

**CHILDREN'S HEALTH QUEENSLAND
HOSPITAL AND HEALTH SERVICE
HUMAN RESEARCH ETHICS COMMITTEE**

Professor Alan Isles AM (Chair) 3069 7002
Mrs Amanda Smith (Co-ordinator) 3069 7002



Level 7, Centre for Children's Health Research
Queensland Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101
Telephone (07) 3069 7002

24th March 2021

Dr Amy Mitchell
Research Fellow
Parenting and Family Support Centre
UQ School of Psychology
Room 133, 13 Upland Toad
St Lucia QLD 4072

Dear Dr Mitchell,

HREC Reference number: HREC/21/QCHQ/73923

Project title: Can a brief online parenting intervention improve outcomes for children with chronic health conditions? A pilot study.

Many thanks for your letter of the 19th March with responses to queries raised in relation to the above project. This has now been reviewed.

I am pleased to advise the proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and the Committee is happy to give approval. This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, the Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.

This project has Ethics approval for the following sites:

- Queensland Children's Hospital, Brisbane/Centre for Children's Health Research

Please note the HREC does not issue pre-determined approval periods. Ethical approval is ongoing, subject to the submission of an annual report on the anniversary of approval.

The documents reviewed and approved include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover Letter		1 March 2021
Application (73923)		1 March 2021
Newsletter Insert	1	3 January 2021
Positive Parenting for Healthy Living Assessment Booklet	1	1 March 2021
Parent/Guardian Information Statement	1	1 March 2021
Parent/Guardian Consent Form	1	1 March 2021
Parent/Guardian Consent to Contact Medical Team Form	1	1 March 2021
Child Information Sheet	1	1 March 2021
Positive Parenting for Healthy Living Diary	1	1 March 2021
Letter of Support – Dr Tania Zappala		1 March 2021
Response to Queries		19 March 2021

Protocol	2	19 March 2021
Study Poster	1	1 March 2021
Study Brochure	1	1 March 2021

Please note the following conditions of approval:

1. We require an annual progress report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC. A comprehensive Final Report upon completion of the project. (In accordance with National Statement 5.5.3)
All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>
2. Please note if identifiable or potentially re-identifiable data for this research project is to be accessed without the written consent of the person to whom the data relates an application for disclosure of this data must be made under the *Public Health Act*. Further information regarding the *Public Health Act* is available via this link:
https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info
3. Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>
4. If the project does not proceed, the Committee must be informed as soon as possible. (In accordance with National Statement 5.5.6)
5. The Committee must be informed of any potential or realised problem with bioethical implications, if such occurs during the conduct of the research project.
6. Safety Reporting for clinical trials must follow the [2018 NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods](#) and the [Reporting of Serious Breaches of Good Clinical Practice \(GCP\) or the Protocol for Trials Involving Therapeutic Goods](#). All Safety Reporting must be submitted via the ERM web portal for researchers, by creating a sub-form under the relevant project and application form. Please see CHQ HREC Website for details of Safety Reporting [CHQ HREC Website](#)
8. The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.
9. Ethical approval to undertake this research project is given on the understanding that you have an intention to publish your findings in a refereed journal or similar peer-reviewed forum. If you do not have this intention, it is an absolute requirement that you notify the Ethics Committee formally. In this latter instance, approval for this research is not given at this time; and will require further negotiation. Your work must be in accordance with the following:
 - *National Statement on Ethical Conduct in Human Research:*
<https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>
 - *Queensland Health Management Research Policy:*
https://www.health.qld.gov.au/_data/assets/pdf_file/0020/164162/qh-pol-013.pdf
 - *Declaration of Helsinki:*
<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
 - *Guidelines under Section 95 of the Privacy Act 1995 and Guidelines approved under Section 95A of the Privacy Act 1995.* <https://nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988>
10. Researchers should note, if not QLD Health employees, a Blue Card may be required for contact with children.
11. The Researcher must send the ‘**Notification of Commencement of Research Protocol**’ as soon as research begins. Status of the project will remain as ‘Not Started’ until this form is received.
All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>

12. In accordance with the National Statement (3.3.12), before beginning the clinical phase of the research, researchers should register clinical trials in a publicly accessible domain.

Should you have any queries about the HREC's consideration of your project please contact Mrs Amanda Smith (Coordinator) or Professor Alan Isles (Chairperson). The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from: http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

You are reminded that this letter constitutes ethical approval only. This project cannot proceed until separate research governance authorisation has been obtained from the institution where the research will be conducted.

The HREC wishes you every success in your research.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Isles'.

Professor Alan Isles AM
Chair
Children's Health Queensland
Hospital and Health Service
Human Research Ethics Committee

Cc: Ethics Committee Files

**CHILDREN'S HEALTH QUEENSLAND
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1st May 2021

Dr Amy Mitchell
Research Fellow
Parenting and Family Support Centre
UQ School of Psychology
Room 133, 13 Upland Toad
St Lucia QLD 4072

Dear Dr Mitchell,

HREC Reference number: HREC/21/QCHQ/73923

Project title: Can a brief online parenting intervention improve outcomes for children with chronic health conditions? A pilot study.

