



# **Lower South Regional Ethics Committee**

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## **Annual Report**

**December 2004 to December 2005**

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# Chairperson's Report

On behalf of the committee, I am very pleased to present this annual report of the Lower South Regional Ethics Committee.

The report provides an overview of the work of the Lower South Regional Ethics Committee from December 2004 to December 2005. The report was presented to the committee at its meeting on 7 March 2006.

The report details applications received for ethical approval and other work undertaken by the committee.

When the committee commenced in December 2004, it had seven members who had not previously served on an ethics committee, but it took only a few meetings for the committee to work well as a group. Eight members attended the new members' training in Christchurch and Wellington in February 2005 and enjoyed the experience.

The committee worked to foster productive relations with researchers by encouraging researchers to attend meetings. Usually at least three researchers address the committee at any one meeting. I addressed a meeting of researchers at the University of Otago, in conjunction with Martin Tolich, Chairperson of the Multi-region Ethics Committee and the National Co-ordinator of Ethics Committees, and this also helped foster our relationship by clarifying what the committee looks for in a research application and what common mistakes can be avoided. Feedback from researchers who attended committee meetings was positive.

The committee looks forward to further refinement of the locality assessment process once consultation on its first year of operation is completed.

My warm thanks go to Deputy Chairperson Phil White, the committee members and Riria Tautau-Grant, our administrator during this period. I have enjoyed being Chairperson this year and am thankful for the valuable insight the work has given me into medical research.

**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 Health 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	2 years
Six-year maximum term	February, 2010
Professional affiliations	Member NZ Law Society, NZ Family Law Section, ODLS Council
Iwi affiliations	None

### Deputy Chairperson

<b>Phil White</b>	General practitioner
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	December 2004
Six-year maximum term	February 2010
Retirement date	December 2007
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

**Nikki Kerruish** BMedSci, BMBS, MRCP, FRACP, MHIth Ethics  
Representation Non-lay member  
Member category Health practitioner  
Gender Female  
Date of appointment December 2004  
Six-year maximum term May 2009  
Retirement date December 2006  
Professional affiliations New Zealand Masonic Postgraduate Fellowship in Paediatrics and Child Health  
Iwi affiliations None

**Fay McDonald** 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  
Iwi affiliations None

**Ken Copland**  
Representation Lay member  
Member category Community representative  
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, Justice of the Peace, Certified Boatmaster, Marriage Celebrant  
Iwi affiliations None

**Sandra Elkin** 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  
Iwi affiliations None

**Gwen Neave**  
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  
Iwi affiliations Ngāti Kahungunu

<b>Khyla Russell</b>	PhD
Representation	Lay member
Member category	Community representative and Māori perspective
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Iwi affiliations	Ngai Tahu, Kati Mamoe, Waitaha, Rapuwai, Hawea

<b>Clare Robertson</b>	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
Iwi affiliations	None

<b>Alan Payne</b>	Doctor of Dental Science (Senior Doctorate)
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
Iwi affiliations	None

<b>Nerida Smith</b>	PhD
Representation	Non-lay member
Member category	Health researcher
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Iwi affiliations	None

## Change to membership

Dr Nerida Smith resigned in February 2005. The following appointment was made by the Minister of Health in July 2005.

<b>Rosemary Beresford</b>	PhD, MSc
Representation	Health professional
Member category	Pharmacologist
Gender	Female
Date of appointment	July 2005
Term of appointment	3 years
Six-year maximum term	June 2011
Iwi affiliations	None

## Deputy Chairperson

Dr Phil White was elected Deputy Chairperson by the Committee at its inaugural meeting on 14 December 2004.

