

**CHILDREN'S HEALTH QUEENSLAND
HOSPITAL AND HEALTH SERVICE
RESEARCH GOVERNANCE**



Enquiries to: CHQ Research Governance
Phone: 07 3069 7003
Email: CHQ_RGO@health.qld.gov.au
SSA Ref: SSA/17/QRCH/228
Dated: 17 November 2017

Dr Mark Harris
Department of Endocrinology
Level 12 Lady Cilento Children's Hospital
501 Stanley St, South Brisbane
QLD 4101

Dear Dr Harris

HREC reference number: HREC/16/HNE/606

SSA reference number: SSA/17/QRCH/228

Project title: Establishment of a safe insulin dosing schedule for high fat, high protein meals in individuals with type 1 diabetes using insulin pump therapy.

The above mentioned research project has successfully received **authorisation** following review in November 2017 for the study to take place at the following site:

CHILDREN'S HEALTH QUEENSLAND HOSPITAL AND HEALTH SERVICE

Please be advised of the allocated Human Research Ethics Committee (HREC) and SSA reference for your study and quote them when communicating with our office for study identification purposes.

Ethics approval for this project was granted on 07 March 2017 by Hunter New England Local Health District (HNE LHD) HREC under streamlined ethical review. A list of approved documents is contained in your HREC approval letter.

In addition, the following site specific documents have been reviewed and authorised:

Document	Version	Date
Site Specific Assessment (AU/3/2FB0314)		14 September 2017
Collaborative Research Agreement		Date of Last Signature
LCCH Information Sheet for Adult Participants	5	01 August 2017
LCCH Information Sheet for Parents of Participants	5	01 August 2017
LCCH Information Sheet for Adolescent Participants	5	01 August 2017
LCCH Information Sheet for Child Participants	3	01 August 2017
LCCH Assent for Participant Aged 8-11 years	1	30 October 2016
LCCH Assent for Participant Aged 12-17 years	1	30 October 2016
LCCH Consent for Participants Aged 18+ years	1	30 October 2016
LCCH Consent for Parent of Participants	1	30 October 2016
Protocol	5	12 September 2017
HREC Approval Letter (RGO Noted)		07 March 2017
HREC Amendment Letter (RGO Noted)		04 August 2017
HREC Amendment Letter (RGO Noted)		27 September 2017

Office
CHQ Research Directorate
Level 7, Centre for Children's Health Research
Lady Cilento Children's Hospital,
62 Graham Street, South Brisbane QLD 4101 Australia

Phone
(07) 3069 7003

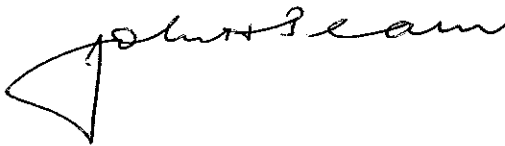
Email
CHQ_RGO@health.qld.gov.au

The following conditions apply to this research proposal. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval.

1. Proposed AMENDMENTS to the research protocol or conduct of the research which may affect the ethical acceptability of the project are to be submitted to the HREC for review. A copy of the HREC approval/rejection letter must be submitted to the Research Governance Office;
2. Proposed AMENDMENTS to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted to the Research Governance Office;
3. Proposed AMENDMENTS to the research protocol or conduct of the research which may affect both the going ethical acceptability of the project and the site acceptability of the project are to be submitted firstly to the HREC for review and then to the Research Governance Office after a HREC decision is made.
4. Annual reports and final reports are to be submitted to your approving HREC as well as the Research Governance Office.
5. Please inform the Research Governance Office of any extension to the duration of the project approved by the HREC. Your site authorisation is in conjunction with the validity of your HREC approval.
6. The Research Governance Office may conduct a random audit of your study at any time.

May I take this opportunity to wish you every success with your research project and the contribution it will make to Children's Health Queensland and the broader research community.

Yours Sincerely,



Prof. John Pearn
A/Director of Research
Children's Health Queensland
Hospital and Health Service

20 / 11 / 2017