

Dr Philip Keightley
Child and Adolescent Mental Health Services
Canberra Health Services
Cosmopolitan Centre
Level 2
21 Bowes Street
Woden ACT 2606

ACT Reference	2024.ETH.00082
REGIS Reference	2024/ETH00808
Study Title	Mother-Infant Dialectical Behavioural Therapy (MI-DBT) Evaluation

Dear Dr Keightley,

The ACT Health Human Research Ethics Committee considered the above referenced proposal at its meeting of 4 June 2024.

I am pleased to inform you that the committee agreed the proposal satisfied the requirements for ethically acceptable research as per the National Statement on Ethical Conduct in Human Research and as such, following further correspondence, the application has been approved.

Approval includes:

- Human Research Ethics Application, created 18 April 2024
- Protocol, version 2, dated 9 August 2024
- Participant Information Sheet, version 1, dated 21 March 2024
- Consent Form, version 1, dated 21 March 2024
- T3 Interview Script, version undated
- T4 Interview Script, version undated
- Composite Caregiving Questionnaire (CCQ) – Time 1, dated 2 November 2022
- Composite Caregiving Questionnaire (CCQ) – Time 2, dated 20 April 2021
- Difficulties in Emotion Regulation Scale - 16 item version (DERS-16), dated 2016
- Edinburgh Postnatal Depression Scale (EPDS), dated 1987
- International Trauma Questionnaire (ITQ), dated 2018
- MacLean Screening Instrument for BPD, version undated
- Borderline Symptom List 23 (BSL-23), dated June 2007
- Zanarini Rating Scale for Borderline Personality Disorder: Self-report Version (ZAN-BPD: SRV), dated 2008
- Template Patient Consent Form (as signed by patients in December 2023), version undated
- ANZCTR Registration Confirmation, dated 1 May 2024
- Response to request for further information, dated 9 August 2024
- CVs and GCP certificates for the following personnel, provided with this application:
 - Dr Philip Keightley
 - Ms Angela Freeman
 - Ms Emily Jacobs
 - Ms Linda Park
 - Ms Lisa Oxman
 - A/Professor Anne Sved Williams
 - Dr Clare Watsford
 - Dr Dimity Crisp

- Dr Dean Buckmaster
- Dr Rebecca Reay

- Ms Rachel Hardy
- Ms Mikayla Pink

The ACT Health Human Research Ethics Committee is constituted according to the National Statement on Ethical Conduct in Human Research²⁰²³ and is certified for single review of multi-centre health and medical research. ACT Health HREC operates in compliance with applicable regulatory requirements and the principles of the International Conference on Harmonization Guidelines on Good Clinical Practice.

Please see attached Conditions of Approval

Approved Sites

Ethical approval is given for this research project to be conducted at the following sites:

- Canberra Health Services – Dr Philip Keightley, Principal Investigator
- University of Canberra – Dr Philip Keightley, Principal Investigator

Site-Specific Assessment (SSA)

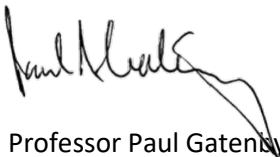
Site specific Approval is given for this research project to be conducted at the following sites:

- Canberra Health Services – Dr Philip Keightley, Principal Investigator

SSA authorisation is required at all sites participating in the study. Research activity must not commence at any site until appropriate authorisation is given. Please contact each proposed site directly for guidance on its SSA requirements. Provide a copy of this ethics approval letter with each SSA request.

If this project is being conducted at the Australian National University or the University of Canberra, please include this letter with your application for expedited review.

Yours sincerely,



Professor Paul Gatensy AM
MBBS PhD FRACP FRCPA
Chairman
ACT Health Human Research Ethics Committee

14 August 2024

Conditions of Approval

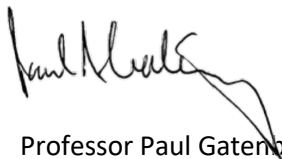
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REGIS Reference	2024/ETH00808
Study Title	Mother-Infant Dialectical Behavioural Therapy (MI-DBT) Evaluation
Principal Investigator	Dr Philip Keightley
Date of Approval	14 August 2024

This project was considered by the ACT Health Human Research Ethics Committee and approved for a period of three years from 14 August 2024 to 14 August 2027.

First Annual Review due: 1 August 2025

Conditions of Approval:

- At regular periods, and not less than annually, Principal Investigators are to provide reports on matters including:
 - unforeseen events that could affect the continued ethical acceptability of the project
 - proposed changes in the protocol
 - updates of the investigator brochures
 - continued compliance with approved consent procedures and updates of consent documentation
 - Data Safety Monitoring Board Reports (where applicable)
 - security of records
 - updated insurance coverage
 - compliance with other approved procedures.
- All published reports are to carry an acknowledgement stating:
 - Approved by ACT Health Human Research Ethics Committee on 14 August 2024



Professor Paul Gatenby AM
MBBS PhD FRACP FRCPA
Chairman
ACT Health Human Research Ethics Committee

14 August 2024