



# **Lower South Regional Ethics Committee**

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## **Annual Report**

**January 2006 to December 2006**

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# Chairperson's Report

On behalf of the Lower South Regional Ethics Committee, I have pleasure in presenting this annual report, providing an overview of the committee's work from February 2006 to December 2006.

This year has been a good one for our committee. We are now permanently situated in a suitably large, sunny boardroom in the Ministry of Health building. Our membership remained stable, but at the end of the year we bade a sad farewell to two long-standing members, Fay McDonald and Gail Tripp. Both are wise, kind individuals who brought to our deliberations reason, academic skill and the ability to see studies from the participants' point of view. We miss them a great deal.

Ongoing education was an important feature of the year. Eight members attended a training day in Wellington in June. Deputy Chairperson Phil White and I attended stem cell research training in Wellington in August, as well as the Bioethics Conference in February. Khyla Russell attended the Māori members' meeting in October 2006.

Researchers continue to attend our meetings, usually three per afternoon. Their presence provides a welcome and pleasantly personal connection with their work and very often we are able to resolve problems more quickly in a face-to-face discussion than would be possible through correspondence. As Chairperson I remain open to direct approaches from researchers asking, for example, whether their research needs ethical approval or what documentation they should produce. The school project and trainee intern requests for ethical approval were a significant feature of my work last year. I suspect that applications for expedited review will become popular in the future.

The committee is pleased with the attempts to redraft the application form to make it more user-friendly. It also appreciates the feedback and regular information it receives from Sally Cook and the chairpersons' meetings.

My warm thanks go to Deputy Chairperson Phil White, the committee members and our administrator Riria Tautau-Grant for their hard work and commitment during this year. I have thoroughly enjoyed being Chairperson for a second year and am grateful for the insight into medical research the position has given me.

Jenny Beck  
Chairperson

# Committee Membership

## Appointments

The following members were appointed in November 2004 by the Minister of Health, pursuant to section 11 of the New Zealand Public Health and Disability Act 2000.

### Chairperson

<b>Jenny Beck</b>	BA (Hons), BTh (Hons), LLB (Hons)
Representation	Lay member
Member category	Lawyer
Gender	Female
Date of appointment	December 2004
Term of appointment	Renewed December 2006
Six-year maximum term	February 2010
Professional affiliations	Member New Zealand Law Society, New Zealand Family Law Section, Otago District Law Society Council
Iwi affiliations	None

### Deputy chairperson

<b>Phil White</b>	MBChB, General Practitioner
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	February 2010
Professional affiliations	Fellow of the Royal New Zealand College of General Practitioners
Iwi affiliations	None

### Members

<b>Gail Tripp</b>	BSc (Hons 1st), DipCIPs, PhD
Representation	Non-lay member
Member category	Health researcher
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	February 2008

Professional affiliations	Registered Clinical Psychologist. Member New Zealand Psychological Society, Association for the Advancement of Behaviour Therapy, Foreign Affiliate American Psychological Association
Iwi affiliations	None
<b>Nikki Kerruish</b>	BMedSci, BMBS, MRCP, FRACP, MHIthEthics
Representation	Non-lay member
Member Category	Health practitioner
Gender	Female
Date of appointment	December 2004
Six-year maximum term	May 2010
Retirement date	December 2006
Professional affiliations	New Zealand Masonic Postgraduate Fellowship in Paediatrics and Child Health, Pharmaceutical Society of New Zealand, Royal Australasian CP, Lady King Fellow
Iwi affiliations	None
<b>Fay McDonald</b>	MSc (Hons)
Representation	Lay member
Member category	Consumer representative
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	December 2006
Professional affiliations	
Iwi affiliations	None
<b>Kenneth Copland</b>	Justice of the Peace
Representation	Lay member
Member category	Community perspective
Gender	Male
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Elected member of the Wanaka Community Board of the Queenstown Lakes District Council, Managing Director of Environmental Waste Ltd, certified boatmaster, marriage celebrant
Iwi affiliations	None
<b>Sandra Elkin</b>	BA (Hons), MBHL (Dist)
Representation	Lay member
Member category	Ethicist
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Professional affiliations	
Iwi affiliations	None

<b>Gwen Neave</b>	ONZM, Justice of the Peace
Representation	Lay member
Member category	Community representative and Māori perspective
Gender	Female
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Board member Presbyterian Support Southland
Iwi affiliations	Ngāti Kahungunu
<b>Khyla Russell</b>	PhD
Representation	Lay member
Member category	Community and Māori perspective
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Professional affiliations	International Academic Advisory Board; Centre for New Zealand Studies, London
Iwi affiliations	Ngai Tahu, Kāti Māmoe, Waitaha, Rapuwai, Hawea
<b>Clare Robertson</b>	BSc (Hons), BCom, PhD
Representation	Non-lay member
Member category	Biostatistician
Gender	Female
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	New Zealand Statistical Association, Injury Prevention Network of Aotearoa New Zealand, associate member Prevention of Falls Network Europe
Iwi affiliations	None
<b>Alan Payne</b>	BDS, MDent (Witw), DDSc (Otago), FCD (SA)
Representation	Non-lay member
Member category	Health researcher
Gender	Male
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Registered prosthodontist, member of International Association of Dental Research
Iwi affiliations	None

<b>Rosemary Beresford</b>	PhD, MSc
Representation	Non-lay member
Member category	Pharmacologist
Gender	Female
Date of appointment	July 2005
Term of appointment	3 years
Six-year maximum term	June 2011
Professional affiliations	(Hon) Member of the Pharmaceutical Society of New Zealand
Iwi affiliations	None

## Changes to membership

Dr Gail Tripp	Retired December 2006
Mrs Fay McDonald	Retired December 2006

The following appointments were reconfirmed by the Minister of Health on 18 December 2006. They will commence in 2007.

Mrs Jenny Beck  
 Dr Nikki Kerruish  
 Mrs Sandra Elkin  
 Dr Khyla Russell

The following new appointments were made by the Minister of Health on 18 December 2006: They will commence in 2007.

<b>Karen Goffe</b>	Diploma Social Work & Community Studies
Representation	Community Representative
Member category	Lay member
Gender	Female
Date of appointment	December 2006
Term of appointment	3 years
Six-year maximum term	June 2012
Professional affiliations	Justice of the Peace Association
Iwi affiliations	Ngai Tahu, Ngāpuhi, Te Atiawa

<b>Dr Sarah Derrett</b>	BA, DipCpN, MPH, PhD
Representation	Non-lay member
Member category	Health researcher
Gender	Female
Date of appointment	December 2006
Term of appointment	3 years
Six-year maximum term	June 2012
Professional affiliations	Member of the EuroQol Scientific Committee
Iwi affiliations	None

## Deputy Chairperson

Dr Phil White, who was elected Deputy Chairperson at the committee's inaugural meeting on 14 December 2004, remained Deputy Chairperson throughout 2006.

