10th September 2018

Women's & Children's Hospital

Research Secretariat
Level 2, Samuel Way Building
72 King William Road
North Adelaide SA 5006
Tel 08 8161 6390
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Dr R Munk
Paediatric Anaesthesia
WCHN

Dear Rebecca

Re: Correction of preoperative iron deficiency in children undergoing elective spinal fusion. A Randomised control trial of intravenous ferric carboxymaltose vs. oral iron therapy. HREC/18/WCHN/3. Ethics expiry date: 30/09/2021.

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

Women's and Children's Health Network

I refer to your letter dated 31st July 2018 and emails dated 15th August 2018 and 5th September 2018 in which you responded to matters raised by the DTC Clinical Trials Group (CTG) at its 14th Junw 2018 meeting and the WCHN Human Research Ethics Committee at its 27th June 2018 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:

Document	*Version*	*Date*
Protocol	1.3	31 July 2018
Patient Data Collection Sheet	3	31 July 2018
Drug data sheet: IV ferric carboxymaltose drug information	1	17 January 2018
Questionnaire/s: The Scoliosis Research Society Questionnaire is a specific instrument to measure health-related quality of life in patients with scoliosis.	SRS 30	12 January 2018
Master Consent Form: Consent Form	2	30 May 2018
Patient Information Sheet/Consent Form: Patient information sheet	1.4	05 September 2018
HREA Application: AU/1/B228317		02 August 2018
Questionnaire/s: Oral iron compliance questionnaire	1	30 May 2018
Ferrous Sulphate Patient Information Sheet	2	31 July 2018
Ferrous Fumerate Patient Information Sheet	1	30 May 2018
Interpretation of Iron Studies Flow Chart	2	30 May 2018

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, Ms Camilla Liddy (telephone 8161 6688, email camilla.liddy@.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.

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.

Yours sincerely

TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE