From: no_reply@regis.health.nsw.gov.au

To: Steve Kisely; Andrea McMurtrie

Cc: cinsw-ethics@health.nsw.gov.au

Subject: 2020/ETH00414: Application HREA - Approved

Date: Thursday, 21 May 2020 3:36:17 PM

Date of Decision Notification: 21 May 2020

Dear Professor Steve Kisely,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2020/ETH00414: What is the impact of the National Bowel Cancer Screening Program on colorectal cancer for people over the age of 50 with severe mental illness? Short title: COSMIC Study - Colorectal cancer Outcomes in people with Severe Mental Illness

This project was considered by the NSW Population and Health Service Research Ethics Committee at its meeting held on 13 May 2020 and was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007).

This project has been Approved to be conducted at the following sites:

- School of Medicine, The University of Queensland via SURE;
- School of Public Health, The University of Queensland via SURE;
- University of Western Australia via SURE;
- System Information & Analytics Branch, NSW Ministry of Health via SURE;
- Centre for Mental Health, Melbourne School of Population, University of Melbourne

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

- Cover Letter dated 04 May 2020
- HREA 2020/ETH00414 version 1, dated 20 February 2020
- PHSREC Protocol version 1.1, dated 20 March 2020
- Data Linkage Flowchart dated 19 February 2020
- NSW Privacy Form dated 09 February 2020
- Admitted Patient Data Collection version 1.1, dated 04 May 2020
- Admitted Patient Data Collection Data Custodian approval provided 04 May 2020
- NSW Cancer Registry version 1, dated 18 February 2020
- NSW Cancer Registry Data Custodian approval provided 04 May 2020
- CHeReL Technical feasibility letter CHeReL ID#2020.05 dated 29 April 2020
- Researcher CVs: Kisely, Jordan, Lawrence, Sara, Kendall, Brophy, Siskind, Protani
- NHMRC Independent Peer Review Report dated from 2018 and Applicant response – provided in lieu of PHSREC Peer Review report

The Committee noted the following:

- Application approved by the University of Queensland HREC.zip
- Approval letter from the University of Queensland HREC dated 30 Apr 2019

- Application approved by AIHW HREC.zip
- Approval letter from AIHW HREC dated 16 Jan 2020
- Application approved by Tasmania HREC.zip
- Approval letter from Tasmania HREC dated 19 Feb 2020
- Application approved by Western Australia HREC.zip
- Approval letter from WA HREC dated 16 Apr 2020
- Funding by Cancer Australia email dated 21 Dec 2018

<u>Application Documents</u> - (Please note: Due to security reasons, this link will only be active for 14 days.)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.00

Date: 04 May 2020

It is noted that the NSW Population and Health Service Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC). The approval is for a period of 5 years from the date of this e-mail (21 May 2020), on condition of the submission of Annual Reports.

We wish you all the best with the project and remind you that any changes to the application and safety reports will need to be submitted and reviewed by the approving HREC prior to implementation.

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 under whose auspices the research will be conducted at that site. Sites may be added via a study amendment.

This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

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 application with you throughout the project lifecycle.

Kind regards,

Chehani Alles, Executive Officer, NSW Population and Health Services Research Ethics Committee,

on behalf of

Professor David Roder

Chairperson, NSW Population and Health Services Research Ethics Committee T (02) 8374 3610 / 8372 5689 E cinsw-ethics@health.nsw.gov.au

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We acknowledge the traditional custodians of the lands on which we work and live, and pay our respect to Elders past, present and future.

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