## Members' attendance in 2006

Member	M/F	Lay/ non-lay	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Jenny Beck	F	Lay	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	10/11
Philip White	M	Non-lay	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	10/11
Gail Tripp	F	Non-lay	Y	Y	Y	Y	Y	Y	Y	A	A	Y	A	8/11
Nikki Kerruish	F	Non-lay	Y	Y	Y	Y	A	Y	A	Y	Y	Y	Y	9/11
Fay McDonald	F	Lay	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Ken Copland	M	Lay	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	10/11
Sandra Elkin	F	Lay	A	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	9/11
Gwen Neave*	F	Lay	A	Y	Y	Y	A	Y	A	Y	Y	Y	Y	8/11
Khyla Russell*	F	Lay	Y	Y	Y	Y	A	A	Y	Y	Y	Y	A	8/11
Clare Robertson	F	Non-lay	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	10/11
Alan Payne	M	Non-lay	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	10/11
Rosemary Beresford	F	Non-lay	Y	Y	Y	A	Y	A	Y	Y	Y	Y	Y	9/11
<b>No. of members present</b>			<b>10</b>	<b>12</b>	<b>12</b>	<b>11</b>	<b>9</b>	<b>7</b>	<b>9</b>	<b>11</b>	<b>11</b>	<b>11</b>	<b>9</b>	
<b>No. of applications</b>			<b>9</b>	<b>6</b>	<b>2</b>	<b>6</b>	<b>6</b>	<b>2</b>	<b>1</b>	<b>9</b>	<b>7</b>	<b>9</b>	<b>3</b>	<b>60</b>

\* = Māori member

Y = Present

A = Apology

No meeting was scheduled for January 2006.

## Training

### New member training

All members of health and disability ethics committees, including those with previous experience, were offered training in April 2006. The training was held in Wellington. The following members attended: Nikki Kerruish, Gwen Neave, Rosemary Beresford.

## Ongoing training

Ongoing training for all members was held in June 2006. For convenience, the one-day programme was run in three centres: Christchurch on 20 June, Auckland on 27 June and Wellington on 29 June. The programme covered research with children, committee relationships, qualitative research and a discussion led by the National Ethics Advisory Committee on observational studies and intervention studies. The following members attended the one-day training programme: Phil White, Rosemary Beresford, Clare Robertson, Fay McDonald, Ken Copland, Sandy Elkin, Nikki Kerruish and Gwen Neave.

The administrator, Riria Tautau-Grant, also attended.

Training regarding using cells from established human embryonic stem cell lines for research was held on 15 August 2006. The following members attended the one-day training programme: Jenny Beck and Phil White.

The following members attended the New Zealand Bioethics Conference in Dunedin from 10–12 February 2006: Jenny Beck and Phil White.

## Meeting of the Māori members

A meeting of the Māori members of all health and disability ethics committees was held on 18 October 2006. It covered the cultural section of the application form, consultation and the work on a Māori ethical framework being carried out by the National Ethics Advisory Committee in conjunction with the Health Research Council and Ngā Pae o Te Maramatanga. The meeting included Māori members of the Ethics Committee on Assisted Reproductive Technology and the Health Research Council Ethics Committee. The following member of the Lower South Regional Ethics Committee attended: Dr Khyla Russell.

## Chairpersons' meetings

Three meetings of the chairpersons of the multi-region and regional ethics committees were held in 2006 on:

- **9 February** – attended by Jenny Beck and Phil White
- **14 and 15 August** – attended by Jenny Beck
- **5 and 6 September** – attended by Jenny Beck.

The September meeting included a discussion on tissue banking with Professor Campbell, previous Professor of Ethics in Medicine at the University of Bristol, United Kingdom, Chair of the Ethics and Governance Council of the UK Biobank and Vice-President of the Chair of the Retained Organs Commission, and currently Centennial Professor of Medical Ethics, Medical School of the National University of Singapore.

## Approval by the Health Research Council

The Committee is approved by the Health Research Council until December 2007.

## **United States Department of Health & Human Services Registration**

The Lower South Regional Ethics Committee is registered with the United States Department of Health & Human Services. This registration enables the committee to review research funded by the United States Government. The registration number is: IRB00004669 – Lower South Regional Ethics Committee.

## Response to Cultural Issues

Number of applications deferred because Māori guidelines were not read	Nil
Number of applications for which consultation with Māori was considered appropriate	Majority
Number of applications returned through insufficient consultation on cultural issues	Nil
Process the committee has for following through on consultation	Requests a letter evidencing that consultation with Māori has occurred
Cases of unsatisfactory reasons for not including Māori	1
Mechanisms in place to facilitate consultation with Māori by researchers	University of Otago protocol for consultation
Examples of Māori not being included in research	(a) Regular teaching exercise (b) Study being undertaken overseas

# Applications

The committee held 11 scheduled meetings from February 2006 to December 2006.

## Lower South Regional Ethics Committee statistics for February–December 2006

<b>Total number of applications received</b>	<b>69</b>
Applications approved	56
Applications deferred, then subsequently approved	4
Applications deferred, at the time of the report	–
Applications deferred, and subsequently withdrawn	1
Applications declined	–
Applications carried forward (approved subject to conditions)	8
Approval not required	–
<b>Total</b>	<b>69</b>
Applications considered under delegated authority (CPD)	9
Number of applications considered by the committee	60
Total	69

## Other committee statistics

Number of matters arising	24
Number of general business items	53
Number of amendments reviewed by committee	28
Number of amendments approved under CPD	16

## Audit or matters not requiring ethical approval

Students are required to seek ethical approval as a part of their studies. In some instances, however, the granting of ethical approval is not strictly necessary as the studies relate to audits or surveys, or gaining approval was required so that the findings could be published. The National Ethics Advisory Committee's *Ethical Guidelines for Observational Studies*, published in December 2006, provide clear guidelines about which projects should be reviewed. These guidelines will be brought to the attention of the supervisors of students and trainee interns.

## Innovative practice

No applications for innovative practice were received.

## **Second opinions**

No second opinions were requested.

## **Complaints**

The Chairperson received a complaint in December 2006 regarding the performance of a committee member. The issues raised were unrelated to that members' contribution as a member of the Lower South Regional Ethics Committee. The petitioner was advised that the Chairperson would take no further action.

# Issues for the Committee

In its previous annual report, the committee reported on a number of issues that delayed the review process unnecessarily.

In 2006 the committee developed a pamphlet detailing the 10 most common problems observed in the applications received. The pamphlet also provided information about how to obviate those problems. It has been circulated widely, and has been received well by the research community.

The following are other issues that are frequently discussed and debated by the committee.

## 1. Clinical trial

The definition of a clinical trial has been debated ad infinitum. It is pleasing that this matter is being addressed in the next version of the application form.

## 2. Researched Medicines Industry (RMI) Guidelines on Clinical Trials

The committee normally expects participants to be offered compensation that is at least in line with the minimum offered by the Accident Compensation Corporation (ACC). In the case of drug companies, the minimum standard for which they are accountable is contained within the RMI guidelines. It is a concern for the committee that the RMI guidelines are minimalist when compared with ACC. It would be beneficial to improve the guidelines so that drug companies are obliged to provide at least the same compensation as ACC.

## 3. Consultation with Māori

The process of consultation with Māori has improved considerably with the appointment of Mark Brunton as Kaitakawaenga Rangahau Māori. The committee continues to grapple with maintaining an agreed perspective about what qualifies as an adequate response to question F3.1.

