

17 July 2019

Dr David Martino
Telethon Kids Institute
15 Hospital Ave
Nedlands, Perth, WA 6009

david.martino@telethonkids.org.au

Dear Dr Martino

RE: The effects of chlorinated drinking water on the assembly of the infant gut microbiome: Water Quality and the Microbiome Study (TUMS) (1911)

I write to inform you that the Joondalup Health Campus Human Research Ethics Committee (JHC HREC) (EC00267) will be **closing shortly**.

Under the *National Statement on Ethical Conduct in Human Research*, all research involving humans or their identifiable data, must be approved and monitored by a properly constituted HREC that has been registered with the NHMRC.

As part of transition arrangements, ethical oversight of this project has been accepted by the Ramsay Health Care (RHC) WA|SA HREC (EC00266), the details of which are as follows:

HREC Name	Ramsay Health Care WA SA HREC
HREC Code	EC00266
HREC Contact Officer	Joanna Brisbane
Position of HREC Contact Officer	Executive Officer
Contact Officer Phone	08 9400 9897
Contact Officer Email	RamsayHREC.WA-SA@ramsayhealth.com.au

Your project approval number is indicated above, please quote this number in all correspondence to the RHC WA|SA HREC.

The approved documents include:

Document	Version	Date
JHC Application Form, including appendices: <ul style="list-style-type: none"> · Study Protocol · Child Consent Form · Eligibility Questionnaire · Study Entry Questionnaire · Water Practices Survey · ORIGINS Scientific review response · Recruiting video storyboard · Draft Media Release · Social media posts 	1	15/03/19

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<ul style="list-style-type: none"> · Microba Participant Information Sheet and Consent Form · Microba example report 		
Participant Information Sheet	2.0	-

Your ethical approval is initially for four years from date of initial approval; current approval for this project expires on 14/06/2023. After this date, you may be asked to apply for an extension or re-apply.

The RHC WA | SA HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007, updated 2018). The Committee's continuing approval of this project is subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC of any event, including new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial /evolving safety profile of the trial, or which may indicate the need for amendments to the trial protocol/documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found on the RHC research website*.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with RHC WA|SA HREC policy and procedures. These instructions can be found on the RHC research website*.
- The Coordinating Principal Investigator will report to the RHC WA|SA HREC annually in the specified format and notify the HREC when the project is completed at all sites.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found on the RHC research website*.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC if the project does not commence within six months of approval.

You are also required to notify the Committee promptly of any changes in your contact details.

A copy of this ethical approval letter should be presented when required as official confirmation of the approval of the RHC WA|SA HREC.

Please note, existing research governance approval has been maintained. Your project is currently approved at the following Ramsay Health Care sites:

RHC Site	Site Investigator	Date of Approval
Joondalup Health Campus	Professor D Silva	14/06/19

What do I need to do?

1. You will need to advise HRECs who have provided reciprocal ethical approval, funding agencies or other regulatory bodies of the change in ethical oversight.
2. Any participant documents will need to be updated (in the next print-run) with the following paragraph:

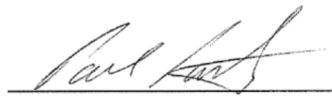
The ethical aspects of this study have been approved by the Ramsay Health Care WA | SA Human Research Ethics Committee (RHC WA | SA HREC). If you have any complaints or reservations about any ethical aspect of your participation in a research project, please contact the Consumer Liaison Office at Joondalup Health Campus on (08) 9400-9404 who will direct your complaint to the most appropriate person. Any complaint you make will be investigated by an independent party, treated in confidence, and you will be informed of the outcome.

The inclusion of this paragraph will not need to be reviewed by the full HREC but version numbers of amended documents will need to be noted by the Executive Officer, the contact details for whom are below.

Procedures relating to the submission of research amendments for existing projects, submission processes for ethical and research governance review of new projects and fees levied have also been modified. Please contact RamsayHREC.WA-SA@ramsayhealth.com.au for more information if required.

Our best wishes for the continued success of your research project.

Yours sincerely



A/Prof Paul Porter

Chairperson, Ramsay Health Care WA | SA HREC

Contact Details:

Joanna Brisbane, RHC WA | SA HREC

RamsayHREC.WA-SA@ramsayhealth.com.au

*website: www.ramsayhealth.com.au/Research/Research-Ethics