



# **Upper South B Regional Ethics Committee**

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## **Annual Report**

**December 2004 to December 2005**

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This report provides an overview of the work of the Upper South B Regional Ethics Committee from December 2004 to December 2005. The report was presented to the Upper South B Regional Ethics Committee at its meeting on 13 March 2006.

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

## **Chairperson's Report**

The committee was established in December 2004 and had its first meeting on 12 December 2004. Over the year, the committee processed 117 new applications. The committee experienced no membership changes, and a core of experienced members was maintained.

Katherine Bell undertook the administration of the Upper South B Regional committee in 2005.

Gray Crawford  
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>Gray Crawford</b>	DipMgt, CertRehabSt, AFNZIM, JP
Representation	Lay member
Member category	Consumer representative
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	February 2009
Professional affiliations	–
Iwi affiliations	None

### Deputy Chairperson

<b>Mark Smith</b>	MBChB, PhD, FRACP
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	February 2009
Professional affiliations	Canterbury District Health Board
Iwi affiliations	None

### Members

<b>Sharon Gardiner</b>	B Pharm (Hons), MClInPharm, FNZCP
Representation	Non-lay member
Member category	Pharmacologist
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Canterbury District Health Board
Iwi affiliations	None

<b>Rosemary Carruthers</b>	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	None
<b>Brenda Moran</b>	BA Social Work
Representation	Lay member
Member category	Consumer representative
Gender	Female
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Professional affiliations	–
Iwi affiliations	None
<b>Kathrine Townshend</b>	Dip 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 2007
Professional affiliations	–
Iwi affiliations	None
<b>Annette Finlay</b>	Bachelor of Health Sciences, Dip Nursing Studies
Representation	Non-lay member
Member category	Health researcher
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	July 2010
Professional affiliations	Canterbury District Health Board, Te Komiti Whakariti
Iwi affiliations	Tainui, Te Arawa
<b>Patrick Graham</b>	PhD
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	University of Otago
Iwi affiliations	None

<b>Robin Fraser</b>	MB BS Hons, PhD (Experimental Path), MD, FRCPA
Representation	Non-lay member
Member category	Researcher
Gender	Male
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	December 2006
Professional affiliations	Christchurch School of Medicine, University of Otago
Iwi affiliations	None

<b>Michael Gough</b>	
Representation	Lay member
Member category	Community representative
Gender	Male
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Professional affiliations	–
Iwi affiliations	Te Atiawa, Ngati Mutunga

<b>Simon Clarke</b>	D.Phil
Representation	Lay member
Member category	Ethicist
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	July 2009
Professional affiliations	University of Canterbury
Iwi affiliations	None

<b>David McGregor</b>	MBChB, PhD, FRACP
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	Canterbury District Health Board
Iwi affiliations	None

### **Deputy Chairperson**

Dr Mark Smith was elected Deputy Chairperson by the Committee at its inaugural meeting on 13 December 2004.

## Members' attendance

Member	M/F	Lay/ non-Lay	Dec 2004	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Gray Crawford Consumer rep	M	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Mark Smith Health practitioner	M	NL	Y	Y	Y	Y	Y	Y	A	Y	Y	A	Y	Y	10/12
Sharon Gardiner Pharmacist/ pharmacologist	F	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Rosemary Carruthers Lawyer	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Brenda Moran Consumer rep	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	11/12
Kathrine Townshend Community rep	F	L	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	11/12
Annette Finlay* Health researcher	F	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Patrick Graham Biostatistician	M	NL	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	11/12
Robin Fraser Health researcher	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Michael Gough* Community rep	M	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Simon Clarke Ethicist	M	L	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	Y	11/12
David McGregor Health practitioner	M	NL	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	11/12
<b>No. members present</b>			12	12	12	11	12	12	8	12	12	11	11	12	
<b>No. of applications</b>			12	6	9	9	8	9	9	10	9	11	11	14	117

\* = Māori member

Y = Present

A = Apology

## 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 following members of the Upper South B Regional Ethics Committee attended one or both of the training days on 4 and 5 February 2005 in Christchurch: Rosemary Carruthers, Brenda Moran, Kathrine Townshend, Annette Finlay, Robin Fraser, Sharon Gardiner, Michael Gough, David McGregor, Mark Smith, Gray Crawford, Simon Clarke, Patrick Graham (all the committee members).

## **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 members of the Upper South B Regional Ethics Committee attended: Gray Crawford and Rosemary Carruthers.

## **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 Upper South B Regional Ethics Committee attended: Annette Finlay.

## **Chairpersons' meeting**

Gray Crawford attend the meetings of the chairpersons of the multi-region and regional ethics committees held on 14 April 2005 and 13/14 October 2005.

## **Meetings with researchers**

Members from the Upper South A Regional Ethics Committee and the Upper South B Regional Ethics Committee met with staff at Christchurch Clinical Studies Trust on 16 May 2005.

Members from the Upper South A Regional Ethics Committee and the Upper South B Regional Ethics Committee met with staff at the Van der Veer Institute for Parkinson's and Brain Research on 12 July 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 Upper South B Regional Ethics Committee is registered with the United States Department of Health & Human Services. The registration number is: IRB00004668 – Upper South B 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	98%
Number of applications returned through insufficient consultation on cultural issues	Less than 10%
Process the committee has for following through on consultation	Feedback to researchers, provision of Māori consultation groups for researchers
Cases of unsatisfactory reasons for not including Māori	3 (Researchers did not grasp the issues)
Mechanisms in place to facilitate consultation with Māori by researchers	Te Komiti Whakarite based at Christchurch Hospital; Research Manager Māori based at the Christchurch School of Medicine
Examples of Māori not being included in research	1 (One case of Māori excluded at request of Māori consultant, but this was sent to the local iwi, and the exclusion was deemed inappropriate and overturned)

## Applications

The committee held 12 scheduled meetings from December 2004 to December 2005.

### Upper South B Regional Ethics Committee statistics for December 2004–December 2005

Applications considered under delegated authority (CPD)	0
Applications approved	92
Applications deferred at first review and subsequently approved	3
Applications deferred at the time of the report	3
Applications declined	2
Applications carried forward (approved subject to conditions)	7
Approval not required	10
<b>Total number of applications received</b>	<b>117</b>

### Other committee statistics

Number of matters arising considered	8
Number of general business items reviewed	14
Number of amendments reviewed by committee	0
Number of amendments approved under CPD	90

### Audit or matters not requiring ethical approval

Ten projects were confirmed as audits or surveys not requiring ethical approval.

### Innovative practice

No applications for innovative practice were received.

### School science fair projects

Twenty applications were received.

## **Second opinions**

One researcher sought a second opinion from the Health Research Council Ethics Committee (HRCEC) when their application was declined. The application was initially deferred due to concerns about the lack of informed consent from all participants. After further information/explanation was obtained from the researchers (including discussions), the application was declined on the basis that informed consent was not going to be obtained from the control group participants, which the committee felt was without sufficient reason to be ethically appropriate as set out in rules 10 and 11 of the Health Information Privacy Code 1994. The second opinion provided by the HRCEC was supportive of the committee's decision, and the committee upheld its original decision to decline the application.

# Complaints

No complaints were received.

## Issues for the Committee

### Tissue banking

During 2005, the Upper South B Regional Ethics Committee debated at length the legal and moral ramifications of the use of tissue for future unspecified research, particularly in regard to children. It was the general view of the committee that, where practical, participants must be able to withdraw from an investigation at any time without waiver of any rights and without giving reasons (see Health Research Council Guidelines on Ethics in Health Research; Section 3.1 Informed consent, criteria, clause 4) even if the information sheet and consent forms are drafted to waive this right.

The Code of Health and Disability Services Consumers' Rights and the Operational Standard for Ethics Committees are unclear in this area, and therefore the committee appreciates that the Ministry of Health has agreed to prepare guidelines on unspecified future use of tissue in consultation with the National Ethics Advisory Committee.

### Section F

Another issue highlighted throughout the year was the apparent inconsistency in which Section F (Cultural and Social Responsibility) was completed by researchers. The committee recommends that the wording in this part of the application form be reviewed in order to promote a better understanding of cultural issues, such as tino rangatiratanga, taonga and tikanga Māori in medical research in order to improve health outcomes for Māori.

## Guidelines for the Chairperson's Delegation

At its meeting on 13 December 2004, the committee agreed to delegate the following authority to the Chairperson.

The Chairperson may approve under delegated authority the following:

- 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 following 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 subcommittee is recommended by the Chairperson, and members will be 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, it will be placed on the agenda for consideration at the next committee meeting, and the researcher will be advised:

- 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, 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.

# Appendix 1: Applications received December 2004 to December 2005

Appendix 1 details the applications considered by the committee from December 2004 to December 2005 in open meetings. Twelve 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
URB/04/12/001	Event-related neuromuscular electrical stimulation for swallowing rehabilitation	Dr Maggie Lee Huckabee	19/11/04	13/12/04	Approved subject to conditions		Approved	19/01/05	Van der Veer Institute for Parkinson's and Brain Research	A		Te Komiti Whakarite
URB/04/12/002	An investigation into the mental health provision needs of mothers in the Canterbury region	Mr Joseph M Boden	23/11/04	13/12/04	Deferred	Information received insufficient for committee to make decision	Approved	4/11/05	Newell House Trust	Nil		Te Korowai Atawhai; Hillmorton Hospital
URB/04/12/003	Minimum date set – home care (MDS HC) post assessment review	Brigitte Larkins	29/11/04	13/12/04	Deferred	Retrospective review form completed, requires full application because contacting participants	Approved	4/04/05	The Princess Margaret Hospital	Nil		Māori Needs Co-ordinator; Princess Margaret Hospital
URB/04/12/004	Developing comprehensive needs assessment in older person's health: context and experiences of informal carers	Dr Sally Keeling	29/11/04	13/12/04	Approved subject to conditions		Approved	5/09/05	Health Care of the Elderly	Nil		Christchurch School of Medicine Research Manager Māori
URB/04/12/005	The acceptability of using reduced nicotine cigarettes to quit smoking – pilot study	Dr Natalie Walker	29/11/04	13/12/04	Approved subject to conditions		Closed	14/02/05	Clinical Trials Research Unit	Nil		CTRU Māori Research Advisory Committee
URB/04/12/006	A study among intending quitters of the acceptability, effect on smoking behaviour and nicotine levels from pre-quit nicotine replacement therapy	Chris Bullen	29/11/04	13/12/04	Approved subject to conditions		Approved	23/12/04	Clinical Trials Research Unit	A		CTRU Māori Research Advisory Committee
URB/04/12/007	The Coonrad-Morrey total elbow arthroplasty in patients with rheumatoid arthritis: a long-term follow-up study	Dr Iliessa Beci	2/12/04	13/12/04	Approved subject to conditions		Completed – report required	28/02/05	Burwood Hospital	A		Te Komiti Whakarite
URB/04/12/010	Detection of early cardiac (asymptomatic) disease by B-type natriuretic peptide ("DETECT" study)	Professor Mark Richards	2/12/04	13/12/04	Approved subject to conditions		Approved	19/01/05	Cardiology Service	B	Roche	Christchurch School of Medicine Research Manager Māori
URB/04/12/011	A pilot, double-blind, crossover trial of the glucocorticoid antagonist mifepristone (RU-486) in the treatment of depression in patients with Parkinson's disease	Dr Richard Porter	29/11/04	13/12/04	Approved subject to conditions		Approved	28/02/05	Van der Veer Institute for Parkinson's and Brain Research	A		Christchurch School of Medicine Research Manager Māori

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
URB/04/12/012	Therapeutic drug monitoring of Azathioprine in rheumatoid arthritis: a pilot study in Canterbury, New Zealand	Andrew Gibson	29/11/04	13/12/04	Approved subject to conditions		Completed – report required	22/02/05	Christchurch School of Medicine and Health Sciences	Nil		Māori Liaison Officer for Christchurch Hospital
URB/05/02/008	A randomised intervention to reduce repeated suicide attempts	Professor Roger Mulder	3/02/05	21/02/05	Deferred	Deferred because informed consent not to be obtained from all participants	Declined		Christchurch School of Medicine	A		Christchurch School of Medicine Research Manager Māori
URB/05/02/009	A nutritional information pamphlet for patients suffering from Xerostomia	Ms Charlene Elaine Tan	7/02/05	21/02/05	Approved subject to conditions		Closed	11/04/05	Christchurch School of Medicine and Health Sciences	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/02/010	Retrospective review of CTPA performed for patients with suspected pulmonary embolism: a follow up study after change of guidelines	Mr Paul Chin	7/02/05	21/02/05	Ethical approval not required		Ethical approval not required	21/02/05	Christchurch Hospital	Nil		
URB/05/02/011	Impact of drug therapy on endochondral bone growth: role of a new bone growth factor (CNP)	Dr MJ Sullivan	7/02/05	21/02/05	Approved subject to conditions		Approved	10/06/05	Christchurch Hospital	A		Christchurch School of Medicine Research Manager Māori
URB/05/02/012	The invisible dimension: identifying the prevalence and needs of children and young people of parents or siblings living with mental health issues in West Coast District Health Board Mental Health Service	Ms Sonja Worthington	7/02/05	21/02/05	Approved subject to conditions		Approved subject to conditions		West Coast DHB	Nil		Māori mental health consultant
URB/05/02/013	Does suppression of AF promote reverse electrical remodelling of the atria?	Dr Ian Crozier	7/02/05	21/02/05	Approved subject to conditions		Approved	2/05/05	Christchurch Hospital	B	St Jude Medical	Te Komiti Whakarite
URB/05/03/021	Understanding edentulism among older New Zealanders	Dr Philip Sussex	3/03/05	21/03/05	Approved subject to conditions		Approved	30/05/05	Nelson Hospital	Nil		Ngai Tahu Research Consultation Committee
URB/05/03/023	Patterns of angiographic coronary artery disease: associations with patient demographics	Dr Paul Bridgman	7/03/05	21/03/05	Ethical approval not required		Ethical approval not required	30/03/05	Christchurch Hospital	Nil		
URB/05/03/024	The use of selected ion flow tube mass spectrometry (SIFT-MS) to measure volatile organic compounds produced in diathermy plume and in the expired breath of operating room staff	Dr Andrew Moot	7/03/05	21/03/05	Approved subject to conditions		Approved	21/04/05	Christchurch School of Medicine and Health Sciences	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/03/025	The use of volatile organic compounds as detected by ino flow tube mass spectrometry (SIFT-MS) in the diagnosis of acute appendicitis	Dr Andrew Moot	7/03/05	21/03/05	Approved subject to conditions		Approved	21/04/05	Christchurch School of Medicine and Health Sciences	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/03/026	A pilot study of high dose allopurinol in the management of gout	Dr Lisa Stamp	7/03/05	21/03/05	Approved subject to conditions		Approved	9/05/05	Christchurch School of Medicine and Health Science	A		Christchurch School of Medicine Research Manager Māori

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
URB/05/03/027	In-flight oxygen saturation in passengers with chronic obstructive lung disease and restrictive lung disease: are the current guidelines valid?	Mr Paul T Kelly	7/03/05	21/03/05	Approved subject to conditions		Approved	2/05/05	CDHB	A		Te Komiti Whakarite
URB/05/03/028	Randomised phase III trial of De Gramont schedule 5: Fluorouracil and Leucovorin plus Irinotecan versus single agent Irinotecan plus or minus celecoxib in patients with previously treated metastatic cancer	Dr M Jeffery	9/03/05	21/03/05	Approved subject to conditions		Approved	16/05/05	Christchurch School of Medicine	A		Te Komiti Whakarite
URB/05/03/029	A phase II trial of Gemcitabine in fixed dose rate infusion combined with Cisplatin in patients with inoperable biliary tract carcinomas	Dr David Gibbs	9/03/05	21/03/05	Approved subject to conditions		Approved	20/05/05	Christchurch School of Medicine	A		Te Komiti Whakarite
URB/05/04/036	Health-related quality of life, disability and impairment among individuals with eating disorders	Dr Janet Latner	29/03/05	18/04/05	Approved subject to conditions		Approved	9/06/05	University of Canterbury CDHB	Nil		Team at South Island Eating Disorders Service
URB/05/04/037	The reproducibility of resting energy expenditure and RQ measurements in healthy human volunteers using the Sensesmedics V Max system	Dr Jane Eimsle	4/04/05	18/04/05	Approved subject to conditions		Approved	10/06/05	Christchurch School of Medicine	A		Christchurch School of Medicine Research Manager Māori
URB/05/04/038	Assessing the effectiveness of a family-based behaviour modification programme aimed at increasing physical activity levels in the treatment of obese and overweight children	Ms Catherine Robinson	4/04/05	18/04/05	Approved subject to conditions		Approved	30/05/05	Sport Canterbury	A		He Oranga Poutama
URB/05/04/039	What are the critical requirements for registered nurses to effectively communicate changes in a patient's condition to doctors in the surgical ward environment	Ms Kim Macfarlane	4/04/05	18/04/05	Approved		Approved	22/04/05	Christchurch School of Medicine	Nil		Te Komiti Whakarite
URB/05/04/041	Optimising antibiotic use in the management of uncomplicated urinary tract infection	Dr Dereile Richards	6/04/05	18/04/05	Approved subject to conditions		Approved	30/05/05	Christchurch School of Medicine and Health Sciences	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/04/042	The use of volatile organic compounds (VOCs) as detected by selected ion flow tube mass spectrometry (SIFT-MS) in the diagnosis of pancreatic malignancy	Dr Andrew Moot	6/04/05	18/04/05	Approved subject to conditions		Approved	20/05/05	Christchurch School of Medicine	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/04/043	Case comparison study of pressure levels, comparing seating pressure from wheelchair and chair with pressure from therapeutic horse riding, for disabled and able-bodied riders	Ms Jane Clifford	6/04/05	18/04/05	Approved		Approved	22/04/05	Christchurch Riding for the Disabled	A		Whanau Support – CCS

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
URB/05/04/044	A phase III international randomised trial of single versus multiple fractions for re-irradiation of painful bone metastases	Dr Scott Babbington	6/04/05	18/04/05	Approved		Approved	22/04/05	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/05/053	A prospective randomised trial comparing interscapular versus abdominal deep subcutaneous injection of Enoxaparin 40 mg (Clexane <sup>®</sup> )	Mr David Lewis	20/04/05	16/05/05	Approved subject to conditions		Approved	22/02/06	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/05/054	The effect of calculated brain sevoflurane concentration on quality and speed of recovery after general anaesthesia	Dr Ross Kennedy	22/04/05	16/05/05	Approved subject to conditions		Approved	7/07/05	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/05/055	Evaluation of pharyngeal surface-EMG measures as a function of swallowing manoeuvre and bolus volume	Mr Sebastian Doeltgen	28/04/05	16/05/05	Approved subject to conditions		Approved	24/06/05	Van der Veer Institute for Parkinson's and Brain Research	A		Te Komiti Whakarite
URB/05/05/056	Service utilisation following discharge from Totara House	Mark Turner	29/04/05	16/05/05	Deferred	Information received insufficient for committee to make decision	Deferred		The Princess Margaret Hospital	Nil		
URB/05/05/057	Large electromagnetic pulses and the human brain	Mr Daniel Adsett	2/05/05	16/05/05	Deferred	Deferred due to concerns about scientific validity	Withdrawn		University of Canterbury	A		
URB/05/05/058	Isolation and genetic comparison of escherichia coli strains from women with urinary tract infections and their pet dogs	Mr Maqhawe Ndlovu	2/05/05	16/05/05	Approved subject to conditions		Approved	18/08/05	Nelson/Marlborough DHB	A		Māori Health at Wairau Hospital
URB/05/05/059	Impact if the use of the functional health assessment tool (TFHAT) by direct-care staff on the interface between people with an intellectual disability and their general practitioner	Ms Henrietta Trip	2/05/05	16/05/05	Approved subject to conditions		Approved	29/06/05	Christchurch School of Medicine	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/05/060	Pre and post surgical assessment of swallowing biomechanics in patients undergoing cricopharyngeal myotomy: a case series	Ms Ulrike Witte	4/05/05	16/05/05	Approved subject to conditions		Approved	8/06/05	University of Canterbury	A		Te Komiti Whakarite
URB/05/06/068	A multicentre, randomised, double-blind, placebo-controlled, one year extension of the Phase IIa clinical efficacy study (026-01) to assess the tolerability of the MK-0524/Niacin combination tablet, Protocol 026-10	Professor Russell Scott	18/05/05	24/06/05	Approved subject to conditions		Approved	14/07/05	CDHB	B	Merck Sharp and Dohme	Peter Mason, Department of Labour