## Members' attendance

Member	M/F	Lay/ non-lay	Dec	Feb	5 Apr	7 Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Jenny Beck Lawyer	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Phil White Health practitioner	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	11/12
Gail Tripp Health researcher	F	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	A	10/12
Nikki Kerruish Health practitioner	F	NL	Y	Y	Leave of absence								Y	Y	4/4
Fay McDonald Consumer rep	F	L	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	11/12
Ken Copland Community rep	M	L	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	Y	11/12
Sandra Elkin Ethicist	F	L	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	11/12
Gwen Neave* Community rep	F	L	A	Y	Y	A	Y	Y	Y	A	Y	A	Y	A	7/12
Khyla Russell* Community rep	F	L	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	Y	A	10/12
Clare Robertson Biostatistician	F	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Alan Payne Health researcher	M	NL	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	Y	11/12
Rosemary Beresford Pharmacist/ pharmacologist	F	NL	Appointed July 2005							A	Y	Y	Y	Y	4/5
Nerida Smith Health researcher	F	NL	Y	Y	Resigned February 2005								2/2		
<b>No. of members present</b>			<b>11</b>	<b>12</b>	<b>9</b>	<b>7</b>	<b>10</b>	<b>10</b>	<b>9</b>	<b>8</b>	<b>10</b>	<b>9</b>	<b>12</b>	<b>9</b>	
<b>No. of applications</b>			<b>5</b>	<b>1</b>	<b>10</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>4</b>	<b>1</b>	<b>4</b>	<b>5</b>	<b>4</b>	<b>5</b>	<b>51</b>

\* = Māori member

Y = Present

A = Apology

The scheduled meetings in January and March were not held because no applications were received.

## **Training**

### **New member training**

All members of health and disability ethics committees, including those with previous experience, were offered training in January and February 2005. The training was held in Auckland, Wellington and Christchurch. The following members of the Lower South Regional Ethics Committee attended: Phil White, Clare Robertson, Ken Copland, Sandra Elkin, Alan Payne, Jenny Beck, Khyla Russell, Fay McDonald.

### **Ongoing training**

While no ongoing training was offered to all members in 2005, the following meetings of specialist members were held:

#### **Meeting of legal members and chairpersons**

A meeting of the legal members and chairpersons was held on 23 June 2005, covering the role of the legal member, indemnity of members, compensation and research on people who are unable to consent themselves. The following member of the Lower South Regional Ethics Committee attended: Jenny Beck.

#### **Meeting of the Māori members**

A meeting of the Māori members of the committees was held on 28 June 2005 and covered a number of topics including the role of the Māori member, consultation with Māori, the cultural section of the application form, tissue banking and recent changes to Right 7(10) of the Code of Health and Disability Services Consumers' Rights. The following member of the Lower South Regional Ethics Committee attended: Gwen Neave.

#### **Chairpersons' meeting**

Two meetings of the chairpersons of the multi-region and the regional ethics committees were held in 2005. Jenny Beck attended the chairpersons' meetings on 14 April 2005 and 13/14 October 2005.

### **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. The registration number is IRB00004669 – Lower South Regional Ethics Committee.

## Response to Cultural Issues

Number of applications deferred because Māori guidelines were not read	0
Number of applications for which consultation with Māori was considered appropriate	Majority
Number of applications returned through insufficient consultation on cultural issues	3
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	2
Mechanisms in place to facilitate consultation with Māori by researchers	University of Otago protocol for consultation
Examples of Māori not being included in research	<ul style="list-style-type: none"> <li>• Study involves one child who is not Māori</li> <li>• Study is a teaching practical</li> <li>• Study pertains to surgical trainees, who are not Māori</li> <li>• Exclusion criteria identified, study sent to Māori committee member for comment</li> </ul>

The committee notes that usually Māori are not being consulted during the formative stage of an application, and few adequately complete the cultural and social responsibility section of the application form.

The University of Otago's singular process for consultation is causing delays for researchers. Researchers who work very closely with Māori in the ongoing course of their work are largely unable to qualify those meaningful discussions as consultation unless they have also followed the university's policy for consultation.

There is no notified process for consultation for researchers in institutions other than the University of Otago, which can result in these researchers consulting with people who are not appropriate.

## Applications

The committee held 11 scheduled meetings from December 2004 to December 2005, with an additional meeting held in April to review three applications that had not been considered due to lack of time at the scheduled meeting.