Training for the committee that is customised to the distinguishing features of this rohe (area of responsibility) and the expectations of mana whenua could assist the committee and have benefits for researchers.

## 4. Accountability

There have been discussions about the ongoing accountability of researchers after a study has been approved. How can the committee be assured that the researchers follow through on negotiated points of compliance? For example, if ongoing consultation with Māori is proposed, how is it possible to monitor the follow-through?

## **5. Recruitment**

There have been instances of recruitment before final approval of a study has been granted. In some cases, recruitment has begun before an application has been submitted.

The next two types of projects are matters that are normally reviewed by the Chairperson or Deputy Chairperson. The review and subsequent decision-making are by delegation and the decision is binding on the whole committee.

## **6. Student and trainee intern projects**

The committee had concerns about the process of reviewing student and trainee intern projects. The *Ethical Guidelines for Observational Studies*, published in December 2006, offer greater distinctions with regard to when full ethical review, expedited review and no ethical review are required.

It is hoped that use of the expedited review form in student and trainee intern projects will mean the appropriate information is presented in the first instance rather than as a result of discussion. This is not to suggest that the ethical review of these projects is not beneficial or essential; it is simply to note that students will probably benefit particularly from the form.

## **7. School projects**

The Committee receives a great number of school projects which generally lack reviewable information about the study or information about the researchers' approach and understanding of the principle of minimisation of harm. There are two issues. The first is whether it is appropriate that this type of study is reviewed by the health and disability ethics committees. The second is whether the application form is in need of review.

# Guidelines for Chairperson's Delegation

At its meeting on 14 December 2004 the committee agreed to delegate the following authority to the Chairperson:

1. protocols that are non contentious:
  - use of non intrusive questionnaires or
  - other simple observational methods or
  - teaching practice
2. requests for the use of tissue/body parts that would normally be discarded and where the patient has given consent
3. student projects where time is at a premium:
  - eg, medical trainee interns, in particular, are given six weeks to develop a research proposal, obtain ethical approval, carry out research, and prepare a report
4. minor amendments and extensions to existing protocols
5. a full approval where an approval in principle has previously been granted by the committee and the researcher has complied with the requests of the committee
6. consultation with Māori where:
  - the investigator provides evidence that consultation with Māori has been initiated and
  - there has been significant time lapse in obtaining a response to that consultation and
  - further delay disadvantages the research.

These delegations are binding on the Deputy Chairperson where that person is required to act on behalf of the Chairperson.

# Appendix 1: Applications Received February–December 2006

Appendix 1 details the applications considered by the committee from February 2006 to December 2006 in open meetings.

No new applications were considered in 'closed' meetings.

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/ funder	Consultation undertaken
LRS/06/02/001	Preventing falls in people with intellectual disability: an innovative clinical placement combining theory, practice and research	Dr Leigh Hale	10/01/06	07/02/06	Approved subject to conditions		Approved	07/03/06	University of Otago	A	University of Otago Research Grant	Christine Rimene; IHC; PACT; Hawkesbury Trust; Community Trust and Donald Beasley Institute
LRS/06/02/002	Improving Māori health and wellbeing through kaitiakitanga: undertaking research that: <ul style="list-style-type: none"> <li>defines cultural based experiences in the environment that can be used as a preventative intervention to enhance Māori health and wellbeing</li> <li>develops tools to assess the effect of different types of cultural based experiences in the environment on Māori health and wellbeing</li> <li>develops a framework for applying the tool and collecting data about health outcomes for Māori resulting from application of such an intervention.</li> </ul>	Dr Gail Tipa	20/01/06	07/02/06	Approved subject to conditions		Approved	21/03/06	Wider Dunedin area	Nil	Health Research Grant; Strategic Development Grant	Regional iwi groups; Moeraki; Otakou; Hokonui; Arowhenua. Māori health researchers; Māori health groups; Manawhenua health group; Kai Tahu ki Otago Ltd.
LRS/06/02/003	Effect of meals rich in thermally oxidised polyunsaturated fat and saturated fat on circulating numbers of endothelial microparticles	Dr Wayne Sutherland	23/01/06	07/02/06	Approved subject to conditions		Approved	04/04/06	Department of Medical and Surgical Sciences; Dunedin Hospital	A	Otago Medical Research Foundation, Laurenson Award	Ngai Tahu Research Consultation Committee
LRS/06/02/004	Prevalence of a multi-drug-resistant <i>Escherichia coli</i> in residents of rest homes in Dunedin	Dr Michael Schultz	23/01/06	07/02/06	Deferred	The application was incomplete	Approved	10/08/06	Various rest homes, Dunedin; University of Otago; Southern Community Labs	Nil		Ngai Tahu Research Consultation Committee
LRS/06/02/005	Mechanisms of cerebral blood flow regulation in healthy humans	Dr Philip N Ainslie	24/01/06	07/02/06	Deferred	Substantial revisions were requested	Approved	01/11/06	University of Otago	A	Start-up fund; Deans Bequest Funds	Mr Darryn Russell, Advisor at University of Otago

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/ funder	Consultation undertaken
LRS/06/02/006	Does intervention for sustained attention improve conversational discourse management in people with traumatic brain injury?	Emma Davies	25/01/06	07/02/06	Approved subject to conditions		Approved	31/07/06	Active Rehab Ltd	Nil	University of Canterbury, Masters of speech language therapy degree programme	Te Waka Hauora, Otepoti Consultancy
LRS/06/02/007	A pilot study to assess the control of noise and vibration within high-risk industries	Dr David McBride	25/01/06	07/02/06	Approved subject to conditions		Approved	17/05/06	Department of Preventive and Social Medicine	A	Otago Research Grant	Ngai Tahu Research Consultation Committee
LRS/06/02/008	Loss of immune tolerance to the normal bowel microbiota as a potential factor in the pathogenesis of ankylosing spondylitis	Dr Simon Stebbings	26/01/06	07/02/06	Approved subject to conditions		Approved	05/05/06	Department of Rheumatology	A	University of Otago faculty grant	Ngai Tahu Research Consultation Committee
LRS/06/02/009	Does the respiratory function of obese individuals return to normal following surgically-induced weight reduction?	Prof D Robin Taylor	26/01/06	07/02/06	Approved subject to conditions		Approved	03/04/06	Otago Respiratory Research Unit; Department of Medical and Surgical Sciences	A	Local funding applications	Ngai Tahu Research Consultation Committee
LRS/06/03/010	Salivary cortisol response related to goal monitoring and task involvement	Dr Elizabeth Franz	01/02/06	07/03/06	Approved subject to conditions		Approved	18/05/06	Canterbury Health Laboratories; Department of Psychology, University of Otago	A	Nil	University of Otago's Māori Consultation Committee
LRS/06/03/011	Factors affecting the perception of dyspnoea in obese subjects	Prof D Robin Taylor	21/03/06	07/03/06	Deferred	Requested assurance that the implementation of this research does not have an adverse effect on the access to treatment of consumers in a facility	Withdrawn		Otago Respiratory Research Unit; Department of Medical and Surgical Sciences; Cardiology Department, Dunedin Hospital	A	Grant applications will be made	Ngai Tahu Research Consultation Committee; Mark Brunton, Research Division
LRS/06/03/012	Men's mental health: What helps and hinders men's access to community mental health teams	Mr Jimi McKay	21/02/06	07/03/06	Approved subject to conditions		Approved	15/05/06	University of Otago; Department of Social Work and Community Development, Castle Street, North, Dunedin	Nil		Ngai Tahu Research Consultation Committee
LRS/06/03/013	What is it like for older women to live with depression? A hermeneutic phenomenological study	Jeanette Allan	21/02/06	07/03/06	Approved subject to conditions		Approved	02/05/06	Various	Nil	ODHB Grant, Older Peoples Health Service; Application to Nurses Association June 06 (NERF) and personal finances	Te Oranga Tonutanga Māori Mental Health Team; Otago District Health Board
LRS/06/03/014	Inducible enzymes in keloid scars	Ms Sharleen Irvine	21/02/06	07/03/06	Approved subject to conditions		Approved	15/05/06	Department of Pharmacology and Toxicology; Cardiothoracic Outpatients Department, Dunedin Hospital	A	Departmental support	Māori researchers

