



# **Upper South A Regional Ethics Committee**

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## **Annual Report**

**January 2006 to December 2006**

***Upper South A Regional Ethics Committee***

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This report provides an overview of the work of the Upper South A Regional Ethics Committee from January to December 2006. The report was presented to the Upper South A Regional Ethics Committee at its meeting on 26 March 2007.

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

## **Chairperson's Report**

The Upper South A Regional Ethics Committee met 11 times in 2006. Over the year, the committee processed 83 new applications. The committee experienced few membership changes.

The committee's decisions were made by consensus, with the exception of two occasions when the committee voted.

The number of researchers attending meetings increased this year. The committee has found that their attendance benefits both the committee and the researchers, by speeding up the approval process and increasing understanding of the processes and concerns of both the researchers and the committee. We are hopeful that researcher attendance at meetings will continue to increase.

Alieke Dierckx undertook the administration of the Upper South A Regional Ethics Committee in 2006, except for a four-month maternity leave period which was covered by Joanne Hamlyn.

Carolyn Mason  
Chairperson

# Committee Membership

## Appointments

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

### Chairperson

<b>Carolyn Mason</b>	BSc, MA (Philosophy)
Representation	Lay member
Member category	Ethicist
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	August 2008
Professional affiliations	British Society for Ethical Theory
Iwi affiliations	–

### Deputy Chairperson

<b>Alison Luckey</b>	BM, Dip Pharm Med, MFPM
Representation	Non-lay member
Member category	Health practitioner
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	October 2009
Professional affiliations	Member Faculty Pharmaceutical Medicine, Member of the Society Pharmaceutical Medicine
Iwi affiliations	–

### Members

<b>Carolynn Bull</b>	MA, LLB
Representation	Lay member
Member category	Lawyer
Gender	Female
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Professional affiliations	–
Iwi affiliations	Kai Tahu

**Derek Cone** JP, Dip Grad (Otago)  
Representation Lay member  
Member category Consumer representative  
Gender Male  
Date of appointment November 2004  
Term of appointment 2 years  
Six-year maximum term November 2010  
Professional affiliations New Zealand Justice of Peace Association, New Zealand  
Christian Counsellors Association  
Iwi affiliations –

**John Horwood** MSc (Hons)  
Representation Non-lay member  
Member category Biostatistician  
Gender Male  
Date of appointment November 2004  
Term of appointment 3 years  
Six-year maximum term November 2010  
Professional affiliations Statistical Association of New Zealand  
Iwi affiliations –

**Tom Marshall** MA, Dip Clin Psych, MNZCC Psych  
Representation Non-lay member  
Member category Health researcher  
Gender Male  
Date of appointment November 2004  
Term of appointment 3 years  
Six-year maximum term April 2008  
Professional affiliations –  
Iwi affiliations –

**Eddie Moke** MBS  
Representation Lay member  
Member category Community representative  
Gender Female  
Date of appointment November 2004  
Term of appointment 3 years  
Six-year maximum term November 2010  
Professional affiliations –  
Iwi affiliations Te Arawa, Ngai Tahu

**Lee-Ann Ryan-Verry** BA Psychology  
Representation Lay member  
Member category Community representative  
Gender Female  
Date of appointment November 2004  
Term of appointment 2 years  
Six-year maximum term November 2006  
Professional affiliations –  
Iwi affiliations Ngai Tahu

**Russell Scott** MBChB, FRACP, PhD  
Representation Non-lay member  
Member category Health practitioner  
Gender Male  
Date of appointment November 2004  
Term of appointment 2 years  
Six-year maximum term November 2010  
Professional affiliations Royal Australasian College of Physicians  
Iwi affiliations –

**Jane Kerr** MBChB, ORCOG, MPH  
Representation Non-lay member  
Member category Health practitioner/researcher  
Gender Female  
Date of appointment March 2006  
Term of appointment 3 years  
Six-year maximum term March 2012  
Professional affiliations –  
Iwi affiliations –

**Ellen McCrae** Bachelor of Pharmacy  
Representation Non-lay member  
Member category Pharmacist  
Gender Female  
Date of appointment July 2005  
Term of appointment 3 years  
Six-year maximum term July 2011  
Professional affiliations Pharmacy Council of New Zealand, Fellow of Pharmaceutical Society of New Zealand  
Iwi affiliations –

**Liz Richards** PQCIH (Professional Qualification of the Chartered Institute of Housing), MA (Housing)  
Representation Lay member  
Member category Community representative  
Gender Female  
Date of appointment July 2005  
Term of appointment 3 Years  
Six-year maximum term July 2011  
Professional affiliations –  
Iwi affiliations –

## Changes to membership

Lee-Ann Ryan-Verry retired in November 2006.

The following appointment was made by the Minister of Health in December 2006.

### **Nicky Murray**

Representation	Lay member
Member category	Consumer representative
Gender	Female
Date of appointment	December 2006
Term of appointment	3 years
Six-year maximum term	December 2012
Professional affiliations	–
Iwi affiliations	–

### **Deputy Chairperson**

Alison Luckey, who was elected Deputy Chairperson at the Committee's inaugural meeting on 7 February 2005, remained Deputy Chairperson throughout 2006.

## Members' attendance

Member	M/F	Lay/ non-lay	31 Jan	27 Feb	27 Mar	1 May	29 May	3 Jul	7 Aug	4 Sep	2 Oct	30 Oct	Dec	Total
Carolyn Mason Ethicist	F	L	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	10/11
Alison Luckey Health practitioner	F	NL	A	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10/11
Carolynn Bull* Lawyer	F	L	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	A	09/11
Derek Cone Consumer rep	M	L	Y	Y	Y	Y	Y	Y	Y	A	Y	A	Y	09/11
John Horwood Biostatistician	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Jane Kerr Health practitioner / researcher	F	NL	Commenced March 2006		Y	Y	Y	Y	Y	Y	Y	Y	Y	9/9
Tom Marshall Health researcher	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	10/11
Ellen McCrae Pharmacist	F	NL	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	10/11
Eddie Moke* Community rep	F	L	Y	A	Y	Y	Y	Y	Y	Y	Y	Y	Y	10/11
Liz Richards Community rep	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Lee-Ann Ryan-Verry* Community rep	F	L	Y	Y	A	Y	Y	A	Y	Y	Y	A	A	7/11
Russell Scott Health practitioner	M	NL	Y	Y	Y	Y	A	Y	Y	Y	A	Y	Y	09/11
<b>No. of members present</b>			10	10	11	12	10	9	12	11	11	11	9	
<b>No. of applications</b>			16	7	5	5	9	5	3	6	12	8	6	82

\* = Māori member

Y = Present

A = Apology

## Training

### New member training

The following members attended training for new members held in Wellington on 1 April 2006: Jane Kerr, Liz Richards, Ellen McCrae.

## **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: Carolyn Mason, John Horwood, Ellen McCrae, Carolynn Bull, Liz Richards, Derek Cone, Edie Moke, Jane Kerr.

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: Carolyn Mason, Alison Luckey.

The following members attended the New Zealand Bioethics Conference in Dunedin from 10–12 February 2006: Carolyn Mason, Alison Luckey.

## **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 members of the Upper South A Regional Ethics Committee attended: Carolynn Bull and Edie Moke.

Edie Moke, Carolynn Bull and Lee-Ann Ryan-Verry, along with Annette Finlay and Michael Gough of the Upper South B Regional Ethics Committee, met with Elizabeth Cunningham, Research Manager – Māori and Virginia Irvine, Research Manager, of the Christchurch School of Medicine.

## **Chairpersons' meeting**

Three meetings of the chairpersons of the multi-region and regional ethics committees were held in 2006. Carolyn Mason attended the chairpersons' meetings on 9 February, 14–15 August and 5–6 September 2006. 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.

## **Research community education**

On 2 February 2006 Carolyn Mason presented 'Ethics and DNA Databases' to 300-level biology students.

Carolyn Mason presented 'Ethics and Ethics Committees' to public health and general practice students doing the Social Research Methods paper in March 2006. Alieke Dierckx gave a presentation on the administration of ethics applications to the same group.

In July 2006 Carolyn Mason gave a presentation on 'Ethics and Organ Donation' to the Christchurch Hospital staff.

At the ethics committee administrators' meeting in July 2006, Carolyn Mason gave a presentation on 'Ethics and Ethics Committees'.

In August 2006 Carolyn Mason gave a presentation on ethics committee processes and problems with ethics committee applications to two groups: thesis students at the Centre for Postgraduate Nursing and a New Zealand Association of Clinical Research meeting.

## **Meetings with researchers**

Various members from both Upper South A and Upper South B Regional Ethics Committees met with representatives from the medical community at the Christchurch School of Medicine in February 2006. The administrators of both committees and the National Co-ordinator also attended this meeting.

## **Meeting outside Christchurch**

All committee meetings were held in Christchurch. The committee did not meet in any of the other main centres covered in the Upper South territory. The committee considered meeting in other centres, but decided that it was inappropriate to use Ministry of Health funds in this way.

## **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 Upper South A 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 IRB00004667 – Upper South A 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	83
Number of applications returned through insufficient consultation on cultural issues	0 (Evidence of consultation required and carried out concurrently)
Process the committee has for following through on consultation	Confirming written evidence of consultation is received, ensuring researchers implement suggestions
Cases of unsatisfactory reasons for not including Māori	0
Mechanisms in place to facilitate consultation with Māori by researchers	Researchers have been given advice on whom to contact, as and when required. Researchers are encouraged to approach the administrator as soon as possible if there are difficulties in finding appropriate people to consult with.
Examples of Māori not being included in research	A study involving only African migrants

# Applications

The committee held 11 scheduled meetings from January to November 2006.

## Upper South A Regional Ethics Committee statistics for January–November 2006

Applications approved	62
Applications deferred but later approved	2
Applications deferred	0
Applications declined	0
Applications withdrawn	1
Applications carried forward (approved subject to conditions)	10
Approval not required	5
Transferred to Multi-region Ethics Committee	3
<b>Total number of applications received</b>	<b>83</b>
Applications considered under delegated authority (CPD)	1
Total number of applications considered by the committee	82
<b>Total</b>	<b>83</b>

## Other committee statistics

Number of matters arising	3
Number of general business items	15
Number of amendments reviewed by committee	10
Number of amendments approved under CPD	37

## Audit or matters not requiring ethical approval

Two projects were confirmed as audits or surveys not requiring ethical approval in accordance with section 4.1, page 26, of the Operational Standard for Ethics Committees, March 2002.

## Innovative practice

No applications for innovative practice were received.

## **Second opinions**

No second opinions were sought.

## **Complaints**

No complaints were received.

# Guidelines for the Chairperson's Delegation

At its meeting on 27 January 2006, the committee agreed to delegate the following authority to the Chairperson.

The Chairperson may approve under delegated authority:

- advertisements, letters or minor information sheet changes
- applications provisionally approved by the committee subject to final approval by the Chairperson, usually after review by nominated committee members.

The Chairperson may approve the matters listed below after review by a minimum of one health professional. A subcommittee of health professional and lay members may be involved, and where possible such a subcommittee should include a Māori member. The membership of the subcommittee is recommended by the Chairperson, and members are contacted by the administrator by phone or email to confirm their availability. If any subcommittee member has a major concern and recommends the application or amendment be reviewed by the full committee, the application or amendment will be placed on the agenda for consideration at the next committee meeting, and the researcher will be advised. The matters that the Chairperson may approve following this process are:

- student applications, especially where there is a time constraint for the course and where there is minimal potential for harm to participants, for example, questionnaires or interviews
- applications where the consequences of delaying approval would be significant
- amendments that do not adversely affect participant safety
- confirmation of approval of ongoing applications after receipt of the researcher's annual report.

Following discussion in June 2006, the Chairperson and Deputy Chairperson were also given delegated authority to approve case studies.

# Appendix 1: Applications Received January to December 2006

Appendix 1 details the applications considered by the committee from January to December 2006. Six 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
URA/06/02/001	A prospective, multi-centre, multinational, observational study compiling data on the natural history and management of patients diagnosed with paroxysmal nocturnal hemoglobinuria (PNH)	Dr RL Spearing	7/12/2005	30/01/2006	Approved subject to conditions		Approved	9/03/2006	Christchurch Hospital	Nil		Annette Finlay (CDHB)
URA/06/02/002	A study to compare dietary modification versus supplementation with glycine betaine, on fasting and post-methionine load homocysteine concentrations in healthy volunteers	Dr Wendy Atkinson	9/12/2005	30/01/2006	Approved subject to conditions		Approved	22/02/2006	Canterbury Health Laboratories Christchurch Clinical Studies Trust	A	National Heart Foundation project grant	Te Komiti Whakarite
URA/06/02/003	A descriptive study of the auditory, oral and visual health needs of Year 9 and 10 students at Linwood College	Ms Lynda Jeffs	22/12/2005	30/01/2006	Approved subject to conditions		Approved	15/02/2006	Linwood College	Nil	Canterbury Community Trust, Wayne Francis Charitable Trust	Māori Department, Linwood College
URA/06/02/004	An evaluation of group cognitive-behavioural treatment for post traumatic stress disorder (PTSD) in motor vehicle accident (MVA) survivors	Paul Wynands	23/12/2005	30/01/2006	Approved subject to conditions		Approved	26/04/2006	Christchurch College of Education	A	ACC approved research grant	Māori Mental Health Unit, Hillmorton Hospital
URA/06/02/005	Attitudes toward voluntary HIV testing among African migrants and refugees in Christchurch	Gerida Joseph Birukila	17/01/2006	30/01/2006	Approved subject to conditions		Approved	24/06/2006	NZ AIDS Foundation	Nil		No consultation undertaken – no Māori participants
URA/06/02/006	Prognostic features and clinical outcomes of idiopathic acute transverse myelitis – retrospective review	Dr John Young	17/01/2006	30/01/2006	Approved subject to conditions		Approved	15/02/2006	Christchurch Hospital	Nil		None undertaken – retrospective review only

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
URA/06/02/007	How does a student doctor's appearance, based on face photographs, correlate with success when interacting with patients?	Marianne Lill	17/01/2006	30/01/2006	Approved subject to conditions		Withdrawn	29/03/2006	Timaru Hospital	Nil	Researchers	Elizabeth Cunningham
URA/06/02/008	Retrospective audit of Christchurch patients using subcutaneous insulin pumps	Dr Juliet Berkeley	17/01/2006	30/01/2006	Approved		Approved	8/02/2006	Christchurch Hospital	Nil		None – retrospective review only
URA/06/02/009	Pharmacokinetics of methotrexate polyglutamates in patients with inflammatory bowel disease	Dr Alenka Brooks	17/01/2006	30/01/2006	Approved subject to conditions		Approved	22/02/2006	Christchurch Hospital	A	Gastroenterology Research Trust	Annette Finlay
URA/06/02/010	Incidence and importance of postural hypotension in transient ischaemic attack (TIA)	Dr Elna Ellis	18/01/2006	30/01/2006	Approved		Approved	22/02/2006	Christchurch Hospital	Nil		Annette Finlay
URA/06/02/011	Feasibility study of new techniques for diagnosis of tuberculosis by breath and urine testing		17/01/2006	30/01/2006	Approved subject to conditions		Approved	26/02/2006	Christchurch School of Medicine	A	Internal funding	Elizabeth Cunningham
URA/06/02/012	Breath test for aspergillus and pseudomonas colonisation or infection	Prof Stephen T Chambers	17/01/2006	30/01/2006	Approved subject to conditions		Approved	27/02/2006	CDHB	A	Child Health Foundation grant	Elizabeth Cunningham
URA/06/02/014	A feasibility study of the safety and effectiveness of the DexCom G3 long term sensor in patients with type 1 diabetes mellitus	Prof Russell Scott	17/01/2006	30/01/2006	Approved subject to conditions		Approved	15/02/2006	Christchurch Clinical Studies Trust Christchurch Hospital Lipid and diabetes research	B	DexCom	Mr Peter Mason
URA/06/02/015	Alcohol and other drug outcome treatment outcome measures. Part II: preliminary work towards validating a draft instrument	Dr G Robinson	Forwarded to Multi-region EC									
URA/06/02/016	Evaluation of pilot Pacific community project	Chris Mene	18/01/2006	30/01/2006	Approved subject to conditions		Approved	20/09/2006	Community-based	Nil	Christchurch School of Medicine	Ministry of Pacific Affairs