### Lower South Regional Ethics Committee statistics December 2004–December 2005

Applications approved	60
Applications deferred, then subsequently approved	11
Applications deferred, at the time of the report	1
Applications declined	1
Applications carried forward (approved subject to conditions)	7
Approval not required	1
<b>Total number of applications received</b>	<b>81</b>
Applications considered under delegated authority (CPD)	30
Number of applications considered by the committee	51
<b>Total</b>	<b>81</b>

### Other committee statistics

Number of matters arising	28
Number of general business items	30
Number of amendments reviewed by the committee	33
Number of amendments approved under CPD	21

### 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 was not strictly necessary as the studies related to audits or surveys or gaining approval was enforced so that the findings could be published. However, in keeping with support for the educative process, all applications of this nature that were made to the Chairperson were subsequently approved under delegated authority.

### Innovative practice

No applications for innovative practice were received.

## **Second opinions**

No second opinions were requested.

## Complaints

The committee received a complaint, initiated in December 2004 and continuing throughout 2005. The complaint was in regard to a study in which the participant believed that pertinent information was not fully disclosed. Further information was gathered from both the complainant and the researchers. The committee felt that a meeting of both parties, along with a member of the committee should be convened to discuss the complaint. The committee continues to have some difficulty convening this meeting, as the complainant has been both intermittently difficult to locate and at times resident outside this committee's jurisdiction. The last correspondence received from the complainant in November 2005 indicated that she is overseas. The complaint remains unresolved.

The committee was asked to re-consider its decision to defer one study where the researcher considered that the requests for amendment were minor. The committee reviewed its decision and advised the researcher that the committee had initially deferred this study on the basis that the committee felt strongly that information to the participant needed to be full and clear and that these were essential rather than cosmetic points in accordance with section 2.2, page 6, of the Operational Standard for Ethics Committees, March 2002.

# Issues for the Committee

## Locality assessment

The locality assessment has caused some consternation for the Otago District Health Board (ODHB) in that it was considered that the researchers were being asked to replicate a process already undertaken; once for the ODHB and then a scaled-down version of the same process for the Ethics Committee. To alleviate the pressure this applied to the researchers, this committee conceded that a researcher providing a locality assessment form with the COO signature on it also represented an assurance of observance of the relevant considerations for which the committee is responsible.

Other issues include:

- uncertainty about who the appropriate signatories are
- researchers being unaware that they are required to provide a locality assessment for each location in which the study is being carried out
- uncertainty as to how much information researchers should provide
- uncertainty as to when an organisation should provide a locality assessment.

## Applications

The standard of information sheet and consent form writing is of concern as these are the foremost mechanisms for transmitting information to the participants in accordance with section 2.2, page 6, of the Operational Standard for Ethics Committees, March 2002.

## Clinical trials

Researchers are confused about what constitutes a clinical trial for the purposes of compensation.

# Guidelines for the Chairperson's Delegation

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

The Chairperson may approve under delegated authority the following:

- (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, for example, 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 would disadvantage the research.

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

## Appendix 1: Applications received December 2004 to December 2005

This appendix details the applications considered by the committee from December 2004 to December 2005 in open meetings. Two 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	Consultation undertaken
LRS/04/12/001	Recurrence of varicose veins following superficial venous surgery: prevention using doxycycline	Professor Andre van Rij	30/11/04	14/12/04	Approved subject to conditions		Approved	2/3/05	Dunedin School of Medicine	A		Research Division, University of Otago
LRS/04/12/002	Establishment of the Australian and New Zealand Renal Biopsy Bank	Professor Robert Walker	28/11/04	14/12/04	Approved subject to conditions		Approved	7/2/05	Department of Nephrology, Dunedin Hospital	Nil		Te Rūnanga o Otakou
LRS/04/12/003	Survival from prostate cancer	Mary Jane Sneyd	29/11/04	14/12/04	Declined	A multicentre study, referred to the Multi-Region Committee	Declined			Nil		Nil
LRS/04/12/004	Chronic fatigue syndrome in children and adolescents: an investigation of autonomic disturbances and anxiety	Dr Pamela Jackson	4/12/04	14/12/04	Approved subject to conditions		Approved subject to conditions		Paediatrics Outpatients, Dunedin Hospital	A		Hine Forsyth, Mana Whenua Health Working Party
LRS/04/12/005	Respiratory and cardiovascular effects of a bronchodilator drug (200 ug salbutamol) in medicine, pharmacy and pharmacology students	Assistant Lecturer Martin LE Nedelec	4/12/04	14/12/04	Approved		Approved	14/12/04	University of Otago	Nil		Nil – study is a teaching practical
LRS/05/02/001	Inheritance of type 2 diabetes in the Parata Whanau	Miss Emma Wyeth	20/1/05	1/2/05	Approved subject to conditions		Approved	16/3/05	University of Otago	Nil		Research Māori, University of Otago; Eleanor Murphy; researcher is a member of Parata Whanau; and Dr Russell is also a member of Parata Whanau
LRS/05/04/002	A N-of-1 trial of melatonin for sleep disturbance in a patient with Smith Maginnis syndrome	Dr David Reith	17/3/05	5/4/05	Deferred	Concern re consenting process	Approved	11/7/05	Private homes Paediatrics Unit, Healthcare Otago	A		Nil – study involves one child only
LRS/05/04/003	The relationship between the patients experiences of post-tonsillectomy pain, analgesics, resumption of activities and return to normal diet in the first 14 days post operatively	Rebecca Aburn	25/2/05	5/4/05	Approved subject to conditions		Approved	5/5/05	Otago District Health Board Dunedin Hospital	Nil		Mana Whenua Health Working Party