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/ declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/ funder	Consultation undertaken
LRS/06/03/015	Prospective outcomes of injury study (POIS): Questionnaire development and pre-testing	Dr Sarah Derrett	21/02/06	07/03/06	Approved subject to conditions		Approved	02/05/06		A	Health Research Council Strategic Development Grant	Christine Rimene; Professor Ka'ai; Dr Brendan Hokowhitu; Professor John Broughton (Director of Ngai Tahu Māori Health Research); University of Otago; Edward Ellison (Pae Arahi ACC)
LRS/06/04/016	Post-operative pain management following arthroscopic rotator cuff repair: A comparison of inter-scalene block with subacromial bursal infusion	Dr Nigel Hartnett	26/03/06	04/04/06	Deferred	Insufficient information was provided, in view of the significant invasiveness of the study	Approved	21/06/06	Mercy Hospital; Dunedin Hospital; University of Otago	Nil	Nil	Mercy Hospital Ethics Committee
LRS/06/04/017	The use of Pulse Transit Time (PTT) in the detection of sleep disruption and respiratory events in children with habitual snoring	Dr Barbara Galland	27/03/06	04/04/06	Approved subject to conditions		Approved	15/05/06	Paediatrics Outpatients, Dunedin Hospital; University of Otago	A	Departmental postgraduate funds	Christine Rimene; Ngai Tahu Research Consultation Committee
LRS/06/05/018	Investigation of the prevalence of heparin-induced antibodies in dialysis patients routinely exposed to heparin, and its influence on the risk of thrombotic and adverse cardiovascular events	Dr Rob Walker	24/04/06	02/05/06	Approved subject to conditions		Approved	26/06/06	Department of Nephrology, Dunedin Hospital; Department of Haematology, Dunedin Hospital	A	Researchers making application to local funding organisations	Ngai Tahu Research Consultation Committee
LRS/06/05/019	A clinical audit of dental implant treatment at the School of Dentistry, 2001–2005	Mr W Duncan	24/04/06	02/05/06	Approved		Closed	04/07/06	University of Otago	A	Intra departmental funding from the Dept of Oral Sciences	Ngai Tahu Māori Health Research Unit; Director
LRS/06/05/020	Long term prosthodontic maintenance for implant overdentures using different implant systems	Dr AGT Payne	24/04/06	02/05/06	Approved subject to conditions		Approved	07/06/06	University of Otago	A	NobelBiocare Australia, Straumann Switzerland, Southern Implants South Africa/ United Kingdom and Innova Australia; ITI Research Foundation Further applications will be made.	NA Māori were not included in the original sample of participants.
LRS/06/05/021	Effect of selenium on inflammatory markers and markers of endothelial function in patients with coronary artery stenosis in Otago	Dr Nathalie van Havre	24/04/06	02/05/06	Approved subject to conditions		Approved	17/05/06	Human Nutrition Clinic, Dunedin	A	Application for research grants include ORG, Otago Medical Research Funds, Dean's Bequest Fund	Ngai Tahu Māori Health Research; Māori Patient Advocate; Christine Rimene
LRS/06/05/022	A clinical audit of graduate periodontal treatment at the School of Dentistry, 2000–2005	Mr W Duncan	24/04/06	02/05/06	Approved		Closed	04/07/06	University of Otago	A	Intra-departmental funding, Dept. of Oral Sciences and Orthodontics	Ngai Tahu Māori Health Research Unit; Director

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/ funder	Consultation undertaken
LRS/06/05/023	Study of the long term results of the off label use of an intravitreal injection of bevacizumab (Avastin) in cases of neovascular age-related macular degeneration	Dr Mylan Van Newkirk	27/04/06	02/05/06	Approved subject to conditions		Approved	26/06/06	Eye Clinic, Dunedin Hospital	A	Grant applications pending	Ngai Tahu Research Consultation Committee
LRS/06/06/024	Exercise Prescription Teaching Clinic, School of Physical Education, University of Otago – repeated teaching activity PHSE 313 Exercise Prescription Practicum – 4th year BPhEd paper, School of Physical Education	Mr Phil Handcock	25/05/06	06/06/06	Approved subject to conditions		Approved	19/07/06	School of Physical Education	Nil		No formal consultation. This is a repeated teaching exercise. Researchers were asked to approach Ngai Tahu Research Consultation Committee to ask whether wider consultation is appropriate for this application
LRS/06/06/025	Synaesthesia: a laboratory and functional MRI study	Dr Elizabeth Franz	25/05/06	06/06/06	Approved subject to conditions		Approved	31/10/06	Otago District Health Board; Psychology Department; University of Otago	A	Otago Medical Research Funds, Dunedin School of Medicine Bequest	Ngai Tahu Research Consultation Committee
LRS/06/06/026	The impact of dietary sodium chloride (NaCl) intake on arterial wall function in normotensive subjects: A randomised controlled cross-over intervention study	Dr Robert MacGinley	19/05/06	06/06/06	Approved subject to conditions		Approved	12/07/06	Dunedin Hospital; Christchurch Endo Lab; Perth Oxidative Stress Lab	A	National Heart Foundation. Resources at Department of Medicine and Surgical Sciences	Ngai Tahu Research Consultation Committee
LRS/06/06/027	Low level laser therapy in the management of achilles tendinopathy: A feasibility study	Mr Steve Tumilty	19/05/06	06/06/06	Approved subject to conditions		Approved	26/06/06	School of Physiotherapy	A	Otago University Grant	Ngai Tahu Research Consultation Committee
LRS/06/06/028	Intravenous immunoglobulin in neurological disorders	Dr Graeme Hammond-Tooke	19/05/06	06/06/06	Approved subject to conditions		Approved	27/06/06	Dunedin Hospital, Dept of Neurology	Nil		None as this is an audit
LRS/06/06/029	Validation of the disabilities of the arm, shoulder and hand (Dash) questionnaire as an outcome measure for upper limb recovery following stroke	Bronagh Quinn	19/05/06	06/06/06	Approved subject to conditions		Approved	14/08/06		A	Costs are negligible	Ngai Tahu Research Consultation Committee
LRS/06/07/030	Experiencing palliative care in the community for those not enrolled in a hospice programme	Roslyne McKechnie	26/06/06	04/07/06	Approved subject to conditions		Approved	06/09/06	Various Otago District Health Board; Southern District Health Board	A	Postgraduate scholarship, department budget	Ngai Tahu Research Consultation Committee and Te Rūnanga o Otakou
LRS/06/07/031	Manual therapy, exercise, and usual care for osteoarthritis of the hip or knee: a preliminary randomised controlled trial	Dr Haxby Abbott	27/06/06	04/07/06	Approved subject to conditions		Approved subject to conditions		Dunedin School of Medicine; Department of Medical and Surgical Sciences; School of Physiotherapy Clinics	A	Health Research Council and Arthritis NZ; NZ Centre for Physiotherapy Research	Ngai Tahu Research Consultation Committee

