is not clear in the case Participant Information Sheet. Please adjust this to clarify that swabs for all participants will be taken under general anaesthetic.
20. Please rephrase the parent/caregiver Participant Information Sheet and Consent Form to be clear that this is being signed by the participant's parent or legal guardian, as not all caregivers can provide legal consent on behalf of child participants.
21. Please provide a suitable Participant Information Sheet for participants deemed competent to provide their own informed consent, including all participants aged 16 and over.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

- You must submit an amendment before starting to recruit control participants. This amendment needs to include an updated protocol detailing the inclusion criteria (specifically matching criteria) for controls.
- Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing your study.

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the Standard Operating Procedures at http://ethics.health.govt.nz/home.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

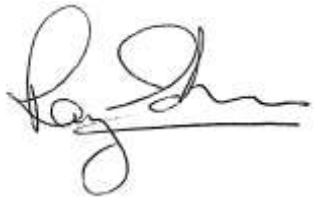
Your next progress report is due by 23 May 2017.

Participant access to ACC

The Southern Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

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

Appendix A
Documents submitted

Document	*Version*	*Date*
CV for CI: CV for CI	1	08 March 2016
Protocol: Study protocol	2	27 April 2016
Evidence of scientific review: Scientific Peer Review	1	12 April 2016
UoA Head of Department Approval	1	27 April 2016
Application		
Other (No Description Entered)		
PIS/CF for persons interested in welfare of non-consenting participant: TAAS Control Parent Caregiver Information Sheet and Consent From_Version 2.docx		
PIS/CF: TAAS Control PIS and Assent Form 7-12 years_Version 2.docx		
PIS/CF: TAAS Control PIS and Assent Form 13-16 years_Version 2.docx		
PIS/CF for persons interested in welfare of non-consenting participant: TAAS Parent Caregiver Information Sheet and Consent From_Version 2.docx		
PIS/CF: TAAS PIS and Assent Form 7-12 years_Version 2.docx		
PIS/CF: TAAS PIS and Assent Form 13-16 years_Version 2.docx		
Covering Letter: Cover Letter_3 May 2016.docx		

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

Name	*Category*	*Appointed*	*Term Expires*	*Present on 17/05/2016?*	*Declaration of interest?*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018	Yes	No
Dr Devonie Eglinton	Non-lay (intervention studies)	13/05/2016	13/05/2019	Yes	No
Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	27/10/2015	27/10/2018	Yes	No
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018	No	No
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2018	Yes	No
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018	Yes	No
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018	Yes	No

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