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
URB/05/06/069	Investigation into the anti-atherogenic potential of adipoecin using human aortic endothelial cells	Dr Stuart Plant	19/05/05	24/06/05	Approved subject to conditions		Approved	4/08/05	Christchurch Hospital	Nil		Te Komiti Whakarite
URB/05/06/070	Supportive care needs survey	Ms Alexa Vardy	19/05/05	20/06/05	Approved subject to conditions		Completed – report required	16/05/05	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/06/071	A model to prediction risk of mortality for up to 30 days after general and vascular surgery	Dr Richard Seigne	19/05/06	20/06/05	Ethical approval not required		Ethical approval not required	24/06/05		Nil		
URB/05/06/072	The prevalence of Wegener's granulomatosis (WG) and microscopic polyangiitis (MPA) in the Canterbury region	Dr JL O'Donnell	23/05/05	24/06/05	Approved		Approved	24/06/05		Nil		
URB/05/06/073	Crohns histology review	Peter Sliven	20/06/05	24/06/05	Deferred	Information received insufficient for committee to make decision, asked to resubmit on updated application form	Deferred		Christchurch hospital	Nil		
URB/05/06/074	Blood pressure and weight changes in the first 12 weeks after commencement of haemodialysis	Ms Suetonia Palmer	30/05/05	24/06/05	Ethical approval not required		Ethical approval not required			Nil		
URB/05/06/075	A single dose, randomised two-period crossover study in patients with haemophilia A to evaluate the pharmacokinetics of Refacto* (B-domain deleted recombinant human factor VIII [BDDrFVIII]) and Advate* (a full-length recombinant factor VIII[FcFVIII]). Wyeth Research Protocol 3082A1-900	Dr Mark Smith	2/06/05	24/06/05	Approved subject to conditions		Approved	4/07/05	Christchurch Hospital	B	Wyeth Research	Te Komiti Whakarite
URB/05/06/076	The effect of glycine betaine on fasting and post methionine load homocysteine concentrations in healthy volunteers	Dr Wendy Atkinson	7/06/05	24/06/05	Approved subject to conditions		Approved	4/08/05	Canterbury Health Laboratories Christchurch Clinical Studies Trust	A		Te Komiti Whakarite
URB/05/06/077	Coenzyme Q10: potential to improve cardiovascular risk in statin-treated patients with the metabolic syndrome	Ms Joanna Young	7/06/05	24/06/05	Approved subject to conditions		Approved	19/01/06	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/07/079	Pharmacokinetics of methotrexate polyglutamates in patients with rheumatoid arthritis	Dr Lisa Stamp	20/06/05	18/07/05	Approved subject to conditions		Approved	1/09/05	Christchurch School of Medicine	A		Christchurch School of Medicine Research Manager Māori
URB/05/07/080	Parenting with a mental illness: using discourse analysis to explore parenting from the personal perspective	Ms Lynere Wilson	6/07/05	18/07/05	Approved subject to conditions		Approved	19/08/05	Christchurch School of Medicine and Health Sciences	Nil		Christchurch School of Medicine Research Manager Māori

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
URB/05/07/081	A single-blind, placebo-controlled, dose escalation study to evaluate the safety, pharmacokinetics, and pharmacodynamics of C-gremlin in healthy male volunteers	Dr Chris Pemberton	6/07/05	18/07/05	Approved subject to conditions		Approved	23/09/05	Christchurch School of Medicine	A		Christchurch School of Medicine Research Manager Māori
URB/05/07/082	A randomised intervention to reduce repeated suicide attempt presentations to the emergency department	Associate Professor Roger Mulder	4/07/05	18/07/05	Approved		Approved	30/08/05	Christchurch School of Medicine	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/07/084	Reproducibility of arterial stiffness and non-invasive endothelial function measurements in healthy controls and subjects with metabolic syndrome using pulse wave analysis	Ms Joanna Young	4/07/05	18/07/05	Approved subject to conditions		Approved	20/10/05	CDHB	A		Te Komiti Whakarite
URB/05/07/085	Implementation of an expanded rapid assessment clinic nursing role in the Emergency Department, Christchurch Hospital	Ms Roxanne McKerras	4/07/05	18/07/05	Approved subject to conditions		Approved	2/09/05	Christchurch Hospital	Nil		Te Komiti Whakarite
URB/05/07/086	Prostate cancer in New Zealand: (1) regional differences in incidence, mortality and intervention for localised disease	Dr Peter Davidson	4/07/05	18/07/05	Approved		Approved	21/07/05	CDHB	Nil		
URB/05/07/087	Anxiety and depression in patients waiting for coronary artery bypass graft surgery	Ms Amanda Scull	6/07/05	18/07/05	Approved subject to conditions		Approved subject to conditions	1/09/05	Canterbury DHB	Nil		Te Komiti Whakarite
URB/05/08/098	Correction of vascular dysfunction: comparison of ezetimibe and low-dose simvastatin to high-dose simvastatin in subjects with the metabolic syndrome	Ms Joanna Young	4/08/05	22/08/05	Approved subject to conditions		Approved subject to conditions		CDHB	A		Te Komiti Whakarite
URB/05/08/099	A phase 1 safety and tolerability study of PV-10 chemoablation of recurrent breast carcinoma (protocol PV-10-BC-04)	Dr Chris Wynne	5/08/05	22/08/05	Approved subject to conditions		Approved	23/09/05	Canterbury Breastcare	B	Provectus	Māori Prospective Group; Department of Labour
URB/05/08/100	Family decision making about the meningococcal B immunisation: a pilot study	Mr Paul Watson	5/08/05	22/08/05	Approved subject to conditions		Approved	20/10/05	Christchurch Polytechnic Institute of Technology	Nil		Te Komiti Whakarite
URB/05/08/101	Evaluating the long-term effect of a specialist orthopaedic medicine service as a model of care for older patients with hip fractures	Dr John Thwaites	8/08/05	22/08/05	Approved subject to conditions		Approved	30/11/05	Christchurch Hospital	Nil		Te Komiti Whakarite
URB/05/08/102	Tissue bank: investigation into possible biological reasons for the discrepancy in cancer survival of Māori vs non-Māori in New Zealand	Dr Gabi Dachs	8/08/05	22/08/05	Approved subject to conditions		Approved	26/08/05	Christchurch School of Medicine and Health Sciences	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
URB/05/08/103	Tissue bank: association between CARD15 polymorphisms and colorectal cancer	Dr Richard Geary	8/08/05	22/08/05	Approved		Approved	26/08/05	Christchurch Hospital	Nil		
URB/05/08/104	Tissue bank: screening of a human tissue micro-array for reductase enzymes	Dr Gabi Dachs	8/08/05	22/08/05	Approved		Approved	26/08/05	Christchurch Hospital	Nil		
URB/05/08/107	Roche sample repository research project in association with Protocol NP18705	Associate Professor Richard Robson	8/08/05	22/08/05	Approved subject to conditions		Approved	14/09/05	Christchurch Clinical Studies Trust	B	Hoffman-La Roche	Mr and Mrs John McManus
URB/05/09/113	Independent nursing practice chlamydia screening study	Dr Jan Arnold	2/09/05	19/09/05	Approved subject to conditions		Approved	21/02/06	Wellington IPA Sexual Health Clinic	Nil		NMDHB
URB/05/09/114	Audit of unplanned anaesthesia admissions to the intensive care unit at Christchurch Hospital	Dr Matthew Bailey	5/09/05	19/09/05	Ethical approval not required		Ethical approval not required			Nil		
URB/05/09/115	Ongoing audit of anaesthesia or perioperative mortality at Christchurch hospitals	Dr Hamish Gray	5/09/05	19/09/05	Ethical approval not required		Ethical approval not required			Nil		
URB/05/09/116	Retrospective note review of the management of acute biliary disease at Christchurch Hospital (March–September/05)	Peter Steven	5/09/05	19/09/05	Approved		Approved	28/09/05		Nil		
URB/05/09/118	The relationship between estimated brain levels of the inhalation anaesthetic agent sevoflurane and responses to airway manipulation	Dr Ross Kennedy	5/09/05	19/09/05	Approved subject to conditions		Approved	29/11/05	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/09/119	An 18-week, multicentre, randomised, double-blind, placebo controlled, parallel-group study of the efficacy, safety, and tolerability of Donepezil HCL (E2020) in patients with CADASIL who have cognitive impairment	Dr John Fink	5/09/05	19/09/05	Approved subject to conditions		Approved	7/11/05	Christchurch Hospital	B	Eisai Ltd, UK	Christchurch School of Medicine Research Manager Māori
URB/05/09/121	Roche sample repository research project in association with protocol BP19292	Associate Professor Richard Robson	5/09/05	19/09/05	Approved subject to conditions		Approved	12/10/05	Christchurch Clinical Studies Trust	B	Hoffman-La Roche	Mr and Mrs John McManus

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
URB/05/10/131	Partnership: a journey together: an analysis of the application of Christensen's Nursing Partnership Model by a nurse practitioner student in the case management of individuals with peripheral vascular disease in the outpatient setting of Christchurch Hospital: a case study approach	Ms Dawn Sutton	26/09/05	17/10/05	Approved subject to conditions		Approved	14/02/06	Christchurch Hospital	Nil		Te Komiti Whakarite
URB/05/10/132	Dimensions of the liver lobules and sinusoids	Mr Sam Dalton	28/09/05	17/10/05	Declined	Retrospective review form completed, full application required because using tissue samples	Declined		Christchurch School of Medicine and Health Sciences	Nil		
URB/05/10/133	Prospective study to determine the relationships between survival and FIGO stage, tumour volume and corpus invasion in cervical cancer	Dr Scott Babbington	4/10/05	17/10/05	Approved subject to conditions		Approved	16/11/05	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/10/134	The effect of a predicative display on simulated changes in anaesthesia delivery	Dr Ross Kennedy	4/10/05	17/10/05	Approved subject to conditions		Approved	14/02/06	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/10/135	Pharmacogenetics of thiopurine drug metabolism	Dr Rebecca Roberts	3/10/05	17/10/05	Approved subject to conditions		Approved	21/02/06	Christchurch School of Medicine and Health Sciences	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/10/136	Resilient indigenous health workforce networks: constructing an international framework	Mr Paul Robertson	3/10/05	17/10/05	Approved subject to conditions		Approved subject to conditions		Christchurch School of Medicine and Health Sciences	Nil		Research Manager
URB/05/10/137	Analysis of x-ray exposures given to premature babies at Christchurch Women's Hospital	Dr Peter Schmidt	3/10/05	17/10/05	Approved		Approved	21/10/05	Christchurch Hospital	Nil		
URB/05/10/138	Impact of a specialised relative insulin nutrition table on glycaemic control in critical illness	Dr Geoffrey Shaw	3/10/05	17/10/05	Ethical approval not required		Ethical approval not required		CDHB	Nil		
URB/05/10/139	A case control study comparing Gonadotropin levels in women with and without endometrial cancer	Dr Peter Sykes	3/10/05	17/10/05	Approved subject to conditions		Approved	28/11/05	Christchurch Women's Hospital	A		Research Manager – Māori
URB/05/10/140	An audit of outcome and accuracy of diagnosis in all cases of major fetal abnormality seen prenatally through fetal medicine over a 14-month period	Professor Pippa Kyle	3/10/05	17/10/05	Ethical approval not required		Ethical approval not required			Nil		
URB/05/10/141	Variability of normal sleep patterns, heart rate, respiration and pulse oximetry in preterm babies at 34 to 36 weeks post menstrual age	Glynn Russell	3/10/05	17/10/05	Approved subject to conditions		Approved	12/01/05	Christchurch Women's Hospital	A		Women's Health Division Cultural Advisory Komiti

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
URB/05/11/150	Symptoms, signs and investigations predictive of a clinically significant finding on computer tomography urography (CTU) for renal colic: a prospective analysis of patients presenting to Christchurch Hospital	Dr David Oxner	19/10/05	14/11/05	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital	Nil		Te Komiti Whakarite
URB/05/11/151	Morbidity of insulin treated diabetes in Canterbury: a follow up study	Dr Shelagh Dawson	27/10/05	14/11/05	Approved		Approved	23/11/05	Christchurch Hospital	Nil		
URB/05/11/152	A study to investigate the possible relationship between betaine hyper-excretion and vascular disease in patients with lipid disorders	Dr Wendy Atkinson	31/10/05	14/11/05	Approved subject to conditions		Approved	8/12/05	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/11/153	Respiratory laboratory quality assurance: development of an automated program for data analysis and identifying a system of best practice	Dr J Stanton	31/10/05	14/11/05	Approved subject to conditions		Approved	2/08/06	Christchurch Hospital	Nil		Te Komiti Whakarite
URB/05/11/154	Physical activity and insulin requirements in children and adolescents with type 1 diabetes	Professor Brian Darlow	31/10/05	14/11/05	Approved subject to conditions		Approved	12/12/05	Christchurch School of Medicine	A		Christchurch School of Medicine Research Manager Māori
URB/05/11/155	The dimension of the liver lobules and sinusoids	Professor Robin Fraser	31/10/05	14/11/05	Approved		Approved	23/11/05	Christchurch hospital	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/11/156	A narrative approach to comprehensive geriatric assessment with a special focus on medication-taking	Lorraine Ritchie	31/10/05	14/11/05	Approved subject to conditions		Approved	19/03/06	The Princess Margaret Hospital	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/11/158	Prospective study of piperazine-based party pill toxicity: a three part research project	Dr Paul Gee	1/11/05	14/11/05	Approved subject to conditions		Approved subject to conditions			Nil		Te Komiti Whakarite
URB/05/11/159	An investigation to examine the effect of using propofol to smooth emergence after inhaled anaesthesia in children	Dr Karen Ryan	31/10/05	14/11/05	Deferred	Further information requested	Approved subject to conditions		Christchurch Hospital	A		Te Komiti Whakarite
URB/05/11/160	Falls injuries in children and older people: an assessment of routinely collected Emergency Department data and its potential to inform community injury prevention initiatives	Ms Elizabeth Pollock	2/11/05	14/11/05	Approved		Approved	23/11/05	CDHB	Nil		
URB/05/12/168	The journey of treatment and care for people with cancer on the West Coast	Ms Fiona Doolan Noble	24/11/05	12/12/05	Approved subject to conditions		Approved	21/02/06	West Coast DHB Wellington School of Medicine and Health Sciences	Nil		Tatau Pounamu

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
URB/05/12/169	Correction of motion artefacts in magnetic resonance imaging (MRI)	Mr Julian Maclaren	28/11/05	12/12/05	Approved subject to conditions		Approved	21/02/06	University of Canterbury	A		None
URB/05/12/170	Retrospective audit of the accuracy of pre-operative sestamibi scan for parathyroid surgery in Canterbury	Dr Kasia McKenzie	28/11/05	12/12/05	Ethical approval not required		Ethical approval not required		Christchurch Hospital	Nil		
URB/05/12/171	A survey of the effectiveness of follow-up after primary melanoma excision	Mr Stewart Sinclair	29/11/05	12/12/05	Approved subject to conditions		Approved	14/02/06	Christchurch Hospital	Nil		Te Komiti Whakarite
URB/05/12/172	Impact of suppertime snack on overnight glucose in type 1 diabetes (summer studentship pilot project)	Dr Helen Lunt	28/11/05	12/12/05	Approved		Approved	20/12/05	Christchurch Hospital	A		
URB/05/12/173	Workplace resilience in hospital-based CDHB medical consultants	Dr Lois Surgenor	28/11/05	12/12/05	Approved subject to conditions		Approved subject to conditions		Christchurch School of Medicine	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/12/175	Medically unexplained symptoms and health anxiety in secondary care	Professor Roger Mulder	29/11/05	12/12/05	Deferred	Request to consider change to study design	Approved	5/01/06	Christchurch School of Medicine	Nil		Christchurch School of Medicine Research Manager Māori
URB/05/12/176	Provision of continuous positive airway pressure using the lifevent CPAP device in the recovery ward	Dr Richard French	21/11/05	12/12/05	Ethical approval not required		Ethical approval not required			Nil		
URB/05/12/177	Volitional saccades in Parkinson's disease: predictive and memory-guided paradigms: a follow-up study (associated with CTR/03/09/154)	Dr Bettina Horvath	29/11/05	12/12/05	Approved subject to conditions		Approved	17/01/06		A		Christchurch School of Med Research Manager – Māori
URB/05/12/178	Detecting changes in renal function by measuring volatile organic compounds in exhaled breath	Dr David McGregor	29/11/05	12/12/05	Approved subject to conditions		Approved	2/08/06	Christchurch Hospital	B	Syft Technologies	Te Komiti Whakarite
URB/05/12/179	Audit of CT of trauma patients in Christchurch Hospital	Dr Chris Cresswell	23/11/05	12/12/05	Approved		Approved	20/12/05		Nil		
URB/05/12/180	Sensitivity and specificity of ultrasound for detecting calculi in the distal ureter	Dr Nigel Anderson	30/11/05	12/12/05	Approved subject to conditions		Approved	20/01/06	Christchurch Hospital	A		Te Komiti Whakarite
URB/05/12/181	Epidemiological trends in oesophageal carcinoma in North Canterbury, New Zealand, 1996–05	Dr Alistair Hepburn	12/01/05	12/12/05	Approved		Approved	20/12/05		Nil		

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

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

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

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

The Upper South B REC shall have responsibility with the Upper South A 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 B REC is jointly responsible with the Upper South A 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 B REC.

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

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

The Upper South B 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 B Regional Ethics Committee**

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

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

The Upper South B 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 Upper South B 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 B 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 B 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 B 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 B 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 B 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 B 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 B 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 B REC. Those persons shall not be eligible for appointment to the Upper South B 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 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 B REC and National Ethics Advisory Committee or the Health Research Council Ethics Committee simultaneously.

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

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

The Upper South B 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 B 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 B REC. This is intended to aid Upper South B REC members by providing them with a common set of principles for appropriate conduct and behaviour.

### **General**

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

### **Conflicts of interest**

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

Upper South B REC members attend meetings and undertake Upper South B REC activities as independent persons responsible to the Upper South B REC as a whole. Members are not appointed as representatives of professional organisations or particular community bodies. The Upper South B REC should not, therefore, assume that a particular group's interests have been taken into account because an Upper South B 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 B 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 B 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 B REC who has a proposal before the Upper South B REC or who has an involvement in the proposal, such as a supervisory role, shall not take part in the Upper South B 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 B 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 B REC meetings should be available to the public. Copies of proposals should be available to individuals outside the Upper South B 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 B 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 B 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 B REC. The Upper South B REC will need to consider the Privacy Act 1993 and the Health Information Privacy Code 1994 in developing these processes.

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

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

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

## **Decision-making process**

Wherever possible, the Upper South B 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 B 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 B 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 B REC members believes there is insufficient expertise on the Upper South B 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 B REC's decision on a proposal.

## **Second opinions and appeals**

At any stage in its deliberations, the Upper South B 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 B 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 NEAC 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 B 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 B REC, including any change in the Upper South B REC's membership or other substantive changes the Upper South B 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. Research title
- ii. Name of principal investigator
- iii. Name of 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 subject to 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 B REC members and a statement on processes for orientation and training of new Upper South B REC members should be included.
- ii. A list of complaints received by the Upper South B 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 Upper South B REC in making a decision on any particular protocol(s) and any questions on policy or other matters the Upper South B REC referred to the National Ethics Advisory Committee or the Health Research Council Ethics Committee for comment or guidance.

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

### **Servicing the Central Regional Ethics Committee**

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