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/ funder	Consultation undertaken
LRS/06/08/032	Beating breathlessness by encouraging adherence to asthma medication and treatment. Study 4: A multifaceted, behavioural-based intervention to increase adherence in an undergraduate asthmatic sample	Ms Michelle N Grainger	26/07/06	01/08/06	Approved subject to conditions		Approved	06/09/06	Psychology Department, University of Otago; participants' homes	A		Ngai Tahu Research Consultation Committee have been consulted in the development stage of the study
LRS/06/09/033	A New Zealand experience of men in a bi-cultural therapeutic community	Karl Meyer	10/08/06	05/09/06	Approved subject to conditions		Approved	20/09/06	Moana House; participants' choice	Nil		Ngai Tahu Research Consultation Committee
LRS/06/09/034	Monitoring antibiotic resistance in Samoa	Ms Pauline Norris	21/08/06	05/09/06	Approved subject to conditions		Approved subject to conditions		Samoa	Nil		Pending
LRS/06/09/035	Bimanual reaction times in mild traumatic brain injury	Dr Graeme Hammond-Tooke	22/08/06	05/09/06	Approved subject to conditions		Approved	19/09/06	Department of Psychology, University of Otago	A		None at the time of submission because this study was developed very quickly as a student project
LRS/06/09/036	A randomised, crossover dose effect trial of paracetamol 40 and 60 mg/kg in third molar surgery	Mr Rohana Kumara De Silva	24/08/06	05/09/06	Approved subject to conditions		Approved	21/11/06	Oral Surgery, Department of Oral Diagnostic and Surgical Sciences; School of Dentistry, Dunedin	A	Internal and external grant funding are being sought	Ngai Tahu Research Consultation Committee
LRS/06/09/037	The clinical anatomy of the anterior neck muscles	Ewan Kennedy	25/08/06	05/09/06	Approved subject to conditions		Approved	09/10/06	Department of Anatomy and Structural Biology; Department of Oncology, Dunedin Hospital	Nil	Department of Anatomy and Structural Biology, University of Otago	Ngai Tahu Research Consultation Committee
LRS/06/09/038	Measurement of quality of life of New Zealand adults and adolescents with cystic fibrosis	Malcolm VK Neall	28/08/06	05/09/06	Approved subject to conditions		Approved	26/09/06	Participants' homes; PI Home; Cystic Fibrosis Association	Nil	New Zealand Society of Physiotherapists Inc, Scholarship Trust Fund, and support for postgraduate from the University of Otago	Ngai Tahu Research Consultation Committee
LRS/06/09/039	Renal dialysis in the elderly: Pilot study	Dr Sarah Derrett	28/08/06	05/09/06	Approved subject to conditions		Approved	28/11/06	Otago District Health Board	A		Ngai Tahu Research Consultation Committee; Peter Ellison; Otago District Health Board
LRS/06/09/040	A prospective evaluation of matrix metalloproteinase-9 as a predictor of coronary artery in-stent restenosis	Dr Michael Williams	30/08/06	05/09/06	Approved subject to conditions		Approved	24/10/06	Department of Surgery; Cardiology Department	A	Research grants, School of Medicine bequest fund, National Heart Foundation (decision pending), internal department funding	Ngai Tahu Research Consultation Committee; Department of Public Health and General Practice

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/ funder	Consultation undertaken
LRS/06/09/041	Replacement of a multi-drug resistant <i>E. coli</i> (MDREC) with the probiotic <i>E. coli</i> strain Nissle 1917 (EcN) in rest home residents in the Otago region	Dr Michael Schultz	31/08/06	05/09/06	Approved subject to conditions		Approved	14/12/06	Rest homes; Department of Microbiology, University of Otago; Southern Community Laboratories	A	Healthcare Otago Charitable Trust grant; EcN (Mutaflor and placebo will be made available by the company at no cost)	Ngai Tahu Research Consultation Committee
LRS/06/10/042	Health implications of salivary composition in head and neck cancer patients	Mr Jamie Ryan	20/09/06	03/10/06	Approved subject to conditions		Approved	11/12/06	Dunedin Public Hospital; School of Dentistry	Nil	University of Otago's School of Medicine Deans fund	Ngai Tahu Research Consultation Committee
LRS/06/10/043	The geometry of the solid hypopharyngeal walls	Dr Ming Zhang	25/09/06	03/10/06	Approved subject to conditions		Approved	24/10/06	Department of Anatomy and Structural Biology; Radiology; School of Surveying	Nil	Dean's Research Advisory Committee	Ngai Tahu Research Consultation Committee
LRS/06/10/044	A comparison of fluorescence-guided Er: YAG laser and mechanical scaling and root planing for no-surgical debridement: a controlled prospective clinical study	Ling Feng Soo	25/09/06	03/10/06	Approved subject to conditions		Approved	20/11/06	School of Dentistry	A	Periodontology Department	Ngai Tahu Research Consultation Committee
LRS/06/10/045	Course and prognosis following first time lateral ankle sprain	Dr Joanne Munn	25/09/06	03/10/06	Approved subject to conditions		Approved	25/10/06	School of Physiotherapy, University of Otago, Gardens Medical Centre, Dunedin Urgent Doctors Service	A	Centre for Physiotherapy Research	Ngai Tahu Research Consultation Committee
LRS/06/10/046	Comparison of the effectiveness of an impairment-based manual therapy and exercise approach versus traditional treatment in the management of heel pain: a randomised clinical trial	Dr Haxby Abbott	25/09/06	03/10/06	Approved subject to conditions		Approved	17/01/07	School of Physiotherapy, University of Otago	A		Ngai Tahu Research Consultation Committee
LRS/06/10/047	Culture of human olfactory mucosal tissue in vitro to evaluate bacterial, fungal and Mycoplasma contamination of olfactory mucosal biopsy samples and to characterise conditions that support growth of neural progenitor (stem) cells, olfactory ensheathing cells and fibroblasts	Dr James Faed	25/09/06	03/10/06	Approved subject to conditions		Approved subject to conditions		Dunedin Hospital; Microbiology Department; Spinal Cord Society Laboratory; Southern Community Laboratory	A	The NZ Centre for Physiotherapy Research	Ngai Tahu Research Consultation Committee
LRS/06/10/048	Understanding the transmission of risk for physical and mental health problems from parents to children	Assoc Prof Richie Poulton	25/09/06	03/10/06	Approved subject to conditions		Approved	07/11/06	Dunedin Multidisciplinary Health and Development Unit, University of Otago	A	The James Hume Bequest Fund, the Distinguished Researcher Award applications to the Health Research Council	Dr Joanne Baxter; Christine Rimene; Ngai Tahu Research Consultation Committee

