

2021/HRE00250: Application HREA - Approved

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Tue 10/19/2021 11:36 AM

To: Abbot, Samuel (Health) <Samuel.Abbot@sa.gov.au>;

Date of Decision Notification: **19 Oct 2021**

Dear Samuel Abbot,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2021/HRE00250: Outcomes of proximal humerus fractures in children.

Your response has been reviewed by the Chair of the WCHN Human Research Ethics Committee. 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*.

This project has been approved to be conducted at the following sites:

- Women's and Children's Hospital

The following documentation was reviewed and is included in this approval:

- Telephone script (for parent/carer)-2-09-Oct-2021
- Structured Questionnaire-2-24-Aug-2021
- SPADI Questionnaire-1-12-Jun-2021
- QuickDASH Questionnaire-1-12-Jun-2021
- ProjectRegistration
- Participant informed consent form (third-party consent)-2-27-Sep-2021
- Participant informed consent form (providing own consent)-2-27-Sep-2021
- Telephone script (for participant over 18 years)-2-09-Oct-2021
- Participant information sheet (Children)-3-17-Oct-2021
- Participant information sheet (Adolescent)-4-17-Oct-2021
- Modified PODCI Questionnaire-1-24-Aug-2021
- Letter of invitation to participants-3-11-Oct-2021
- HREA
- Correspondence with AHREC-1-24-Aug-2021
- Participant information sheet (for parent/carer)-3-09-Oct-2021
- WCHN HREC Protocol - 2.0.docx

[Application Documents](#) - (Please note : Due to security reasons, this link will only be active for 14 days.)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.03

Date: 17 Oct 2021

The approval is for a period of **3 years from the date of this e-mail (19 Oct 2021)** , on condition of the submission of annual reports for both ethics and governance applications.

This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007) (Updated 2018). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council. Confidentiality of the research subjects must be maintained at all times as

required by law.

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.

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;
- 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.

Please contact us if you would like to discuss any aspects of this process further.

The WCHN HREC wishes you every success with your research.

Yours sincerely

Dr Tamara Zutlevics
Chair, WCHN Human Research Ethics Committee

