Dart, Julie

From: HealthPoint
Sent: Wednesday, 29 November 2023 8:07 AM
To: Dart, Julie
Subject: RGS: Project Letter (Automated Message - Please do not reply)

Child and Adolescent Health Service Human Research Ethics Committee
15 Hospital Avenue
Nedlands Western Australia 6009

29 November 2023

Dr Mary Abraham
Perth Children's Hospital
15 Hospital Avenue
Nedlands Western Australia 6009

Dear Dr Abraham,

PRN:	RGS0000006405
Project Title:	Redefining Glucose Thresholds for Hypoglycaemia Management in Children with Type 1 Diabetes on Closed Loop Therapy: A Cross-over Clinical Trial.
Protocol Number:	1

Thank you for submitting the above research project for ethical review. This project was reviewed by the Clinical Trials Sub0committee (CTS) and the Child and Adolescent Health Service Human Research Ethics Committee at its meeting held on 19 October 2023.

I am pleased to advise you that the above research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2023)* and ethical approval for this research project has been granted by Child and Adolescent Health Service Human Research Ethics Committee.

The nominated participating site in this project is: Perth Children's Hospital

The approved documents include:

Document	Version	Version Date
RGS6405 DSMB Charter Redefining glycose level for hypo V1 28112023	1	28/11/2023
RGS6405 Protocol V2_27Nov2023	2	27/11/2023
RGS6405 Redefining glucose level for hypo Rx_PICF Parent_V2_27Oct2023	2	27/10/2023
RGS6405 Reefining Glucose Thresholds for Hypo Treatment Recruitment Templates V1 27Sep2023	1	27/09/2023

RGS6405_Log book V1 27Oct2023	1	27/10/2023
RGS6405_Redefining Glucose Thresholds for Hypo Treatment Recruitment Email Template V1_27Sep2023	1	27/09/2023

Ethical approval of this project from Child and Adolescent Health Service Human Research Ethics Committee is valid from 29 November 2023 to 29 November 2026 subject to compliance with the **Conditions of Ethics Approval for a Research Project** (Appendix A - attached below).

Note: This project cannot commence until site governance approval has been obtained.
Please ensure that you submit a site authorisation application (SSA) to the Research Governance Office/s for review.

You will receive an RGS-generated email reminder when your **progress report** is due (on the anniversary of this approval). This report, as well as any **amendment** requests or **safety reports** can be submitted via the grey 'Monitoring' tab in your RGS project workspace.

Should you have any queries about the Child & Adolescent Health Service Human Research Ethics Committee's consideration of your project, please contact the Ethics Office at CAHS.Ethics@health.wa.gov.au or on (08) 6456 8639.

The CAHS HREC Terms of Reference and Standard Operating Procedures are available from the Ethics Office or from Child and Adolescent Health Service | CAHS - Applying to HREC

The HREC wishes you every success in your research.

Yours sincerely,
Dr Natalie Giles
Delegate of the Chair
Child and Adolescent Health Service Human Research Ethics Committee

Appendix A
CONDITIONS OF ETHICS APPROVAL FOR A RESEARCH PROJECT

The following general conditions apply to the research project approved by the Human Research Ethics Committee (HREC) and acceptance of ethical approval will be deemed to be an acceptance of these conditions by all project investigators:

1. The responsibility for the conduct of this project lies with the Coordinating Principal Investigator (CPI).
2. The investigators recognise the reviewing HREC is registered with the National Health and Medical Research Council and that it complies with the current version of the National Statement on Ethical Conduct in Human Research.
3. A list of HREC member attendance at a specific meeting is available on request, but no voting records will be provided.
4. The CPI will immediately report anything that might warrant review of ethical approval of the project.
5. The CPI will notify the HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments to approved documents, or any new documents, for ethics approval. Amendments cannot be implemented at any participating site until ethics approval is given.
6. The CPI will submit any necessary reports related to the safety of research participants in accordance with the WA Health Research Governance Standard Operating Procedures.
7. Where a project requires a Data Safety Monitoring Board (DSMB), the CPI's will ensure this is in place before the commencement of the project and notify the HREC. All relevant reports from the DSMB should be submitted to HREC.
8. For investigator-initiated and collaborative research group projects the CPI may take on the role of the sponsor. In this case, the CPI is responsible for reporting to the Therapeutic Goods Administration (TGA) any unexpected serious drug or device adverse reactions, and significant safety issues in accordance with the TGA guidelines.
9. If the project involves the use of an implantable device, the CPI will ensure a properly monitored and up to date system for tracking participants is maintained for the life of the device.
10. The CPI will submit a progress report to the HREC annually from the ethics approval date and notify the HREC when the project is completed at all sites. The HREC can request additional reporting requirements as a special condition of a research project. Ethics approvals are subject to the receipt of these reports and approval may be suspended if the report is not received.
11. The CPI will notify the HREC of his or her inability to continue as CPI and will provide the name and contact information of their replacement. Failure to notify the HREC can result approval for the project being suspended or withdrawn.
12. The CPI will notify the HREC of any changes in investigators and/or new sites that will utilise the ethics approval.
13. The HREC has the authority to audit the conduct of any project without notice if some irregularity has occurred, a complaint is received from a third party or the HREC decides to undertake an audit for quality improvement purposes.
14. The HREC may conduct random monitoring of any project. The CPI will be notified if their project has been selected. The CPI will be given a copy of the monitor's report along with the HREC and Research Governance (RG) Office at the site/s.
15. Complaints relating to the conduct of a project should be directed to the HREC Chair and will be promptly investigated according to the WA Health's complaints procedures.
16. The CPI should ensure participant information and consent forms are stored within the participant's medical record in accordance with the WA Health's RecordKeeping Plan.

17. The CPI will notify the HREC of any plan to extend the duration of the project past the expiry date listed above and will submit any associated required documentation. A request for an extension should be submitted prior to the expiry date. One extension of 5 years may be granted but approval beyond this time period may necessitate further review by the HREC.
18. Once the approval period has expired or the project is closed, the CPI will submit a final report. If the report is not received within 30 days the project will be closed and archived.
19. Projects that do not commence within 12 months of the approval date may have their approval withdrawn and the project closed. The CPI must outline why the project approval should remain.
20. The CPI will notify the HREC if the project is temporarily halted or prematurely terminated at a participating site before the expected completion date, with reasons provided. Such notification should include information as to what procedures are in place to safeguard participants.
21. If a project fails to meet these conditions the HREC will contact the CPI to address the identified issues. If, after being contacted by the HREC, the issues are not addressed, the ethics approval will be withdrawn. The HREC will notify the RG Office at each site within WA Health that the project procedures must discontinue, except for those directly related to participant's safety.