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/ funder	Consultation undertaken
LRS/06/11/049	What is the incidence and awareness of asthma in the Southland region	Jill Parsons	09/10/06	07/11/06	Approved subject to conditions		Approved	13/12/06	Participants' homes; Southern Institute of Technology	Nil		Local iwi, Murihiku Marae, Waihopai Rūnaka, Kawa Whakaruruhau Roopu Southland
LRS/06/11/050	An audit of prescribing patterns in patients who are obese	Prof Stephen Duffull	11/10/06	07/11/06	Approved subject to conditions		Approved	17/01/07	School of Pharmacy, University of Otago; Otago District Health Board	Nil		Ngai Tahu Research Consultation Committee
LRS/06/11/051	Enoxaparin and the risk of bleeding: an impact study	Prof Stephen Duffull	18/10/06	07/11/06	Approved subject to conditions		Approved subject to conditions	30/01/07	Dunedin Hospital; School of Pharmacy, University of Otago	Nil	No funding required	Ngai Tahu Research Consultation Committee
LRS/06/11/052	A randomised single blind study to improve health related quality of life as measured by the SF-36 vitality score by correcting anaemia of chronic kidney related disease with Aranesp® (darbepoetin alfa) in the elderly (STIMULATE)	Dr John Schollum	24/10/06	07/11/06	Approved subject to conditions		Approved subject to conditions		Department of Medical and Surgical Sciences	B	Amgen Inc, Australia	Ngai Tahu Research Consultation Committee
LRS/06/11/053	Double blind randomised controlled trial of an orally administered probiotic in the treatment of spondylo arthritis	Dr Simon Stebbings	25/10/06	07/11/06	Approved subject to conditions		Approved subject to Conditions		Rheumatology Outpatient Department; Microbiology Department; Chemistry Department	A	Applications to Healthcare Otago Charitable Trust and the Laurenson Foundation	Ngai Tahu Research Consultation Committee
LRS/06/11/054	Retrospective analysis of dental implant treatment provided at the School of Dentistry since 1989	Rajiv Verma	26/10/06	07/11/06	Approved subject to Conditions		Approved	14/12/06	School of Dentistry	A	NZ Dental Research Foundation	Ngai Tahu Research Consultation Committee
LRS/06/11/055	Does obesity influence the pattern of lung function during acute bronchoconstriction? (the INCA study – Investigating broncho-constriction in asthma)	Prof D Robin Taylor	26/10/06	07/11/06	Approved subject to conditions		Approved	10/01/07	Otago Respiratory Research Unit; Department of Medical and Surgical Sciences	A	Applications will be made during local funding rounds	Ngai Tahu Research Consultation Committee
LRS/06/11/056	The management of non-eosinophilic asthma: a randomised controlled trial	Prof D Robin Taylor	26/10/06	07/11/06	Approved subject to conditions		Approved subject to conditions		Otago Respiratory Research Unit; Department of Medical and Surgical Sciences	A	Asthma and Respiratory Foundation of NZ	Ngai Tahu Research Consultation Committee
LRS/06/11/057	The impact of dietary salt (NaCl) intake on arterial wall function in hypertensive subjects: a randomised controlled cross-over study	Dr Robert MacGinley	26/10/06	07/11/06	Approved subject to conditions		Approved	18/01/07	Department of Medical and Surgical Sciences; Endolab, Christchurch; Royal Perth Hospital	A	Applied to the National Heart Foundation	Ngai Tahu Research Consultation Committee

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/ funder	Consultation undertaken
LRS/06/12/058	Exercise-induced cardiac and cerebral dysfunction and damage in young and old athletes	Dr Philip N Ainslie	23/11/06	05/12/06	Approved subject to conditions		Approved	31/01/07	Department of Physiology	A		Darren Russell, University of Otago Advisor; Mark Brunton, Ngai Tahu Research Consultation Committee
LRS/06/12/059	The role of statin therapy on the management of persistent atopic asthma	Prof D Robin Taylor	28/11/06	05/12/06	Deferred	Further information was requested to demonstrate that the research design, methods and proposed analyses are adequate and appropriate	Approved	01/02/07	Otago Respiratory Research Unit; Dunedin School of Medicine	A		Ngai Tahu Research Consultation Committee
LRS/06/12/060	Cerebral and systemic vascular function in patients undergoing cardiac surgery	Dr Sean David Galvin	28/11/06	05/12/06	Approved subject to conditions		Approved	28/02/07	Department of Physiology, Intensive Care Unit, Dunedin Public Hospital	A		Ngai Tahu Research Consultation Committee

## Applications approved by the Chairperson under delegated authority

Project key	Full title	Primary investigator	Date received	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
LRS/06/01/CPD	Influenza pandemic: community preparedness and ethical considerations	Mr Richard Walsh	24/01/06	Approved		Closed	30/01/06	University of Otago	Nil		
LRS/06/02/CPD	Campylobacter and antibiotic use	Mark Longman	03/03/06	Approved		Approved	07/03/06	Department of Preventive and Social Medicine	Nil		
LRS/06/03/CPD	An audit of outcomes for the early intervention in Psychosis Service	Kate Kerr	21/04/06	Approved		Approved	21/04/06	Department of Preventive and Social Medicine	Nil		
LRS/06/04/CPD	The impact of head lice on primary school children in Dunedin	Animesh Chatterjee	21/07/06	Approved		Approved	21/07/06	Department of Social and Preventative Medicine; Dunedin schools	Nil		
LRS/06/05/CPD	Medical students' perception of patient aggression	Jasmine MacKay	29/08/06	Approved		Approved	12/10/06		A		
LRS/06/06/CPD	Follow-up of patients with rheumatoid arthritis	Deborah Johnstone	19/10/06	Approved		Approved	26/10/06	Department of Rheumatology	A		
LRS/06/07/CPD	The changing face of coeliac disease	Raymond Chan	05/09/07	Approved		Approved	05/09/06	Department of Preventive and Social Medicine	Nil		
LRS/06/08/CPD	Medically initiated DNR's: the ethics of asymmetrical decision making in clinical practice	Adelle Hanna	09/11/06	Approved		Approved	08/12/06	Dunedin Public Hospital	Nil	Health Research Council	Ngai Tahu Research Consultation Committee
LRS/06/09/CPD	Preparedness of Otago general practitioners for the avian flu	Chris Ford	20/11/06	Approved		Approved	30/11/06		Nil		

# **Appendix 2: Lower South Regional Ethics Committee Terms of Reference**

## **Public authority of the Lower South Regional Ethics Committee**

The Lower South Regional Ethics Committee (Lower South REC) was established as a Ministerial committee under section 11 of the New Zealand Public Health and Disability Act 2000. These Terms of Reference outline the role and functions of the Lower South REC.

## **Authority of the Lower South Regional Ethics Committee**

The Lower South REC shall have responsibility for ethics committee review of health and disability research and innovative practice occurring in the following District Health Board regions:

- Otago
- Southland.

