Research Ethics and Governance Office Human Research Ethics Committee Low Risk Sub-Committee

Ms Chelsea Hillenaar Level 2, 1 Moore Street Canberra ACT 2601

ACT Reference	2024.LRE.00007
REGIS Reference	2023/ETH02957
Study Title	Applying the Flinders Program to support self-management in people with chronic conditions in a group setting: a feasibility study.

Dear Ms Hillenaar,

The ACT Health Human Research Ethics Committee's Low Risk Sub-Committee considered the above referenced proposal at its meeting of 10 January 2024.

I am pleased to inform you that, following further correspondence, 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 the application has been approved out of session.

Approval includes:

- Human Research Ethics Application, created 21 December 2023
- Protocol, Version 1, dated 14 December 2023
- Participant Consent Form, Version 1, dated 14 December 2023
- Participant information sheet, Version 1, dated 12 December 2023
- Take Control Live Well Feedback Survey
- Take Control Live Well Welcome Survey
- Work and Social Adjustment Scale
- CV and GCP certificates for the following personnel:
 - o Ms Chelsea Hillenaar
- Response to request for further information, dated 16 January 2024

The ACT Health Human Research Ethics Committee is constituted according to the National Statement on Ethical Conduct in Human Research 2023 and is certified for single review of multicentre 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 – Ms Chelsea Hillenaar, 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 – Ms Chelsea Hillenaar, 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 Gatenby

MBBS PhD FRACP FRCPA

Chairman

ACT Health Human Research Ethics Committee

17 January 2024

Research Ethics and Governance Office Human Research Ethics Committee Low Risk Sub-Committee

Conditions of Approval

ACT Reference	2024.LRE.00007
REGIS Reference	2023/ETH02957
Study Title	Applying the Flinders Program to support self-management in people with chronic conditions in a group setting: a feasibility study.
Principal Investigator	Ms Chelsea Hillenaar
Date of Approval	17 January 2024

This project was considered by the ACT Health Human Research Ethics Committee's Low Risk Sub-Committee and approved for a period of three years from 17 January 2024 to 17 January 2027.

First Annual Report due: 17 January 2025

Reporting requirements:

- Amendments to the protocol or project plan
- Changes to project personnel
- Breaches of security of records
- Breaches of compliance with approved consent procedures and documentation
- Breaches of compliance with other approved procedures
- Unexpected adverse effects on participants
- Unforeseen events that might affect continued ethical acceptability of the project.
- All published reports are to carry an acknowledgement stating:
 - o Approved by ACT Health Human Research Ethics Committee on 17 January 2024

Professor Paul Gatenby A

MBBS PhD FRACP FRCPA

Chairman

ACT Health Human Research Ethics Committee

17 January 2024