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
URA/06/03/017	Patient expectations of Adalimumab therapy and quality of life improvements following adalimumab therapy in rheumatoid arthritis	Jan Ipenburg	14/02/2006	27/02/2006	Approved subject to conditions		Approved	15/03/2006	Christchurch Hospital	Nil	Rheumatology Department, Christchurch Hospital	Annette Finlay
URA/06/03/018	An eight-week randomised, double-blind, placebo-controlled, parallel group proof of concept dose ranging study to assess the efficacy, safety and tolerability as well as the pharmacokinetic profile of oral Solabegron (GW427353) 125 mg and 50mg administered twice daily vs placebo, in women with overactive bladder	Dr Sharon English	14/02/2006	27/02/2006	Approved subject to conditions		Approved	7/04/2006	Canterbury Urology Research Trust	B	GlaxoSmithKline	Te Runanga o Ngati Awa group
URA/06/03/019	Continence among people recently moving to resthome care: a Christchurch audit	Prof Edwin Arnold	14/02/2006	27/02/2006	Approved subject to conditions		Approved	17/03/2006	Canterbury Urology Research Trust, Burwood Hospital	Nil	Urological Research Foundation Grant	Peter Mason
URA/06/03/020	Effect of pre-emptive gabapentin on chronic neuropathic pain following inguinal hernia repair	Prof Edward A Shipton	14/02/2006	27/02/2006	Approved subject to conditions		Approved	3/07/2006	Christchurch School of Medicine and Health Sciences	A	Academic Department of Anaesthesia, Christchurch School of Medicine	Elizabeth Cunningham
URA/06/03/021	How specific and sensitive is a test which screens for the presence of a mutation in JAK2 in patients with increased haemoglobin compared with other investigations in establishing a diagnosis of polycythaemia vera? – retrospective review	Dr Peter Ganly	14/02/2006	27/02/2006	Approved		Approved	6/03/2006	Christchurch Hospital	Nil		None – retrospective review only
URA/06/03/022	Incidence and outcome of bacterial discitis in the elderly in Canterbury – retrospective review	Dr Chris Hutchinson	14/02/2006	27/02/2006	Approved subject to conditions		Approved	12/04/2006	The Princess Margaret Hospital	Nil		None – retrospective review only

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
URA/06/03/023	Measurement of volatile organic compounds in exhaled breath using selective ion flow mass spectroscopy (SIFT-MS) – a pilot study	Dr Michael Epton	14/02/2006	27/02/2006	Approved subject to conditions		Approved	24/05/2006	Syft Technologies Ltd	B	Syft Technologies	Elizabeth Cunningham
URA/06/04/025	Refinement and validation of a computerised driving assessment tool for prediction of driving in persons with brain disorders	Dr Carrie RH Innes	14/03/2006	27/03/2006	Approved subject to conditions		Approved	10/04/2006	Driving and Vehicle Assessment Service	A	Canterbury Medical Research Foundation	Elizabeth Cunningham
URA/06/04/026	A pilot study to test the feasibility of conducting a blinded randomised controlled trial to evaluate the effects of chloral hydrate and nasal continuous positive airway pressure versus chloral hydrate and oxygen, on infants with severe bronchiolitis	Ms Tracey Bruce	13/03/2006	27/03/2006	Approved subject to conditions		Approved	18/04/2006	Christchurch Hospital	A	CDHB	Te Komiti Whakarite
URA/06/04/027	An exploration of how occupational health and safety can be more effectively applied within the brothel sector of the sex industry	Mr Timothy Weir	14/03/2006	27/03/2006	Request for information	Pending further assessment of necessity for ethical approval	Ethical approval not required			Nil	Christchurch School of Medicine	Suzanne Pitama – no written evidence
URA/06/04/028	Simulation training to help junior medical staff manage acutely unwell patients – does the learning transfer into the clinical setting? – retrospective review	Dr John Thwaites	14/03/2006	27/03/2006	Approved		Approved	30/03/2006	Christchurch Hospital	Nil		None – retrospective review only
URA/06/05/029	Understanding the viscoelastic and tensile properties of striae distensae	Dr B Nye	18/04/2006	1/05/2006	Approved subject to conditions		Approved	19/12/2006	Christchurch Hospital	A	Otago University	Elizabeth Cunningham
URA/06/05/030	The STOP children's programme: experiences of those involved	Ms Lyn Jansen	11/04/2006	1/05/2006	Approved subject to conditions		Approved	27/06/2006	STOP Trust	Nil	Researcher-funded	None undertaken

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
URA/06/05/031	Public deliberations about health priorities	Assoc Prof Susan Goad	12/04/2006	1/05/2006	Deferred	Pending further assessment of necessity for ethical approval	Approved	31/05/2006	Nelson Marlborough DHB	Nil	Elizabeth Crosby award	Ms Aroha Metcalf; Director of Māori Health; NMDHB
URA/06/05/033	A retrospective case note review of the natural history following acute diverticulitis at Christchurch Hospital from January 1996–January 2001	Dr Richard Tapper	11/04/2006	1/05/2006	Approved		Approved	3/05/2006	Christchurch Hospital	Nil		None – retrospective review only
URA/06/06/034	Prospective note review of the management of acute biliary disease at Christchurch Hospital March–September 2005	Dr C Wakeman	9/05/2006	29/05/2006	Approved		Approved	31/05/2006	Christchurch Hospital	Nil		None undertaken – retrospective review only
URA/06/06/035	Assessment of patients who have a cardiac catheterisation within six months of percutaneous transluminal coronary angioplasty (PTCA): a retrospective chart audit	Ms Carmel Harris	10/05/2006	29/05/2006	Approved		Approved	31/05/2006	Christchurch Hospital	Nil		None – retrospective review only
URA/06/06/036	Use of botulinum toxin type A to treat acute urinary retention caused by benign prostatic hyperplasia	Dr Morgan Pokorny	12/05/2006	29/05/2006	Approved subject to conditions		Approved	12/07/2006	Christchurch Hospital	A	Urology Department	Peter Mason
URA/06/06/037	Continuous positive airways pressure (CPAP) therapy on the general ward following open elective repair of abdominal aortic aneurysm	Mr David Lewis	12/05/2006	29/05/2006	Approved subject to conditions		Approved	4/10/2006	Christchurch Hospital	A	CDHB Research Grant	Annette Finlay
URA/06/06/038	A multi centre, randomised, open-label trial to assess the steady state pharmacokinetics of Bevacizumab given with either XELOX or FOLFOX-4 in patients with metastatic colorectal cancer	Assoc Prof Bridget Robinson	15/05/2006	29/05/2006	Approved subject to conditions		Approved	21/06/2006	Christchurch Hospital	B	Hoffman-La Roche	Te Komiti Whakarite
URA/06/06/040	The effect of unique manuka factor honey on gut health	Dr Alison Wallace	17/05/2006	29/05/2006	Approved subject to conditions		Approved	3/07/2006	CDHB	A	Foundation for Research, Science and Technology	Annette Finlay

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
URA/06/06/041	An exploration of the challenges for remote rural nurses when providing an on call service 24/7 under the PRIME (primary response in medical emergencies) scheme	Ms Barbara Smith	17/05/2006	29/05/2006	Approved subject to conditions		Approved	31/07/2006	West Coast DHB	Nil	Privately funded by researcher	Gary Coughlan – verbal only due to time constraints. Confirmed no issues by telephone to Alieke 31/07/06.
URA/06/07/043	Experiences of nursing and living in the same rural New Zealand community – an interpretive descriptive study	Ms Michele Anne Barber	20/06/2006	3/07/2006	Approved subject to conditions		Approved	2/08/2006	West Coast DHB	Nil	West Coast DHB and researcher	Gary Coughlan – West Coast DHB General Manager Māori Health
URA/06/07/044	Walking on the path of recovery: reflections on the music therapy process with individuals with mental illness	Ms Chi-Yun Lee	20/06/2006	3/07/2006	Approved subject to conditions		Approved	11/08/2006	Stepping Stone Trust	A	No funding required	Cultural Liaison Officer, New Zealand School of Music
URA/06/07/045	Responding to the mental health needs of people with an intellectual disability: a pilot education programme for nurses	Dr Caroline Mohr	20/06/2006	3/07/2006	Approved subject to conditions		Approved	26/07/2006	Hillmorton Hospital	A	Christchurch Polytechnic Research Committee	Te Kahui Pou Hauora Māori; Te Korowai Atawhai
URA/06/07/046	The interaction of patient characteristics and therapeutic process in motivational enhancement therapy for alcohol dependence – retrospective review	Mr Duncan Edwards	21/06/2006	3/07/2006	Approved subject to conditions		Approved	12/07/2006	University of Canterbury	Nil	Retrospective review only	None – retrospective review only
URA/06/07/047	Serious infections in patients on Leflunomide: an audit at Christchurch Hospital	Dr Katherine Meuli	24/06/2006	3/07/2006	Approved subject to conditions	Needs locality assessment	Approved	19/07/2006	Christchurch Hospital	Nil	Retrospective review only	None – retrospective review only
URA/06/08/048	Minimally invasive step up approach versus maximal necrosectomy in patients with acute necrotising pancreatitis; a randomised controlled trial (PANTER)	Mr Saxon Connor	24/07/2006	7/08/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital	A	CDHB	Pending

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
URA/06/08/049	Resuscitation status: How is this information transferred from aged care facilities to hospital in the event of a patient's admission?	Ms Jane Goodwin	24/07/2006	7/08/2006	Approved subject to conditions		Approved	16/10/2006	Christchurch Hospital	Nil	Christchurch Hospital volunteers and Department of Nursing	Pending
URA/06/08/050	Surgery versus stent insertion for the management of non-curable large bowel obstruction	Prof F Frizelle	25/07/2006	7/08/2006	Approved subject to conditions		Approved	14/12/2006	Christchurch Hospital	A	SOuRCe (University of Sydney) bridging grant – form A pending	Te Komiti Whakarite
URA/06/09/051	Early life predictors of later parenting and family formation patterns in the Christchurch health and development study HRC ref: 06/458	Assoc Prof Lianne Woodward	15/08/2006	4/09/2006	Approved subject to conditions		Approved subject to conditions		University of Canterbury	A	HRC (Grant Ref# 06/458)	Te Awatea Violence Research Centre
URA/06/09/052	Fluid balance and adverse effects of intravenous fluid therapy in general surgical patients at Christchurch Public Hospital in 2006	Dr Hilmar Kjartansson	15/08/2006	4/09/2006	Request for information	Audit – subject to clarifications	Ethical approval not required			Nil		
URA/06/09/053	An evaluation of a new continuous positive airway pressure device in volunteers	Dr Richard French	21/08/2006	4/09/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital	A		Annette Finlay
URA/06/09/054	Mathematical modelling of glucose kinetics in babies at risk of abnormal glycaemic control: retrospective review	Glynn Russell	21/08/2006	4/09/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Women's Hospital	Nil		None – retrospective review only
URA/06/09/055	Health staff attitudes towards suicidal and self-harming patients	Dr Annette Beautrais	21/08/2006	4/09/2006	Approved subject to conditions		Approved	24/11/2006		Nil		Mrs Elizabeth Cunningham
URA/06/09/056	Sonographic and biochemical criteria predicting the likelihood of detecting bile duct calculus on MRCP in the symptomatic patients with gallstone diseases: retrospective review	Dr Teck Siew	15/08/2006	4/09/2006	Approved subject to conditions		Approved	15/11/2006		Nil		None – retrospective review only

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
URA/06/10/057	Review of morbidity and outcome of broncho alveolar lavage (BAL) under general anaesthetic in paediatric patients in Christchurch Hospital	Dr Rebecca Smith	7/09/2006	2/10/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital	Nil		None – retrospective review only
URA/06/10/058	Conceptions from a steering group on the implementation of clinical supervision for nurses	Helen Shaw-Brown	11/09/2006	2/10/2006	Approved subject to conditions		Approved	10/11/2006	Princess Margaret Hospital Burwood Hospital	Nil		Te Komiti Whakarite
URA/06/10/059	The influence of proline betaine in orange juice on homocysteine concentrations in healthy male caucasians	Dr Wendy Atkinson	13/09/2006	2/10/2006	Approved subject to conditions		Approved	23/10/2006	Canterbury Health Laboratories Christchurch Clinical Studies Trust	A	Christchurch School of Medicine (Summer Studentship)	Te Komiti Whakarite CDHB
URA/06/10/060	The role of evaluation within mental health services in Aotearoa, New Zealand: an organisational case study	Nicola Stanley-Clarke	15/09/2006	2/10/2006	Approved subject to conditions		Approved	13/11/2006	Canterbury DHB	A	Massey University – Graduate Research Fund	None – case study only
URA/06/10/061	Psychoeducation and support for people affected by bipolar disorder: developing a community service evaluation questionnaire	Dr Carolyn Doughty	15/09/2006	2/10/2006	Approved subject to conditions		Approved	8/11/2006	Bipolar Support Canterbury	Nil	Bipolar Support Canterbury; Christchurch School of Medicine (summer studentship)	Te Korowai Atawhai
URA/06/10/062	Retrospective review of PCA efficacy and associated complications following gynaecological surgery at Christchurch Women's Hospital	Dr James Dalby-Ball	18/09/2006	2/10/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital	Nil		None – retrospective review only
URA/06/10/063	Comparative study of CoQ10 bioavailability of Trilogie CoQ10 versus soybean oil emulsion CoQ10 dietary supplements	Prof Russell Scott	18/09/2006	2/10/2006	Approved subject to conditions		Approved subject to conditions		Lipid and diabetes research, Christchurch Hospital	A		Te Komiti Whakarite
URA/06/10/064	The experience of fatigue: exploring the nature and course of fatigue in chronic conditions using an email forum	Dr Lisa Whitehead	Forwarded to Multi-region EC						Christchurch School of Medicine & Health Sciences	Nil	Centre for post-graduate nursing studies	Elizabeth Cunningham

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
URA/06/10/065	The experience of fatigue: exploring the nature and course of fatigue in chronic conditions using research methods	Dr Lisa Whitehead	Forwarded to multi-region EC						Christchurch School of Medicine and Health Sciences	Nil	Centre for post-graduate nursing studies	Elizabeth Cunningham
URA/06/10/066	Parkinson's disease – cognitive impairment, eye movements and brain imaging	Prof Tim Anderson	18/09/2006	2/10/2006	Approved subject to conditions		Approved	3/11/2006	Van der Veer Institute for Parkinson's and Brain Research	A	Neurological Foundation	Elizabeth Cunningham
URA/06/10/067	Neuropsychological indicators of treatment response in severe depression	Assoc Prof Richard Porter	18/09/2006	2/10/2006	Deferred	Committee unable to assess application due to lack of information	Approved	22/11/2006		A		Elizabeth Cunningham; Phillip Patira (Te Korowai Atawhai)
URA/06/10/068	Development of functional magnetic resonance imaging and acquisition of normative MRI data	Dr Richard Watts	20/09/2006	2/10/2006	Approved subject to conditions		Approved	27/10/2006	University of Canterbury	A	Canterbury Medical Research Foundation (studentship and MRI scan time)	Annette Finlay; Te Komiti Whakarite
URA/06/11/069	Neuropsychological function, emotion recognition and blood plasma oxytocin in a healthy control group	Dr Lynden Miles	13/10/2006	30/10/2006	Approved subject to conditions		Approved subject to conditions		University of Canterbury	A	University of Canterbury research grant 480ELCJ	Elizabeth Cunningham
URA/06/11/070	Transportation of very low birthweight/very preterm infants in New Zealand – 20 years on: retrospective review	Ms Claire Vivian	16/10/2006	30/10/2006	Ethical approval not required	Audit	Ethical approval not required		Christchurch Women's Hospital	Nil		
URA/06/11/071	Assessing the information-seeking behaviour, skills and needs of different clinical health professional groups at the Canterbury District Health Board	Phil Hider	18/10/2006	30/10/2006	Approved subject to conditions		Approved	8/12/2006	Christchurch District Health Board	Nil	Christchurch School of Medicine	Annette Finlay (CDHB)
URA/06/11/072	The impact of neighbourhood characteristics and support on wellbeing, housing satisfaction, and residential stability for people with a mental illness	Ms Joanna Elgin	16/10/2006	30/10/2006	Approved subject to conditions		Approved	30/11/2006	ComCare Trust	Nil	Centre for Housing Research Aotearoa New Zealand and ComCare Trust	Te Awa O Te Ora Trust

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
URA/06/11/074	A descriptive case study of practice development in a rural nurse-led chemotherapy clinic	Ms Glynnis James	18/10/2006	30/10/2006	Approved subject to conditions		Approved	1/12/2006	West Coast DHB	Nil	Primary health care scholarship; WCDHB study leave	Gary Coghlan; WCDHB General Manager Māori Health
URA/06/11/075	Pilot study to assess the feasibility and cost benefit of human papilloma virus testing in the follow-up of women treated for high grade squamous intraepithelial lesions within the National Cervical Screening Programme	Dr Olivia Smart	20/10/2006	30/10/2006	Approved subject to conditions		Approved	30/11/2006	Christchurch Women's Hospital	A	Digene Corporation, USA	Annette Finlay
URA/06/11/076	Role of ultrasound in the diagnosis of temporal arteritis (giant cell arteritis)	Dr Nigel Anderson	20/10/2006	30/10/2006	Approved subject to conditions		Approved	13/11/2006	Christchurch Hospital	A	CDHB	Annette Finlay
URA/06/11/077	The relationship between parenting stress and asthma in new entrant children with parent-identified internalising disorders	Kathleen Liberty	1/11/2006	3/10/2006	Approved subject to conditions		Approved subject to conditions		University of Canterbury	Nil	University of Canterbury	
URA/06/12/078	Retrospective audit or blood sugar control in pump cardiac surgery patients following introduction of insulin protocol	Matthew A Jenks	7/11/2006	27/11/2006	Ethical approval not required		Ethical approval not required		Christchurch Hospital	Nil		
URA/06/12/079	Aspire weight loss programme – an evaluation of a nutritionally sound web-based approach to weight loss	Dr Alison Wallace	13/11/2006	27/11/2006	Approved subject to conditions		Approved subject to conditions		CDHB	A	Bakers and Flour Millers Research Trust Industry is providing co-funding	Te Komiti Whakarite
URA/06/12/080	Dynamic modelling of renal failure in critical illness: estimation of glomerular filtration rate in intensive care using aminoglycoside clearance, empirical formulae and dynamic models	Dr Zoltan Andre	13/11/2006	27/11/2006	Approved		Approved	29/11/2006	Christchurch Hospital	Nil		None – retrospective review only

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
URA/06/12/081	Audit of use of appropriate prophylactic anticoagulation for venous thromboembolism and documenting incidence of venous thromboembolism (VTE) in oncology patents	Dr Paul Chin	16/11/2006	27/11/2006	Ethical approval not required		Ethical approval not required			A		
URA/06/12/082	Measuring the sensitivity of leukaemia cells to cytotoxic	Dr Mark Hampton	15/11/2006	27/11/2006	Approved		Approved	4/12/2006		Nil		Research Manager – Maori; Christchurch School of Medicine
URA/06/12/083	The control group: studying cells of biomarkers in the blood and urine of healthy donors	Assoc Prof Tony Kettle	15/11/2006	27/11/2006	Approved subject to conditions	Russell Scott to review	Approved subject to conditions			A	HRC	Research Advisor Māori CSM & HS

## Applications 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
URA/06/02/013	A non-randomised, open-label, single dose study to assess the safety and pharmacokinetics of RO4908463 and its major metabolite in subjects with varying degrees of renal function	Assoc Prof Richard Robson	17/01/2006	30/01/2006	Approved		Completed	8/02/2006	Christchurch Clinical Studies Trust	B	F Hoffmann–La Roche Inc	Mr and Mrs John McManus
URA/06/04/024	A phase 1, randomised, multicentre, double-blind study of MK-0429 in the treatment of men with hormone refractory prostate cancer and metastatic bone disease	Dr Peter Davidson	10/03/2006	27/03/2005	Approved subject to conditions		Approved	19/04/2006	Canterbury Urology Research Trust Christchurch Clinical Studies Trust	B	Merck Sharpe and Dohme	Mr Peter Mason

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
URA/06/05/032	An open-label, non-randomised pharmacokinetic and safety study of a single oral dose of 50mg Eltrombopag in healthy subjects and in volunteers with mild, moderate or severe hepatic impairment	Assoc Prof Richard Robson	19/04/2006	5/01/2006	Approved subject to conditions		Approved	12/06/2006	Christchurch Clinical Studies Trust	B	GlaxoSmith Kline	Mr and Mrs J McManus – pending
URA/06/06/039	Open label, two-period, two-treatment cross-over drug-drug interaction study to investigate the pharmacokinetics, safety and tolerability of RO4874441 after multiple-dose and in combination with multiple-dose Atorvastatin and vice versa in healthy volunteers	Dr Chris Wynne	15/05/2006	29/05/2006	Approved subject to conditions		Approved	14/06/2006	Christchurch Clinical Studies Trust	B	Hoffman–La Roche	Mr and Mrs J McManus
URA/06/06/042	Roche sample repository research project in association with Protocol BP19786	Dr Chris Wynne	17/05/2006	29/05/2006	Approved subject to conditions		Approved	14/06/2006	Christchurch Clinical Studies Trust	B	F Hoffmann–La Roche Inc	Mr and Mrs J McManus
URA/06/11/073	Roche Integrin antagonist follow-up for undetected PML	Assoc Prof Richard Robson	16/10/2006	30/10/2006	Approved subject to conditions		Approved	9/01/2007	Christchurch Clinical Studies Trust	B	Hoffman–La Roche	Mr and Mrs John McManus

### Applications approved by the Chairperson under delegated authority

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
URA/06/01/CPD	Quality of life before and after hip joint surgery in patients under age 65 from the Timaru area	Ms C Ulrich	11/12/2006	–	Approved		Approved	13/12/2006	Timaru Hospital	None	None	None – retrospective review only

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

### **Public authority of the Upper South A Regional Ethics Committee**

The Upper South A Regional Ethics Committee (Upper South A 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 Upper South A REC.

### **Authority of the Upper South A Regional Ethics Committee**

The Upper South A REC shall have responsibility with the Upper South B Regional Ethics Committee for ethics committee review of health and disability research and innovative practice occurring in the following District Health Board regions:

- Nelson Marlborough
- West Coast
- Canterbury
- South Canterbury.

The Upper South A REC is jointly responsible with the Upper South B Regional Ethics Committee 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 Upper South A REC.

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

The Upper South A REC shall liaise with other relevant ethics committees on matters of common interest, such as jurisdiction over borderline cases. The Upper South A 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 Upper South A Regional Ethics Committee**

The Upper South A 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 Upper South A Regional Ethics Committee**

The primary role of the Upper South A 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 Upper South A 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 Upper South A REC is to ensure that the Upper South A 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 Upper South A 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 Upper South A REC's lay membership shall include:

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

The Upper South A 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 New Zealand Public Health and Disability Act requirements for District Health Boards, the Upper South A 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 Upper South A REC are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

The Upper South A 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 committees 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, Upper South A REC 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 Upper South A REC as equal individuals of sound judgement, relevant experience and adequate training in ethical review.

## **Terms and conditions of appointment**

Members of the Upper South A 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 Upper South A 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 until at least three years after their retirement from the Upper South A 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 Upper South A REC. Those persons shall not be eligible for appointment to the Upper South A 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 ethics committee will be eligible to be appointed to the Upper South B 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 Upper South A 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 Upper South A REC shall continue in office until their successor comes into office. Any member of the Upper South A REC may at any time resign as a member by advising the Minister of Health in writing.

Any member of the Upper South A 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 Upper South A REC, or discharge any member of the Upper South A REC, or appoint new members to the Upper South A 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 Upper South A REC to be its Chairperson. The terms and conditions of appointment for members of the Upper South A REC also apply to the person appointed as Chairperson. The Chairperson shall preside at every meeting of the Upper South A REC at which they are present.

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

The Chairperson and Deputy Chairperson may act with the delegated authority of the Upper South A 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 Upper South A REC. This is intended to aid Upper South A REC members by providing them with a common set of principles for appropriate conduct and behaviour.

### **General**

Upper South A 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 Upper South A REC members will make every effort to attend all Upper South A REC meetings and devote sufficient time to become familiar with the affairs of the Upper South A 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 Upper South A REC and the use of Upper South A REC funds.

### **Conflicts of interest**

Upper South A 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 Upper South A REC and its members and will ensure Upper South A REC retains public confidence.

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

When Upper South A 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 Upper South A REC's functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.

A member of the Upper South A REC who has a proposal before the Upper South A REC or who has an involvement in the proposal, such as a supervisory role, shall not take part in the Upper South A 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 Upper South A REC must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

### **Confidentiality and information sharing**

Agendas and minutes of all Upper South A REC meetings should be available to the public. Copies of proposals should be available to individuals outside the Upper South A 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 Upper South A 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 Upper South A 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 Upper South A REC. The Upper South A REC will need to consider the Privacy Act 1993 and the Health Information Privacy Code 1994 in developing these processes.

Within the Upper South A 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 Upper South A 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 Upper South A REC to be open to the public. Meetings of the Upper South A REC should therefore be:

- i. open meetings for the discussion of broad issues, particularly if the Upper South A 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 Upper South A REC may have. Attendance is not mandatory. The Upper South A REC should advise applicants that they may be asked to leave the meeting while the Upper South A REC considers the proposal.

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

### **Decision-making process**

Wherever possible, the Upper South A 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 an Upper South A 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 Upper South A 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, it must specify the conditions, the grounds for these, and its process for assessing whether these conditions are subsequently met. In all cases, it 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 Upper South A REC members believes there is insufficient expertise on the Upper South A 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 Upper South A REC's decision on a proposal.

## **Second opinions and appeals**

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

The decisions of the Upper South A 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 Upper South A 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 Upper South A REC, including any change in the Upper South A REC's membership or other substantive changes the Upper South A 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 treatment protocols reviewed in the preceding year outlining the following details:

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

In compiling annual reports, the Upper South A 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 Upper South A 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 Upper South A REC by the Chairperson and Deputy Chairperson. The Ministry of Health shall pay actual and reasonable travel and accommodation expenses of the Upper South A REC members.

### **Servicing of the Upper South A Regional Ethics Committee**

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