Many thanks for your submission of an amendment received 19th April for the above project. This has now been reviewed and I am pleased to advise that the amended documents reviewed and approved were:

Document	Version	Date
Amendment submission		19 April 2021
Protocol	3	19 April 2021
Newsletter Item	2	19 April 2021
Brochure	2	19 April 2021
Poster	2	19 April 2021
Parent/Guardian Information Sheet	2	19 April 2021
Child/Adolescent Information Sheet	2	19 April 2021
Parent/Guardian Consent Form	2	19 April 2021
Parent/Guardian Consent to contact Medical Team Form	2	19 April 2021
Questionnaire Booklet	2	19 April 2021
Diary Print Layout	2	19 April 2021

The Children's Health Queensland HREC is constituted and operates in accordance with the National Health and Medical Research Council's "*National Statement on Ethical Conduct in Human Research (2007)*", *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the "*CPMP/ICH Note for Guidance on Good Clinical Practice*".

A copy of this letter must be forwarded to any Research Governance Office that is impacted by this amendment. It should be noted that all requirements of the original approval still apply.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Isles'.

Professor Alan Isles AM
Chair, Children's Health Queensland
Hospital and Health Service
Human Research Ethics Committee

Cc: Ethics Committee Files

Ratification of External Human Research Ethics Approval

Project Number: 2021/HE000945

Project Title: Can a brief online parenting intervention improve outcomes for children with chronic health conditions? A pilot study

Version: 0.02

UQ Lead Investigator: Associate Professor Alina Morawska
School of Psychology

Co-Investigator(s) Miss Elana Jayne Forbes

Funding Body (UQ ref#):

External HREC Name: Children's Health Queensland Hospital and Health Service Human Research Ethics Committee

Approval End Date: 31 Mar 2022

Date of Ratification: Friday, 14 May 2021

As per Section 5.3 of the National Statement on Ethical Conduct in Human Research the University of Queensland has accepted the ethical review of the external review body.

Proviso (if applicable)

1.

Approved Documents: As listed on reviewing HREC approval and below if required

Document Type	File Name	Document Title	Application Version	Document Version	Last Modified
Change Tracking	2021_HE000945 v0_01 - v0_02 Changes.pdf	2021/HE000945 v0_01 - v0_02 Changes	0.2	1	13/05/2021 11:44:28 AM
Application Attachment	Brochure v2 19.4.21.docx	Brochure v2 19.4.21	0.2	2	13/05/2021 11:44:26 AM
Application Attachment	Child Information Sheet v2 19.4.21.doc	Child Information Sheet v2 19.4.21	0.2	2	13/05/2021 11:44:25 AM

CREATE CHANGE

External Ethics Approval Certificate	CHQ HREC amendment approval 1.5.21.pdf	CHQ HREC amendment approval 1.5.21	0.2	2	13/05/2021 11:44:24 AM
External Ethics Approval Certificate	CHQ HREC approval v1 24.3.21.pdf	CHQ HREC approval v1 24.3.21	0.2	2	13/05/2021 11:44:24 AM
Application Attachment	Consent Form - Contact Medical Team v2 19.4.21.doc	Consent Form - Contact Medical Team v2 19.4.21	0.2	2	13/05/2021 11:44:25 AM
Application Attachment	Consent Form v2 19.4.21.doc	Consent Form v2 19.4.21	0.2	2	13/05/2021 11:44:25 AM
Application Attachment	Diary Print Layout v2 19.4.21.docx	Diary Print Layout v2 19.4.21	0.2	2	13/05/2021 11:44:26 AM
Application Attachment	HREA v1 1.3.21.pdf	HREA v1 1.3.21	0.2	2	13/05/2021 11:44:25 AM
Application Attachment	Letter of support v1 1.3.21.pdf	Letter of Support	0.2	2	13/05/2021 11:44:26 AM
Application Attachment	Newsletter Item v2 19.4.21.docx	Newsletter Item v2 19.4.21	0.2	2	13/05/2021 11:44:26 AM
Application	Output Form.pdf	Output Form	0.2	2	13/05/2021 11:44:24 AM
Application Attachment	Parent Information Sheet v2 19.4.21.doc	Parent Information Sheet v2 19.4.21	0.2	2	13/05/2021 11:44:25 AM
Application Attachment	Poster v2 19.4.21.docx	Poster v2 19.4.21	0.2	2	13/05/2021 11:44:26 AM
Application Attachment	Questionnaire Booklet v2 19.4.21.doc	Questionnaire Booklet v2 19.4.21	0.2	2	13/05/2021 11:44:25 AM

CREATE CHANGE

Application Attachment	Response to Request for Further Information 19.3.21.pdf	Response Letter to CHQ HREC	0.2	1	13/05/2021 11:44:26 AM
Application Attachment	Study Protocol v3 19.4.21.docx	Study Protocol v3 19.4.21	0.2	2	13/05/2021 11:44:25 AM

Delegated Officer
Research Ethics and Integrity
The University of Queensland