The Lower South REC is responsible for any health and disability research that is currently being undertaken in the above DHB regions, provided that such research has previously been given ethical approval by an approved regional ethics committee.

## **Relation to the Operational Standard for Health and Disability Ethics Committees**

These Terms of Reference have precedence over the Operational Standard for Health and Disability Ethics Committees (Operational Standard) on any point of conflict, but otherwise, the Operational Standard applies to the Lower South REC.

## **Relations with other public sector organisations**

The Lower South REC shall liaise with other relevant ethics committees on matters of common interest, such as jurisdiction over borderline cases. The Lower South REC shall inform the Ministry of Health and the National Ethics Advisory Committee of any matters that arise in its operation that potentially have policy significance.

## **Approval of the Lower South Regional Ethics Committee**

The Lower South REC has to be approved for the purposes outlined in the following enactments:

- The Injury Prevention, Rehabilitation, and Compensation Act 2001
- The Health Research Council Act 1990
- The Health Information Privacy Code 1994.

## **Role of the Lower South Regional Ethics Committee**

The primary role of the Lower South REC is to provide independent ethical review of health research and innovative practice that will be conducted in its region of authority to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy. In order to do this, the Lower South REC shall:

- i. foster an awareness of ethical principles and practices in the health and disability sector and research community
- ii. facilitate excellence in health research and innovative practice for the wellbeing of society
- iii. collaborate with researchers to ensure the interests, rights, dignity, welfare, health and wellbeing of participants and consumers are protected
- iv. give due consideration to community views
- v. consistent with section 4 of the New Zealand Public Health and Disability Act 2000 and He Korowai Oranga, recognise and respect the principles of the Treaty of Waitangi
- vi. operate in accordance with the Operational Standard for Health and Disability Ethics Committees
- vii. operate in accordance with any guidance issued or approved by the Minister of Health.

## **Composition and membership**

### **Guiding principle**

The primary guiding principle for appointing members to the Lower South REC is to ensure that the Lower South REC has the appropriate expertise, skills, knowledge and perspectives to conduct ethical review of the best quality.

### **Member numbers**

The number of members of the Lower South REC should be 12.

## **Lay/non-lay membership**

One half of the total membership shall be lay members, including a lay Chairperson and a non-lay Deputy Chairperson. A lay person is a person who is not:

- currently, nor has recently been, a registered health practitioner (for example, a doctor, nurse, midwife, dentist, pharmacist)
- involved in conducting health or disability research or who is employed by a health agency and who is in a sector of that agency that undertakes health research
- construed by virtue of employment, profession or relationship to have a potential conflict or professional bias in a majority of protocols reviewed.

## **Member categories**

The Lower South REC's lay membership shall include:

- an ethicist
- a lawyer
- consumer perspectives
- community perspectives.

The Lower South REC's non-lay members shall include:

- two health researchers
- a pharmacist or pharmacologist
- a biostatistician
- two health practitioners.

## **Whole committee requirements**

At any time, consistent with the requirements of the New Zealand Public Health and Disability Act requirements for District Health Boards, the Lower South REC shall have at least two Māori members. Māori members should have a recognised awareness of te reo Māori and an understanding of tikanga Māori. All members of the Lower South REC are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

The Lower South REC's membership should include expertise in the main kinds of health and disability research (for example, interventional, observational, kaupapa Māori, and social research) and in both quantitative and qualitative research methods.

Members should possess an attitude that is accepting of the values of other professions and community perspectives, and it is important for the Lower South REC to be comprised of people from a range of backgrounds and ethnicities.

Despite being drawn from groups identified with particular interests or responsibilities in connection with health and community issues, Lower South REC committee members are not in any way the representatives of those groups. They are appointed in their own right, to participate in the work of the Lower South REC as equal individuals of sound judgement, relevant experience and adequate training in ethical review.

## **Terms and conditions of appointment**

Members of the Lower South REC are appointed by the Minister of Health, pursuant to section 11 of the New Zealand Public Health and Disability Act 2000, for a term of office of up to three years. The terms of office of members of the Lower South REC shall be staggered to ensure continuity of membership. Members may be reappointed from time to time. No member may hold office for more than six consecutive years. After serving the maximum six-year term, members shall not be considered for reappointment to any Health Research Council (HRC)-approved ethics committee until at least three years after their retirement from the Lower South REC.

Persons who have served six consecutive years on any Health Research Council (HRC)-approved ethics committee shall not be immediately eligible for appointment to the Lower South REC. Those persons shall not be eligible for appointment to the Lower South REC until at least three years after their retirement from any HRC-approved ethics committee. Persons who have served less than six years on any HRC-approved committee will be eligible to be appointed to the Lower South REC for a term that is equal to the difference of six years and the term already served by that person on any HRC-approved ethics committee, or a shorter period.

A person may not be a member of the Lower South REC and National Ethics Advisory Committee or the Health Research Council Ethics Committee simultaneously.

Unless a person sooner vacates their office, every appointed member of the Lower South REC shall continue in office until their successor comes into office. Any member of the Lower South REC may at any time resign as a member by advising the Minister of Health in writing.

Any member of the Lower South REC may at any time be removed from office by the Minister of Health for inability to perform the functions of office, bankruptcy, neglect of duty or misconduct, proved to the satisfaction of the Minister.

The Minister may from time to time alter or reconstitute the Lower South REC or discharge any member of the Lower South REC or appoint new members to the Lower South REC for the purpose of decreasing or increasing the membership or filling any vacancies.

## **Chairperson and Deputy Chairperson**

The Minister shall appoint a member of the Lower South REC to be its Chairperson. The terms and conditions of appointment for members of the Lower South REC also apply to the person appointed as Chairperson. The Chairperson shall preside at every meeting of the Lower South REC at which they are present.

The Lower South REC shall appoint a non-lay member as Deputy Chairperson.

The Chairperson and Deputy Chairperson may act with the delegated authority of the Lower South REC between meetings.

## **Duties and responsibilities of a member**

This section sets out the duties and responsibilities generally expected of a person appointed as a member of the Lower South REC. This is intended to aid Lower South REC members by providing them with a common set of principles for appropriate conduct and behaviour.

### **General**

Lower South REC members should have a commitment to protecting the interests of human participants while promoting and facilitating excellence in research and innovative practice.

There is an expectation that Lower South REC members will make every effort to attend all Lower South REC meetings and devote sufficient time to become familiar with the affairs of the Lower South REC and the wider environment within which it operates.

Members have a duty to act responsibly with regard to the effective and efficient administration of the Lower South REC and the use of Lower South REC funds.

### **Conflicts of interest**

Lower South REC members should perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect the Lower South REC and its members and will ensure it retains public confidence.

Lower South REC members attend meetings and undertake Lower South REC activities as independent persons responsible to the Lower South REC as a whole. Members are not appointed as representatives of professional organisations or particular community bodies. The Lower South REC should not, therefore, assume that a particular group's interests have been taken into account because a Lower South REC member is associated with this group. Members should declare, and the committee regularly review, their actual and potential conflicts of interest.

When Lower South REC members believe they have a conflict of interest on a subject that will prevent them from reaching an impartial decision or from undertaking an activity consistent with the Lower South REC's functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.

A member of the Lower South REC who has a proposal before the Lower South REC or who has an involvement in the proposal, such as a supervisory role, shall not take part in the Lower South REC's assessment of that proposal. The member may be present to answer questions about a proposal but should take no part in the discussion surrounding the consideration of the proposal or any decision relating to the proposal. This will allow proposals to be considered in a free and frank manner. The Lower South REC must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

## **Confidentiality and information sharing**

Agendas and minutes of all Lower South REC meetings should be available to the public. Copies of proposals should be available to individuals outside the Lower South REC, subject to deletions in accordance with the Official Information Act 1982 and any deletions necessary to protect the privacy of individual persons. If an applicant would like their proposal to remain confidential, they must give reasons, consistent with the Official Information Act 1982, to satisfy the Lower South REC that the proposal should remain confidential. The reasons for keeping a proposal confidential are subject to review by the Ombudsmen.

It is desirable for the members of the Lower South REC to have an opportunity to discuss issues arising from applications with key contacts and support people prior to the consideration of proposals. This process should be encouraged. However, due to the need to protect any personal information, names or identifying details should not be circulated or made known outside the Lower South REC. The Lower South REC will need to consider the Privacy Act 1993 and the Health Information Privacy Code 1994 in developing these processes.

Within the Lower South REC, members with particular community expertise should be consulted and provide advice on the appropriate consultative process for all ethical issues concerning particular communities of interest.

## **Committee meetings**

Meetings of the Lower South REC shall be held monthly or less frequently, as determined by the workload.

At any meeting, a quorum shall consist of at least seven members or the minimum number constituting a majority. The quorum must include a reasonable representation of members with health practitioner, research, ethical and community/consumer expertise, knowledge and perspectives.

As part of the accountability to the public they protect, it is desirable for the meetings of the Lower South REC to be open to the public. Meetings of the Lower South REC should therefore be:

- i. open meetings for the discussion of broad issues, particularly if the Lower South REC is reviewing health research
- ii. closed meetings when necessary to ensure the privacy and confidentiality of participants
- iii. closed meetings when applicants provide good and sufficient reasons for this to occur, and the minutes of the meeting should reflect these reasons.

Information about the dates and times of committee meetings should be made available to the public.

Applicants may attend meetings in person or by teleconference to talk to their proposal and answer any questions the Lower South REC may have. Attendance is not mandatory. The Lower South REC should advise applicants that they may be asked to leave the meeting while the Lower South REC considers the proposal.

Subject to the provisions set out in this document, the Lower South REC may regulate its own procedures.

## **Decision-making process**

Wherever possible, the Lower South REC should determine matters by consensus decision. Where a consensus cannot be reached, a vote shall apply, with a two-thirds majority of those voting required for any decisions, and the Chairperson having a casting vote.

In relation to research involving Māori, it is important that Māori expertise be available to ensure that all issues are appropriately considered. Where it is not possible for Māori members to attend a Lower South REC meeting or for those members' views to be sought and represented at the meeting, the matter should be deferred.

On occasion, individual members may wish to abstain from some or all of the decision-making process because of strong personal moral or religious reasons. Such abstentions shall not affect the approval process.

## **Ethics committee actions**

For each application it reviews, the Lower South REC must state to its applicant whether its action is to approve, approve subject to conditions, defer, or decline that application. It must state its grounds for any action to defer or decline. For any action to approve subject to conditions, the Lower South REC must specify the conditions, the grounds for these conditions and its process for assessing whether these conditions are subsequently met. In all cases, the Lower South REC must state which matters its action is based upon and which are instead matters of comment, information or advice to its applicant.

## **Expert advice and consultation**

Members may wish to consult on ethical issues with, for example, individuals, groups, iwi and hapū, and this should be encouraged and supported. Consultation should be carried out in a timely manner.

Where the Chairperson or a quorum of Lower South REC members believes there is insufficient expertise on the Lower South REC to assess an application or an issue, the committee should seek additional expert advice.

Advice may be sought from recognised experts with:

- i. specialist knowledge in particular fields of science and medicine
- ii. knowledge of the experiences and perspectives of people with disabilities
- iii. awareness of gender health perspectives
- iv. consumer and/or research participant perspectives
- v. an understanding of community health issues
- vi. an understanding of relevant cultural perspectives
- vii. an understanding of developing Māori research methodologies
- viii. expertise in te reo Māori
- ix. expertise in ethical theory.

It should be noted that the above list gives examples, without restricting the range, of external expertise that may be sought.

Where external consultation has taken place or advice has been sought, this should be documented, and recorded where appropriate in the Lower South REC's decision on a proposal.

## **Second opinions and appeals**

At any stage in its deliberations, the Lower South REC may seek a second opinion from the Health Research Council Ethics Committee, in accordance with the Operational Standard.

The decisions of the Lower South REC may be appealed to the Standing Committee on Appeals convened by the National Ethics Advisory Committee, in accordance with the Terms of Reference of the National Ethics Advisory Committee and any guidance promulgated by the Standing Committee on the appeals process.

## **Training for members**

Training should be provided for new members and chairpersons within six months of appointment to the Lower South REC.

## Reporting requirements

The following provides a checklist of requirements for annual reporting. Annual reports should be submitted to the Minister of Health and will be tabled by the Minister of Health in the House of Representatives.

The annual report shall include information on the membership of the Lower South REC, including any change in the Lower South REC's membership or other substantive changes the Lower South REC or its chairperson feels should be noted.

The annual report shall also include a list of the national and multi-region research and innovative practice protocols reviewed in the preceding year outlining the following details:

- i. Research title
- ii. Principal investigator
- iii. Institutions where the research is to be/has been undertaken
- iv. Date of first review
- v. Date of final outcome
- vi. Outcome (which will be one of: approved, approved with conditions, deferred, declined)
- vi. For each protocol deferred or declined, the reason(s) for the decision.

The annual report shall also include:

- i. A list of training undertaken by Lower South REC members, and a statement on processes for orientation and training of new Lower South REC members should be included.
- ii. A list of complaints received by the Lower South REC (if any), the actions taken to resolve the complaint(s) and a comment on the outcome of the complaint(s).
- iii. Any areas of review that caused difficulty for the Lower South REC in making a decision on any particular protocol(s), and any questions on policy or other matters the Lower South REC referred to the National Ethics Advisory Committee or the Health Research Council Ethics Committee for comment or guidance.

In compiling annual reports, the Lower South REC should take care not to provide information that would involve a breach of the Privacy Act 1993 and/or the Health Information Privacy Code 1994.

## Fees and allowances

Members of the Lower South REC are entitled to be paid fees for attendance at meetings. The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies.

The Chairperson shall receive an attendance fee of \$330 per day (plus half a day's preparation fee). The attendance fee for members is set at \$250 per day (plus half a day's preparation fee). The Chairperson and Deputy Chairperson shall receive an allowance of up to one extra day each per month to cover additional work undertaken under the delegated authority of the Lower South REC by the Chairperson and Deputy Chairperson. The Ministry of Health shall pay actual and reasonable travel and accommodation expenses of the Lower South REC members.

## **Servicing of the Lower South Regional Ethics Committee**

The Ministry of Health shall employ staff and provide resources to service, advise and administer the Lower South REC out of the allocated budget for ethics committees.

