

From: no_reply@regis.health.nsw.gov.au
To: Judith.lacey@lh.org.au
Date: 4/14/2022 12:27:00 AM
Subject: 2022/ETH00098: Application HREA - Approved

Date of Decision Notification: 14 Apr 2022

Dear Associate Professor Judith Lacey,
Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2022/ETH00098: Effect of acute exercise on endocannabinoid and mood responses in adults with cancer: A pilot study

This Application was reviewed as a Greater than low risk review pathway and was initially considered by the St Vincent's Hospital Human Research Ethics Committee at its meeting held on 10 February 2022.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was APPROVED.

This email constitutes ethical and scientific approval only.

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.

This project has been Approved to be conducted at the following sites:
Chris O'Brien Lifehouse

The following documentation was reviewed and is included in this approval:

- Exercise and eCB_Study protocol_v1_29 March 2022
- Exercise and eCB_PICF_v1_15 March 2022
- Appendix 1a_Exercise and eCB_Recruitment Checklist - Cancer Patient, Version 1, no date
- Appendix 1b_Exercise and eCB_Recruitment Checklist - Healthy Control, Version 1, no date
- Appendix 2_Exercise and eCB_Demographic and Medical History Form, Version 1, no date
- Appendix 3_Exercise and eCB_ESAS, dated 19 January 2022
- Appendix 4_Exercise and eCB_HADS, dated 19 January 2022
- Appendix 5_Exercise and eCB_Main Data Sheet, Version 1, no date
- Appendix 6 - Exercise and eCB_Recruitment Flyer_v2_15MAR2022

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.02

Date: 12 Apr 2022

The approval is for a period of 5 years from the date of this e-mail (14 Apr 2022)

The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS
- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

- submit any necessary reports related to the safety of research participants in accordance with NHMRC Safety and Reporting Guidance. This will be through the Significant Safety Issue or Third Party Breach form in REGIS.
- Interventional trials must be registered on one of the clinical trial registeries e.g. <https://www.anzctr.org.au> .

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the [REGIS website](#) .

It is noted that the St Vincent's Hospital Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Human Research, 2007 (NHMRC).

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this study with you throughout the project lifecycle.

Regards,

Monica Logan

Research Office

St Vincent's Hospital Sydney

monica.logan@svha.org.au

(Part-time: Monday, Wednesday, Thursday)



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HOSPITAL
SYDNEY