From:	Andrea McMurtrie
To:	Andrea McMurtrie
Subject:	Notification of Ethics Approval: 18672 What is the impact of the National Bowel Cancer Screening Program on colorectal cancer outcomes for people over the age of 50 with severe mental illness? Short title: COSMIC Study Colorect (H0018672)
Date:	Thursday, 20 February 2020 11:21:47 AM

From: donotreply@infonetica.net <donotreply@infonetica.net>
Sent: Wednesday, 19 February 2020 1:19 PM
To: Steve Kisely <s.kisely@uq.edu.au>
Subject: Notification of Ethics Approval: 18672 What is the impact of the National Bowel Cancer Screening Program on colorectal cancer outcomes for people over the age of 50 with severe mental illness? Short title: COSMIC Study Colorect (H0018672)

Dear Steve

Ethics project Id: 18672

Project title: What is the impact of the National Bowel Cancer Screening Program on colorectal cancer outcomes for people over the age of 50 with severe mental illness? Short title: COSMIC Study Colorect (H0018672)

We are pleased to advise that the above named project submission and associated documentation has been approved by the Tasmania Health and Medical Human Research Ethics Committee .

The decision and authority to commence the associated research may be dependent on factors beyond the remit of the ethics review process. For example, your research may need ethics clearance from other organisations or review by your research governance coordinator or Head of Department. It is your responsibility to find out if the approvals of other bodies or authorities are required. It is recommended that the proposed research should not commence until you have satisfied these requirements.

All committees operating under the Human Research Ethics Committee (Tasmania) Network are registered and required to comply with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018).

Therefore, the Chief Investigator's responsibility is to ensure that:

(1) All investigators are aware of the terms of approval, and that the research is conducted in compliance with the HREC approved protocol or project description.

(2) Modifications to the protocol do not proceed until **approval** is obtained from the HREC. This includes, but is not limited to, amendments that:

(i) are proposed or undertaken in order to eliminate immediate risks to participants;

(ii) may increase the risks to participants;

(iii) significantly affect the conduct of the research; or

(iv) involve changes to investigator involvement with the project.

(3) Safety reporting for Clinical Trials must follow the 2016 NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods.

(4) The HREC is informed as soon as possible of any new safety information, from other published or unpublished research, that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project.

(5) All research participants must be provided with the current Participant Information Sheet and Consent Form (if applicable), unless otherwise approved by the Committee.

(6) This study has approval for four years contingent upon annual review. A *Progress Report* is to be provided each year on the anniversary date of your approval, and you will be sent a courtesy reminder closer to this due date. Ethical approval for this project will lapse if a Progress Report is not submitted in the time frame provided.

*Generally ethics approval is granted for a maximum of 6 years for applications; this includes the initial approval and up to two 1-year extension requests. However applications will be reviewed on a case by case basis as to whether additional extensions will be granted. It is up to the discretion of the Tasmania Health and Medical Human Research Ethics Committee , whether additional 1 year extensions will be granted, or if a new revised application is to be submitted to the HREC, or a final report is required.

(7) A *Final Report* and a copy of the published material, either in full or abstract, must be provided for HREC review and approval at the end of the project.

(8) The HREC is advised of any complaints received or ethical issues that arise during the course of the project.

(9) The HREC is advised promptly of the emergence of circumstances where a court, law enforcement agency or regulator seeks to compel the release of findings or results. Researchers must develop a strategy for addressing this and seek advice from the HREC.

In accordance with the National Statement on Ethical Conduct in Human Research, it is the responsibility of institutions/organisations and researchers to be aware of both general and specific legal requirements, wherever relevant. If researchers are uncertain they should seek legal advice to confirm that their proposed research is in compliant with the relevant laws. University of Tasmania researchers may seek legal advice from Legal Services at the University.

Additional Information:

For all Clinical trials approved by the Tasmania Health and Medical HREC

Please note that all clinical trials are to be registered on a clinical trial registry. In Australia, registration must occur prospectively, that is before enrollment of the first participant. For more information please refer to NHMRC: Clinical Trial registries

IF YOUR PROJECT IS AN EXTERNALLY SPONSORED CLINICAL TRIAL (commercial or collaborative not-for-profit) YOU ARE REQUIRED TO PROVIDE (if you have not already done so):

1. Where the University of Tasmania is not the sponsor or a site: provide 3 copies of

the Medicines Australia HREC Review Only Indemnity Forms, signed by the sponsor

2. Where the University of Tasmania is a site only: provide 3 copies of the Standard Medicines Australia Indemnity Forms, signed by the sponsor

Kind regards

Ethics Executive Officer