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	Consultation undertaken
LRS/05/04/004	Ageing in place and quality of life: the views of older people receiving low levels of home support in a selected locale in New Zealand	Penny Hambleton	18/3/05	5/4/05	Approved subject to conditions		Approved	3/6/05	Participants' homes	Nil		Hine Forsyth, Rūnanga o Otakou
LRS/05/04/005	Clinical application of exhaled nitric oxide measurements in primary care	Professor D Robin Taylor	24/3/05	5/4/05	Deferred	Insufficient information	Approved	23/10/05	Mornington Health Centre	Nil		Nil
LRS/05/04/006	Breast International Group (BIG) Trial 1-98/IBCSG Trial '98-98 Bone Sub Study investigating bone density and bone loss without baseline information for postmenopausal women with operated breast cancer, randomized and receiving adjuvant Letrozole vs Tamoxifen treatment within the BIG 1-98 Trial	Dr Blair McLaren	18/3/05	5/4/05	Approved subject to conditions		Approved	2/8/05	Dunedin Hospital	B	Novartis Pharmaceuticals, ANZ Breast Cancer Group (ANZBCTG) International Breast Cancer Group (IBSCG)	Mana Whenua Health Working Party
LRS/05/04/007	Family perspectives of end of life care in the Dunedin community	Professor Rod McLeod	4/4/05	5/4/05	Deferred	Privacy concerns	Approved	2/8/05	Otago Community Hospice	Nil		NTRCC
LRS/05/04/008	Optimising the procedures for the isolation proliferation, characterisation and differentiation of mesenchymal stem cells (MSCs) from adult human bone marrow	Dr Deborah Stuart	18/3/05	5/4/05	Deferred	Insufficient information	Approved	23/3/06	Centre for Innovation	A		Otakou Executive Committee
LRS/05/04/009	The longitudinal study of pelvic floor dysfunction and obstetric practice	Professor Don Wilson	18/3/05	5/4/05	Approved subject to conditions		Approved	31/5/05	Dunedin Hospital	Nil		Hine Forsyth
LRS/05/04/010	The effects of exercise on pregnancy: The views and opinions of expecting mothers and health professionals	Jane Stewart	21/3/05	5/4/05	Deferred	Insufficient information	Approved	31/5/05	Dunedin Hospital in conjunction with the University of Otago	Nil		Hine Forsyth
LRS/05/04/011	Non-curative terminal illness, empowerment and decision-making: lesson for nursing practice	Ms Carolyn (Kate) Richardson	30/3/05	5/4/05	Approved subject to conditions		Approved	5/9/05	Otago Community Hospice	A		NTRCC; Te Rūnanga o Otakou; Sonja Birch at Araiteuru Whare Hauora
LRS/05/04/012	How surgeons make management decisions in the acute setting and its impact on the training and assessment of surgical trainees decision-making skills	Sarah Rennie	24/3/05	7/4/05	Approved subject to conditions		Approved subject to conditions		Dunedin Hospital Southland Hospital	Nil		Study pertains to surgical trainees. Researchers consider it unlikely that the planned research process will have a direct impact on Māori.
LRS/05/04/013	Are the early thrombotic events after successful percutaneous coronary stenting related to a poor response to aspirin and clopidogrel?	Dr Stuart Tie	5/4/05	7/4/05	Deferred	Concerns re respect for persons	Deferred		Dunedin Hospital	A		The Māori Health Committee of the Health Research Council of New Zealand
LRS/05/04/014	Automatic and controlled memory in individuals with schizophrenia	Ms Daria Korbanova	24/3/05	7/4/05	Deferred	Insufficient information	Approved	15/7/05	University of Otago	A		NTRCC

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	Consultation undertaken
LRS/05/05/015	Initial evaluation of an awareness training programme using virtual environments following traumatic brain injury	Ms Rachel Schembri	3/4/05	1/5/05	Approved subject to conditions		Closed	18/7/05	University of Otago	Nil		Nil
LRS/05/05/017	The VALID trial: is ventilation affected by leaving in dentures	Dr Niamh Conlon	29/3/05	1/5/05	Approved subject to conditions		Approved	31/5/05	Dunedin Hospital	A		NTRCC
LRS/05/05/018	Experiences of interdisciplinary team members involved in the rehabilitation of clients with somatoform disorder	Ms Bridget Dickson	24/4/05	1/5/05	Deferred	Insufficient information	Approved	23/6/05	ISIS Centre	A		NTRCC
LRS/05/06/019	Primiparous women's perceptions of contextual factors impacting on the initiation and duration of breastfeeding: a socio-ecological approach	Mrs Maria Stanley	29/5/05	1/6/05	Approved subject to conditions		Approved	15/7/05		A		Consultation has not occurred, exclusion criteria identified. File sent to Maori member for comment
LRS/05/06/020	Activity of bacteriocin-producing <i>Micrococcus luteus</i> Q24 on the bacterial populations occupying human skin	Professor John Tagg	16/5/05	1/6/05	Deferred	Concern re validity of proposal	Approved	15/9/05	Department of Microbiology and Immunology Centre for Innovation (BLIS Technologies)	B	BLIS Technologies Ltd	NTRCC
LRS/05/06/021	Doctors and death: patients informing practitioners about quality palliative care	Dr Rod MacLeod	24/5/05	1/6/05	Approved subject to conditions		Approved	15/9/05	Otago Community Hospice	Nil		NTRCC
LRS/05/06/022	Efficacy and safety of a topical keratin gel in patients with chronic diabetic ulcers	Dr PV Peplow	24/5/05	1/6/05	Approved subject to conditions		Approved	5/8/05	Dunedin School of Medicine Dunedin Hospital	A		NTRCC; Maori Research and Enterprise, University of Otago
LRS/05/06/023	Four-year follow up after a normal upper and lower endoscopy in patients with iron deficiency anaemia	Dr Golam Moinuddin Khadem	28/5/05	1/6/05	Deferred	Study has since been suspended	Approved	1/11/05	Dunedin Hospital	Nil		NTRCC
LRS/05/07/024	Discovering Southland's hidden IDU populations and assessing their health and risk behaviours in relation to blood borne viruses and the sharing of injecting drug paraphernalia	Mr Stephen Farquhar	20/6/05	1/7/05	Approved subject to conditions		Approved	15/9/05	DIVO	Nil		Dion Williams of SDHB
LRS/05/07/025	Estimating the disease burden from diabetes using multiple lists of people with diabetes	Claire Cameron	23/6/05	1/7/05	Approved subject to conditions		Approved	9/10/05	Department of Preventive and Social Medicine and Department of Maths & Statistics	Nil		NTRCC
LRS/05/07/026	The potential for diet modification to improve glycaemic control and cardiovascular risk factors over and above drug therapy in type 2 diabetes at high risk of cardiovascular disease	Dr Jim Mann	23/6/05	1/7/05	Approved subject to conditions		Approved subject to conditions		Edgar National Centre for Diabetes Research	Nil		Maori Advisory Komiti of Human Nutrition Department, 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	Consultation undertaken
LRS/05/07/027	A randomised controlled trial of GPSI versus usual care in the treatment of general practice patients with orthopaedic injuries	Professor Murray Tilyard	30/6/05	1/7/05	Deferred	Insufficient information	Approved	4/10/05	South Link Health	A		PHO Māori representatives
LRS/05/08/028	Photography of the ocular surface of eyes using an ultraviolet light source pre and post LASIK (laser in situ keratomileusis) and other forms of corneal surgery	Professor ACB Molteno	8/7/05	1/8/05	Approved subject to conditions		Approved	4/11/05	Dunedin Hospital, Eye Clinic	A		NTRCC; Professor Ka'ai
LRS/05/09/029	Reliability of the RT3 accelerometer to measure activity in people with neurological dysfunction	Dr Leigh Anne Hale	11/8/05	1/9/05	Approved subject to conditions		Approved	31/10/05	School of Physiotherapy	A		NTRCC
LRS/05/09/030	Cerebrovascular control and endothelial function in humans with and without obstructive sleep apnoea	Dr Philip N Ainslie	22/8/05	1/9/05	Approved subject to conditions		Approved	21/12/05	Department of Physiology	Nil		NTRCC
LRS/05/09/031	The role of the Schwann cell in the pathogenesis of peripheral neuropathies, especially diabetic peripheral neuropathy	Dr Noelyn Hung	31/8/05	1/9/05	Deferred	Insufficient information	Approved	25/10/05	Dunedin School of Medicine	Nil		NTRCC; Professor Anthony Braithwaite
LRS/05/09/032	Molecular studies using archival paraffin-embedded tissues	Dr Noelyn Hung	31/8/05	1/9/05	Deferred	Insufficient information	Approved	25/10/05	Dunedin School of Medicine	Nil		NTRCC; Professor Anthony Braithwaite
LRS/05/10/033	Survey of mental health professionals about defensive practice	Dr Richard Mullen	25/9/05	1/10/05	Approved subject to conditions		Approved	31/1/06	Department of Psychological Medicine	A		Māori Mental Health Team
LRS/05/10/034	A mini mental status examination for the hearing impaired	Dr Graeme Hammond-Tooke	26/9/05	1/10/05	Approved subject to conditions		Approved	7/11/05	Dunedin Hospital	A		NTRCC
LRS/05/10/035	The use of the multidimensional task ability profile as a measure of functional capacity in patients with rheumatoid arthritis	Dr Margot Skinner	20/9/05	1/10/05	Approved subject to conditions		Approved	16/1/06	School of Physiotherapy	A		NTRCC
LRS/05/10/036	The effects of music therapy on intractable distress for people with a terminal illness at the end of life: a pilot project	Ms Natalie Nugent	27/9/05	1/10/05	Approved subject to conditions		Approved	9/1/06	Otago Community Hospice	Nil		NTRCC; Southlink Health; Erina Rewi
LRS/05/10/037	Comprehensive assessment of patients with exercise induced respiratory symptoms and a comparison of second line therapies	Professor Robin Taylor	27/9/05	1/10/05	Approved subject to conditions		Approved	8/11/05	Otago Respiratory Research Unit	A		NTRCC
LRS/05/11/038	Assessment of pelvic floor dysfunction in nulliparous women: a case control study	Professor Don Wilson	11/10/05	1/11/05	Approved subject to conditions		Approved	22/11/05	Obstetrics and Gynaecology, University of Otago and Otago District Health Board	A		Runaka; Hine Forsyth

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	Consultation undertaken
LRS/05/11/039	Evidence-based medicine – is it relevant to patients?	Ms Jennifer Fife	19/10/05	1/1/05	Approved subject to conditions		Approved subject to conditions		Otago District Health Board	Nil		NTRCC
LRS/05/11/040	Baroreceptor sensitivity in infants: a pilot study	Dr Barbara Galland	23/10/05	1/1/05	Approved subject to conditions		Approved	9/1/06	Dunedin Hospital Otago District Health Board	A		Huirapa, Otakou; Moeraki; and Hine Forsyth
LRS/05/11/041	Development of a scale to measure family outcomes after traumatic brain injury	Ms Zena Piggden	23/10/05	1/1/05	Approved subject to conditions		Approved	20/12/05	ISIS Centre	A		Mana Whenua Health Working Party
LRS/05/12/042	Complex Carer Group: pilot project for a national network of carers of people with high and complex needs: a replication in Otago	Dr Anne Bray	21/11/05	1/12/05	Approved subject to conditions		Approved subject to conditions		Paediatrics Unit, Healthcare Otago Ministry of Education, Special Education, Dunedin Access Ability IDEA Family Whanau Service Autism New Zealand, Otago Branch Sara Cohen School ENZ The Family Network CCS	Nil		Ministry of Education; Ministry of Health; Tainui; Waitemata DHB; Wai Health; H&D Commissioners Office; Family Whanau Co-ordinator
LRS/05/12/043	Development of a prehospital neurological screening tool for use in concussive brain injury: sensitivity, specificity and reliability	Dr S John Sullivan	21/11/05	1/12/05	Approved subject to conditions		Approved	31/1/06	University of Otago, School of Physiotherapy Otago District Health Board	A		NTRCC
LRS/05/12/044	Do regional diabetes registers improve quality of care for diabetic patients?	Dr Kirsten Coppel	28/11/05	1/12/05	Approved subject to conditions		Approved	1/2/06	Otago Diabetes Project	Nil		Mana Whenua Health Working Party
LRS/05/12/045	The needs of participants in end-of-life situations in Dunedin Hospital	S McLenman	30/11/05	1/12/05	Approved subject to conditions		Approved	23/1/06	Dunedin Hospital	Nil		NTRCC
LRS/05/12/046	Immediate loading of Branemark implants with fixed full arch prosthesis: all-on-four concept	Mr Dushan Kuzmanovic	12/11/05	1/12/05	Deferred	Concerns re respect for persons	Approved subject to conditions		School of Dentistry	Nil		NTRCC
LRS/05/01/CPD	Randomised clinical trial investigating the use of sports drinks as fluid replacement pre and post colonoscopy	Mr Mathew McDonald	14/2/05		Approved subject to conditions		Approved	3/8/05	Dunedin Hospital University of Otago	A		NTRCC
LRS/05/02/CPD	Evaluation project of Presbyterian Support's home-based support services within the department of preventive and social medicine	Associate Professor Charlotte Paul	8/3/05		Approved subject to conditions		Approved subject to conditions		Department of Preventive and Social Medicine	Nil		

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	Consultation undertaken
LRS/05/03/CPD	Pharmacology practicals: aspirin excretion, effects of atropine, effects of diuretics, histamine and antihistamines, effects of GTN (glyceryl trinitrate)	Assistant Lecturer Martin LE Nedelec	16/3/05		Approved		Approved	16/3/05	Department of Pharmacology, University of Otago, Dunedin	Nil		
LRS/05/04/CPD	The contribution of family and school factors to the academic functioning of children with ADHD	Sarah Fahey	18/3/05		Approved		Approved	18/3/05	University of Otago	Nil		
LRS/05/05/CPD	The contribution of family factors to the children's emotional functioning	Ms Amy Smith	18/3/05		Approved		Approved	18/3/05	University of Otago	Nil		
LRS/05/06/CPD	Retrospective review of a patient's neurorehabilitation treatment: a student study	Justine Greve	4/4/05		Approved		Closed	29/5/05	ISIS Centre	Nil		
LRS/05/07/CPD	Gout in the community	Nusrat Zahan	19/4/05		Approved		Approved	19/4/05	Mornington Health Centre	Nil		
LRS/05/08/CPD	Bachelor of Physiotherapy student's case report	Mr James Panton	29/5/05		Approved		Approved	29/5/05	School of Physiotherapy	Nil		
LRS/05/09/CPD	Matching summary diabetes and diabetes-related hospital data	Dr Kirsten Coppell	31/5/05		Approved		Approved	31/5/05		Nil		
LRS/05/10/CPD	To assess the acceptability of the MeNZb immunisation programme	Maarjie O'Brien	6/6/05		Approved		Approved	6/6/05	Department of Preventive and Social Medicine	Nil		
LRS/05/12/CPD	Retrospective review of a patient's rehabilitation treatment: a student study	Mrs Cath Smith	15/6/05		Approved		Approved	15/6/05	School of Physiotherapy	Nil		
LRS/05/13/CPD	To investigate scapular stabilisation exercises as a conservative management option of anterior shoulder instability due to repetitive overhead action	Ms Anna Scarlett	20/6/05		Approved subject to conditions		Closed	16/8/05	School of Physiotherapy	Nil		
LRS/05/14/CPD	An audit of the Otago District Health Board's general practice database	Associate Professor Susan Dovey	24/6/05		Approved		Closed	24/6/05	RNZCGP Research Unit	Nil		
LRS/05/15/CPD	Student's case report: retrospective analysis of a clinical case	Miss Julia Whitehead	18/7/05		Approved subject to conditions		Closed	22/7/05	School of Physiotherapy	Nil		
LRS/05/16/CPD	Retrospective comparative analysis of gastroenterology inpatient and outpatient characteristics in Dunedin Public Hospital	Susan Weggery	19/7/05		Approved		Approved	19/7/05	University of Otago	Nil		
LRS/05/17/CPD	Professional development and recognition programme: portfolio development – is it more than a means to an end?	Miss Deborah Ashworth	25/7/05		Approved		Approved	26/8/05	Southland District Health Board	Nil		

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	Consultation undertaken
LRS/05/18/CPD	Cervicogenic headache: differential diagnosis and management	Mr Murray Singleton	1/8/05		Approved subject to conditions		Closed	17/8/05	Dunstan Hospital	Nil		
LRS/05/19/CPD	Disease monitoring by mining electronic health records	Mrs Susan Dovey	4/8/05		Approved		Approved	9/8/05		Nil		
LRS/05/20/CPD	Controlled sleep position versus nCPAP therapy in the management of obstructive sleep apnoea	Dr Margot Skinner	24/8/05		Approved		Approved	23/10/05	School of Physiotherapy	Nil		
LRS/05/21/CPD	The objective evaluation of cataracts by photoscreening	Professor ACB Molteno	24/8/05		Approved subject to conditions		Approved	16/12/05	Ophthalmology, University of Otago	Nil		
LRS/05/22/CPD	Assessing current community attitudes to mental health: a student study	George Downward	24/10/05		Approved subject to conditions		Approved	26/10/05	Dunedin City	Nil		
LRS/05/23/CPD	Sugary drink consumption in secondary school students	Jonathan Graham	24/10/05		Approved		Approved	24/10/05	University of Otago	Nil		
LRS/05/24/CPD	Proposed trainee intern analysis of the endoscopy service	Angus Turnbull	28/11/05		Approved		Closed	28/11/05	Gastroenterology Department, Dunedin Hospital	Nil		
LRS/05/25/CPD	A study of human cerebral spinal fluid	Associate Professor Ian McLennan	30/11/05		Approved		Approved	28/11/05	Department of Anatomy and Structural Biology	Nil		
LRS/05/26/CPD	An audit of the costs associated with a drug eluting stent strategy versus a bare metal stent strategy for coronary intervention at Dunedin Hospital	Preeshapon Tovaranonte	13/12/05		Approved subject to conditions		Approved	30/11/05	Dunedin Hospital	Nil		
LRS/05/27/CPD	An audit of continuation of medicines five years after discharge following artery stenting	Tina Liu	13/12/05		Approved subject to conditions		Approved	16/12/05	Dunedin Hospital	Nil		
LRS/05/28/CPD	An audit of carotid stent procedures at Dunedin Hospital	Cameron Simmers	13/12/05		Approved subject to conditions		Approved	16/12/05	Dunedin Hospital	Nil		
LRS/05/29/CPD	Audit on cost effectiveness of patient-controlled analgesia: a comparison between morphine and fentanyl	Erica Hsu	16/12/05		Approved		Approved	16/12/05		Nil		
LRS/05/30/CPD	An audit of bleeding incidents in patients receiving enoxaparin for the management of no-ST-elevation acute coronary syndrome (NSTEACS) at Dunedin Hospital	Mr Hesham Al-Sallami	20/12/05		Approved		Approved	20/12/05	Dunedin Hospital	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.

