



Upper South B Regional Ethics Committee

Annual Report

January 2006 to December 2006

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Contents

Chairperson's Report	1
Committee Membership	2
Appointments	2
Retirements	5
New appointments	5
Members' attendance in 2006	5
Training	6
Approval by the Health Research Council	7
United States Department of Health & Human Services Registration	7
Response to Cultural Issues	8
Applications	9
Upper South B Regional Ethics Committee statistics for January–December 2006	9
Other committee statistics	9
Audit or matters not requiring ethical approval	9
Innovative practice	9
School science fair projects	9
Second opinions	9
Complaints	10
Issues for the Committee	11
National application form, Section F	11
Withdrawal from a study	11
Guidelines for the Chairperson's Delegation	12
Appendices	
Appendix 1: Applications Received January to December 2006	13
Appendix 2: Upper South B Regional Ethics Committee Terms of Reference	31

This report provides an overview of the work of the Upper South B Regional Ethics Committee from January to December 2006. The report was presented to the Upper South B Regional Ethics Committee at its meeting on 12 March 2007.

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

Chairperson's Report

The Upper South B Regional Ethics Committee was established in December 2004 and had its first meeting on the 12th of that month. In its second year (January to December 2006), the committee processed 101 new applications.

Two members, Robin Fraser and Kathrine Townshend, retired after the committee's December 2006 meeting. Both had served six consecutive years which included, prior to their term with the Upper South B Regional Ethics Committee, time on the Canterbury Ethics Committee for Robin Fraser and on the Nelson/Marlborough Ethics Committee for Kathrine Townshend. Robin and Kathrine's breadth of experience and skills was much appreciated by the committee, and I would like to thank them for their time and commitment. The committee welcomes new members Derelie Mangin and Patricia Costigan, who commence in 2007.

Katherine Bell undertook the administration of the Upper South B Regional Ethics Committee until November 2006. Temporary administration was provided by Jo Hamlyn until the permanent appointment of Di Rutledge in December 2006.

Gray Crawford
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

Gray Crawford	NZ Dip Mgt, Cert Pers, Cert Rehab St (Massey), 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

Mark Smith	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

Sharon Gardiner	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

Rosemary Carruthers	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
Brenda Moran	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
Kathrine Townshend	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
Annette Finlay	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 Whakarite
Iwi affiliations	Tainui, Te Arawa
Patrick Graham	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

Robin Fraser	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

Michael Gough	
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, Ngāti Mutunga

Simon Clarke	DPhil
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

David McGregor	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, who was elected Deputy Chairperson by the committee at its inaugural meeting on 13 December 2004, remained Deputy Chairperson in 2006.

Retirements

Robin Fraser and Kathrine Townshend retired in December 2006.

New appointments

Patricia Costigan was appointed as a community representative and Derelie Mangin was appointed as a health researcher by the Minister of Health on 16 December 2006. They will attend their first meetings in 2007.

Members' attendance in 2006

Member	M/F	Lay/ non-lay	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	11/11
Mark Smith Health practitioner	M	NL	Y	Y	A	Y	Y	Y	Y	Y	A	Y	Y	9/11
Sharon Gardiner Pharmacist/ pharmacologist	F	NL	Y	A	Y	Y	Y	Y	Y	Y	Y	A	Y	9/11
Rosemary Carruthers Lawyer	F	L	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	10/11
Brenda Moran Consumer rep	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Kathrine Townshend Community rep	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Annette Finlay* Health researcher	F	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	10/11
Patrick Graham Biostatistician	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Robin Fraser Health researcher	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Michael Gough* Community rep	M	L	A	Y	Y	A	Y	Y	Y	Y	A	Y	A	7/11
Simon Clarke Ethicist	M	L	A	A	A	Y	Y	Y	Y	Y	Y	Y	Y	8/11
David McGregor Health practitioner	M	NL	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	10/11
No. members present			10	10	10	11	11	11	12	12	10	10	11	
No. of applications			11	11	8	11	12	4	2	10	13	7	12	101

* = Māori member

Y = Present

A = Apology

Training

Ongoing training

Ongoing training for all members was held in June 2006. 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. 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 following members attended the one-day training programme: Gray Crawford, Sharon Gardiner, Annette Finlay, David McGregor, Brenda Moran, Rosemary Carruthers.

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: Gray Crawford, Mark Smith.

Gray Crawford attended the New Zealand Bioethics Conference in Dunedin from 10 -12 February 2006.

Meeting of the Māori members

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

The following member of the Upper South B Regional Ethics Committee attended: Annette Finlay.

Christchurch School of Medicine meeting

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

Chairpersons' meetings

Three meetings of the chairpersons of the multi-region and regional ethics committees were held in 2006. Gray Crawford attended the chairpersons' meetings on 9 February 2006, 14–15 August 2006 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.

Meetings with researchers

Various members from both Upper South B and Upper South A 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.

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. This registration enables the committee to review research funded by the United States Government. 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	99%
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 (Māori excluded as specific genetic mutation (<i>CARD 15</i>) being studied is not found in Māori)

Applications

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

Upper South B Regional Ethics Committee statistics for January–December 2006

Applications considered under delegated authority (CPD)	0
Applications approved	84
Applications deferred at first review and subsequently approved	5
Applications deferred at the time of the report	0
Applications declined	3
Applications carried forward (Approved subject to conditions)	4
Approval not required	5
Total number of applications received	101

Other committee statistics

Number of matters arising considered	10
Number of general business items reviewed	22
Number of amendments reviewed by committee	5
Number of amendments approved under CPD	84

Audit or matters not requiring ethical approval

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

Innovative practice

No applications for innovative practice were received.

School science fair projects

Eight applications for school science fair projects were received.

Second opinions

No second opinions were sought in 2006.

Complaints

A researcher wrote to the committee with concerns that it had not fully addressed the methodological issues discussed with the researcher when it first reviewed the study. The committee considered the researcher's concerns at its December meeting and apologised for the omission.

Issues for the Committee

National application form, Section F

Section F of the national application form continued to raise issues for the committee, which supported a rewriting of the questions.

Where tissue was being retained or genetic research was being undertaken, the committee asked that the following statement be inserted in the information sheet to ensure participants were aware of concerns for some Māori.

If you are the descendant of a New Zealand Māori you may wish to consult your whānau or hapū group before entering this study as some iwi groups maintain beliefs involving the collective ownership of tissue.

Withdrawal from a study

There was concern that in some studies, when participants withdrew, the information collected up to the time of their withdrawal would continue to be used. The following statement was approved by the committee for use in these studies.

Data and tissue samples collected up until your voluntary withdrawal from the study will continue to be analysed and the results of such analysis will be included in the study. This is to protect the quality of the study and ensure safety of the study drug is properly assessed.

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:

- 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, it 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.

Appendix 1: Applications Received January to December 2006

Appendix 1 details the applications considered by the committee from January to December 2006. Nine 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
URB/06/02/001	Urinary tract infection symptoms in women: pilot urine testing project	Dr Dee Mangin	18/01/2006	20/02/2006	Approved subject to conditions		Approved	12/04/2006	Christchurch School of Medicine and Health Sciences	Nil		Elizabeth Cunningham
URB/06/02/002	A correlation of angiogenesis related factors and prognostic features in endometrial cancer as studied by tissue micro array	Dr Peter Sykes	25/01/2006	20/02/2006	Approved subject to conditions		Approved	19/03/2006	Christchurch Women's Hospital	A	Trust Grant	Elizabeth Cunningham
URB/06/02/003	To determine whether the sensitivity of chlamydia trachomatis testing on midstream and first void urine specimens is equivalent	Dr Dee Richards	25/01/2006	20/02/2006	Approved subject to conditions		Approved	29/03/2006	Youth Health Centre, Christchurch; Christchurch Sexual Health Centre; Family Planning Association (FPA)	Nil		Elizabeth Cunningham
URB/06/02/004	A retrospective comparison of the effect of intravenous pamidronate and oral alendronate on bone mineral density and fracture risk	Dr Anna Fenton	26/01/2006	20/02/2006	Approved subject to conditions		Approved	18/05/2006	Oxford Clinic, Christchurch	A	Signet Research	Te Komiti Whakarite
URB/06/02/005	A comparison of vaginal oestradiol tablets and oestriol cream in the management of menopausal atrophic vaginitis	Dr Anna Fenton	26/01/2006	20/02/2006	Approved subject to conditions		Approved	5/05/2006	Oxford Clinic, Christchurch	A	Signet Research	Te Komiti Whakarite
URB/06/02/006	Respiration and swallowing integration in Parkinson's disease: on and off levodopa	Mr Anthony Lim	30/01/2006	20/02/2006	Approved subject to conditions		Approved	17/03/2006		A	Research grant	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
URB/06/02/007	A randomised open-label multicentre study of VELCADE with Rituximab or Rituximab alone in subjects with relapsed, or refractory, Rituximab Naive or sensitive B-cell follicular non-Hodgkins lymphoma	Dr Steve Gibbons	30/01/2006	20/02/2006	Approved subject to conditions		Approved	20/04/2006		B	Janssen-Cilag Pty Ltd	Maori Advisory Group
URB/06/02/008	Renal impairment in decompensated heart failure	Prof Mark Richards	30/01/2006	20/02/2006	Approved subject to conditions		Approved	28/02/2006	Christchurch Hospital	A	Christchurch Cardioendocrine Research Group	Elizabeth Cunningham
URB/06/02/009	What is the role of the nurse practitioner in the emergency department? Defining the role by developing patient care pathways: a case study approach	Mr Justin Moore	30/01/2006	20/02/2006	Approved subject to conditions		Approved	22/03/2006	Christchurch Hospital	Nil		Te Komiti Whakarite
URB/06/02/010	Regional plasma concentrations of vasoactive peptides and correlations with Haemodynamic state in cardiac disease	Prof Mark Richards	30/01/2006	20/02/2006	Approved subject to conditions		Approved	16/03/2006	Christchurch School of Medicine and Health Sciences	A	CCRG	Elizabeth Cunningham
URB/06/02/011	Roche repository research project in association with WP19270	Assoc Prof Richard Robson	30/01/2006	20/02/2006	Approved subject to conditions		Approved	22/03/2006		B	Hoffman-La Roche	Mr and Mrs John McManus
URB/06/02/012	Keratin wound dressing: patient and nurse acceptability study	Dr Martin Than	30/01/2006	20/02/2006	Approved subject to conditions		Approved	11/04/2006	Nurse Maude Association	B	Keratec	Te Komiti Whakarite
URB/06/02/013	Relapsed Wilm's tumour study	Dr Rob Corbett	16/02/2006	19/03/2006	Expedited review for one patient extended at 19/3/06 meeting to all eligible participants		Approved	16/02/2006	Christchurch Hospital	A		

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
URB/06/03/014	Retrospective audit of serious post-operative complications, in elective orthopaedic patients in Burwood Hospital between June and December 2005	Dr John Oisin O'Connell	23/02/2006	13/03/2006	Ethical approval not required		Ethical approval not required		Christchurch Hospital	A		
URB/06/03/015	Pilot randomised clinical trial of prolotherapy injections and eccentric loading exercises individually and in combination for the treatment of painful Achilles tendonosis	Dr John Lyftogt	23/02/2006	13/03/2006	Approved subject to conditions		Approved	13/04/2006		Nil	Research funds	
URB/06/03/016	Effect of thiazide diuretics on plasma metformin concentration in patients with type 2 diabetes already established on metformin	Dr Eileen Sung	24/02/2006	13/03/2006	Approved subject to conditions		Approved	1/05/2006	Christchurch Hospital	A	Research grants	Te Komiti Whakarite
URB/06/03/017	Novel markers in inflammatory arthritis	Dr Lisa Stamp	24/02/2006	13/03/2006	Approved subject to conditions		Approved	5/05/2006	Christchurch Hospital	A	Arthritis NZ	Elizabeth Cunningham
URB/06/03/018	Integrating 'family' into nursing practice	Ms Judy Yarwood	27/02/2006	13/03/2006	Approved subject to conditions		Approved	4/05/2006	Christchurch Polytechnic Institute of Technology	Nil		Te Komiti Whakarite
URB/06/03/019	A study to establish the effect of angiotensin receptor signalling upon haemodynamics, oxidative stress and hormones in healthy volunteers of different AT1R genotype	Dr John Irvine	27/02/2006	13/03/2006	Approved subject to conditions		Approved	26/04/2006	Christchurch School of Medicine and Health Sciences	A	HRC	Elizabeth Cunningham
URB/06/03/021	Optimising investigation and antibiotic use in women with urinary tract symptoms	Dr Derelie Richards	1/03/2006	13/03/2006	Approved subject to conditions		Approved	15/04/2006	Christchurch School of Medicine and Health Sciences	Nil		Elizabeth Cunningham
URB/06/03/022	Survival of babies with congenital diaphragmatic hernia (CDH)	Glynn Russell	1/03/2006	13/03/2006	Approved		Approved	20/03/2006		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/funder	Consultation undertaken
URB/06/04/023	Subclinical thyrotoxicosis in an outpatient population: audit of clinical and biochemical outcome	Dr Belinda Robb	9/03/2006	10/04/2006	Deferred	Retrospective review application submitted. Full application required.	Deferred		Christchurch Hospital	Nil		
URB/06/04/024	CRESCENDO: randomised, multinational, multicentre, double-blind, placebo-controlled, two-arm parallel group trial of Rimanoabnt (SR141716) 20 mg OD for reducing the risk of major cardiovascular events in abdominally obese patients with clustering risk factors	Dr John Elliott	24/03/2006	10/04/2006	Approved subject to conditions		Approved	23/06/2006	Lipid & Diabetes Research, Christchurch Hospital	B	Sanofi-Aventis	
URB/06/04/025	Management of gynaecological cancer: a study of the perceived acceptable and the actual waiting time for surgery	Dr Heidi Su	27/03/2006	10/04/2006	Deferred	Minimisation of harm, validity of research	Approved	1/06/2006	Christchurch Women's Hospital	Nil		Te Komiti Whakarite
URB/06/04/026	Psychosocial correlates of physical activity levels and biochemical measures in a group of New Zealand adults with type two diabetes: implications for the design of effective interventions in health care settings	Mr David Brinson	27/03/2006	10/04/2006	Approved subject to conditions		Approved	15/05/2006	Diabetes Centre	Nil		Te Komiti Whakarite
URB/06/04/027	Design of a nutritional screening tool for lactating mothers of premature infants	Lisa Clark	27/03/2006	10/04/2006	Approved subject to conditions		Approved	2/06/2006	Christchurch Women's Hospital	Nil		Maori Health at Christchurch Women's Hospital
URB/06/04/028	Patterns of medication use in older people in rural Canterbury	Dr Nadim Khan	28/03/2006	10/04/2006	Approved subject to conditions		Approved	12/09/2006		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/funder	Consultation undertaken
URB/06/04/029	Monitoring of pilot introduction of community stroke rehabilitation team	Dr Carl Hanger	29/03/2006	10/04/2006	Deferred	Not enough information to make decision	Ethical approval not required		CDHB	Nil		
URB/06/04/030	Genetic profiles of kidney disease and transplant patients	Dr John Irvine	29/03/2006	10/04/2006	Approved subject to conditions		Approved	18/05/2006	Christchurch Cardioendocrine Research Group	A	HRC	Christchurch School of Medical Research Manager – Maori
URB/06/05/031	Machine learning and statistical modelling in environmental science	Kyoko Fukuda	20/04/2006	15/05/2006	Approved		Approved	19/05/2006	University of Canterbury	Nil		
URB/06/05/032	Computerised assessment of bone age from hand-wrist radiographs	Dr Michael Hurrell	27/04/2006	15/05/2006	Approved		Approved	19/05/2006	Christchurch Hospital	Nil		
URB/06/05/033	A multicentre, double-blind, randomised, placebo-controlled, parallel-group study of the safety and efficacy of repeat treatment with two dose levels of BOTOX (botulinum toxin type A) purified neurotoxin complex followed by a treatment with BOTOX in patients with urinary incontinence due to neurogenic detrusor overactivity	Dr Sharon English	1/05/2006	15/05/2006	Approved subject to conditions		Approved	13/07/2006	Canterbury Urology Research Trust	B	Allergan Australia Pty Ltd	Peter Mason; Department of Labour
URB/06/05/035	Markers of thromboembolism in cancer	Assoc Prof B Robinson	1/05/2006	15/05/2006	Request for Information		Approved	19/07/2006	Christchurch Hospital	Nil		
URB/06/05/036	Staphylococcus aureus bacteraemia: clinical comparison and outcomes in patients with or without associated staph aureus bacteruria	Dr Paul Huggan	1/05/2006	15/05/2006	Approved		Approved	19/05/2006		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/funder	Consultation undertaken
URB/06/05/037	Assessment of short stature and growth hormone deficiency in children: role of a new bone growth factor, NT pro CNP	Dr James Hector-Taylor	1/05/2006	15/05/2006	Approved subject to conditions		Approved	23/06/2006	Christchurch Hospital	A	Christchurch Medical Research Foundation	Christchurch School of Medical Research Manager Maori
URB/06/05/038	Identification of gaps in current practice in the management of soft tissue injuries of the knee which require surgery	Ms Clare Palmer	2/05/2006	15/05/2006	Approved subject to conditions		Approved	6/07/2006	Pegasus Health	Nil		Pegasus Health Maori Project Manager
URB/06/05/039	A randomised controlled trial of computerised cognitive behaviour therapy (CBT) for the treatment of anxiety disorders and effects on neuropsychological functioning and plasma oxytocin levels	Dr Caroline Bell	2/05/2006	15/05/2006	Approved subject to conditions		Approved	23/06/2006	Christchurch School of Medicine and Health Sciences	A	Lottery Health Research Committee	Christchurch School of Medicine Research Manager – Maori
URB/06/05/040	The recovery approach: exploration of the practical application and the constraints of using a recovery approach in a mental health adult residential service from a staff perspective	Ms Kay Heard	3/05/2006	15/05/2006	Approved subject to conditions		Approved	22/06/2006	Stepping Stone Trust	Nil		Te Kahui Pou Hauora Maori
URB/06/05/041	The role of allocated attention on working memory on inference comprehension in adults with traumatic brain injury	Dr Catherine Moran	5/05/2006	15/05/2006	Approved subject to conditions		Approved	13/07/2006	Van der Veer Institute for Parkinson's and Brain Research	Nil		
URB/06/06/042	The effect of ABO and Rh(D) mismatched allogeneic stem cell transplantation on red cell and isoagglutinin kinetics and red cell transfusion requirements – a retrospective review	Dr Liam Fernyhough	22/05/2006	19/06/2006	Approved		Approved	27/06/2006	New Zealand Blood Service	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/funder	Consultation undertaken
URB/06/06/043	Phase III clinical study of allogeneic stem cell transplantation with reduced conditioning (RICT) versus best standard of care in acute myeloid leukaemia (AML) in first complete remission	Dr RL Spearing	2/06/2006	19/06/2006	Approved subject to conditions		Approved	22/08/2006	Canterbury Health Laboratories	A	None	Te Komiti Whakarite
URB/06/06/044	Tissue bank: PR-104A reductase activity in human tumours	Professor William R Wilson	2/06/2006	19/06/2006	Approved		Approved	27/06/2006		Nil		
URB/06/06/045	Prevalence and importance of abnormalities of glycine betaine metabolism among patients with cerebrovascular disease: a cross-sectional study	Dr John Fink	2/06/2006	19/06/2006	Approved subject to conditions		Approved	28/08/2006	Christchurch Hospital	A	Neurological Foundation of NZ	Te Komiti Whakarite
URB/06/06/046	What is the potential role of music therapy in a deaf education centre	Ms Kimberley Jones	6/06/2006	19/06/2006	Approved subject to conditions		Approved	19/07/2006	Van Asch College	Nil		Evidence of consultation requested
URB/06/06/047	An audit of the value of chest CT in new head and neck cancer patients	Dr Byron Oram	6/06/2006	19/06/2006	Approved		Approved	27/06/2006	Radiation Department, Christchurch Hospital	Nil		
URB/06/06/048	How does a music therapy student facilitate verbal interactions in a group of developmentally delayed adolescents	Ms Megan Potter	6/06/2006	19/06/2006	Approved subject to conditions		Approved	28/08/2006	Middleton Grange School	Nil		Evidence of consultation requested
URB/06/06/049	LACE – laparoscopic approach to cancer of the endometrium: an international multicentre randomised phase 3 clinical trial (version 4 incorporating amendment 1)	Dr Peter Sykes	6/06/2006	19/06/2006	Approved subject to conditions		Approved	21/07/2006	Christchurch Women's Hospital	A	CDHB	Cultural Komiti CWH; Research Manager – Maori

