

22nd May 2020



Prof H Marshall
VIRTU
WCHN

Research Secretariat
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Dear Helen

Re: Utilising provider-parent strategies to improve influenza vaccination in children and adolescents with special risk medical conditions: a randomised controlled trial. HREC/20/WCHN/5. Ethics expiry date: 31/05/2023.

Lead HREC for the above study for the following institutions/sites:

Women's and Children's Health Network

I refer to your letters dated 24th April 2020 and 12th May 2020 and email dated 14th May 2020 in which you responded to matters raised by the WCHN Human Research Ethics Committee at its 26th February 2020 meeting. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

Specifically, the following documents have been noted/approved:

<i>Document</i>	<i>Version</i>	<i>Date</i>
FT4U Parent SMS	1.0	24 April 2020
FT4U WCH Postertext	1.0	24 April 2020
Protocol	2.1	06 May 2020
FT4U Sticker prompt	0.01	12 February 2020
FT4U GP letter	1.0	24 April 2020
FT4U Parent Survey	1.1	06 May 2020
HREA Application: AU/1/423B36		13 February 2020
Information Sheet	1.1	14 May 2020

This letter constitutes advice on ethical consideration only. You must not commence this research project at a site until you have obtained separate research governance approval from the site concerned. A copy of this letter should be forwarded to all site investigators for submission to the relevant Research Governance Officer.

At the WCHN, or any other SA Health site, separate authorisation from the Chief Executive or delegate of that site must be obtained through a Site Specific Assessment (SSA) request. For information on this process at the WCHN, please contact the WCHN Research Governance Officer, Dr Carmel Murone (telephone 8161 6688, email carmel.murone@sa.gov.au).

I remind you approval is given subject to:

- immediate notification of any serious or unexpected adverse events to participants;
- immediate notification of any unforeseen events that might affect continued ethical acceptability of the project;
- submission of any proposed changes to the original protocol. Changes must be approved by the Committee before they are implemented;



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- immediate advice, giving reasons, if the protocol is discontinued before its completion;
- submission of an annual report on the progress of the study, and a final report when it is completed to the WCHN Research Governance Officer. It is your responsibility to provide these reports, without reminder. The proforma for the report may be found on the WCHN Research Governance and Ethics website.

Approval is given for three years only. If the study is more prolonged than this, an extension request should be submitted unless there are significant modifications, in which case a new submission may be required. Please note the expiry date in the title above and include it in any future communications.

The WCHN HREC wishes you every success with your research.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Tamara Zutlevics', with a long horizontal flourish extending to the right.

TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE