

24 November 2015

Dr Ptries Herst  
Department of Radiation Therapy  
UOW  
23 Mein Street  
Newtown 6242

Dear Dr Herst

Re: <b>Ethics ref:</b>	<b>15/STH/217</b>
Study title:	Efficacy of standardized cranberry capsules in the prevention and management of acute radiation cystitis using a novel assessment scale

I am pleased to advise that this application has been approved by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

#### Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

#### Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, [www.anzctr.org.au](http://www.anzctr.org.au)).
3. Before the study commences at a *given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

#### After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

**Your next progress report is due by 23 November 2016.**

Participant access to ACC

The Southern Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Raewyn Idoine', with a horizontal line underneath the name.

Ms Raewyn Idoine  
Chairperson  
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted  
appendix B: statement of compliance and list of members

**Appendix A**  
**Documents submitted**

<i>Document</i>	<i>Version</i>	<i>Date</i>
Survey/questionnaire: new scoring system for measuring the severity of acute radiation cystitis	v1	28 October 2015
Survey/questionnaire: Standard measuring tool for radiation cystitis	v1	28 November 2015
PIS/CF: PIS/CF	v1	28 October 2015
Protocol: Protocol	v1	28 October 2015
CV for CI: CV of PI	HRC/CanSo c	28 October 2015
Covering Letter: Covering letter	v1	09 November 2015
Evidence of scientific review: Scientific peer review	v1	11 November 2015

## Appendix B Statement of compliance and list of members

### Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

### List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2019
Dr Devonie Eglinton	Non-lay (intervention studies)	01/07/2013	01/07/2016
Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	27/10/2015	27/10/2021
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2021
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2021
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2021
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2021
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2021

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

<http://www.ethics.health.govt.nz>