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
URB/06/06/050	An assessment of preferences and perceived outcomes of selected music therapy methods in individual music therapy treatment conducted with women seeking recovery from long-term alcohol addiction	Ms Raelene Savage	6/06/2006	19/06/2006	Approved subject to conditions		Approved	6/10/2006	Salvation Army	A	Bridge Programme	Evidence of consultation requested. Maire Kipa consulted.
URB/06/06/051	Health literacy concepts in health promotion for disadvantaged groups: a case study with particular reference to the physical activity and nutrition resources of the Cancer Society of New Zealand	Mr Martin Witt	6/06/2006	19/06/2006	Approved subject to conditions		Approved	3/10/2006	Cancer Society of New Zealand	Nil		Hauora Matakaka
URB/06/06/053	Randomised, double-blind, placebo-controlled efficacy and safety study of colesevelam HCl to paediatric patients with heterozygous familial hypercholesterolemia on a stable dose of statins or treatment naive to lipid-lowering therapy	Prof Russell Scott	8/06/2006	19/06/2006	Approved subject to conditions		Approved	21/07/2006	Christchurch Hospital	B	Sankyo Pharma Development	
URB/06/07/054	Balo's concentric sclerosis : the Canterbury experience	Dr John Young	3/07/2006	19/07/2006	Approved		Approved	19/07/2006	Christchurch Hospital	Nil		
URB/06/08/058	Exploring counselling for clients with a mild intellectual disability from multiple perspectives	Ms Marilyn Raffensperger	2/08/2006	31/08/2006	Approved subject to conditions		Approved	5/10/2006		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/funder	Consultation undertaken
URB/06/09/060	Investigation into the effect of a nutritional supplement on mood and function in a clinical sample of young adolescents with bipolar disorder: naturalistic clinical case series ABAB patient preference design	Dr Julia Rucklidge	24/08/2006	18/09/2006	Deferred	Potential risks outweighed potential benefit	Declined		Princess Margaret Hospital	A	University of Canterbury	Te Komiti Whakarite
URB/06/09/061	Compassionate use protocol for the use of AMD3100 to mobilise peripheral blood stem cells for collection and transplantation	Dr Peter Ganly	29/08/2006	18/09/2006	Deferred	More information required	Approved	20/12/2006	Christchurch Hospital	A	None	Te Komiti Whakarite
URB/06/09/062	Analysis of a complex scuba diving accident – French Pass June 2000	Dr Graham McGeoch	30/08/2006	18/09/2006	Deferred	Information sheet/ consent form required	Approved	16/11/2006	Christchurch Hospital	A	Hyperbaric Unit Education Trust may contribute	
URB/06/09/063	Exploring ways of working effectively with families living with chronic illness: engaging families living with heart failure	Dr Lisa Whitehead	1/09/2006	18/09/2006	Approved subject to conditions		Approved	19/10/2006	University of Otago	Nil		Research Manager Maori; Christchurch School of Medicine
URB/06/09/064	Exploring the positive contribution of families/whanau in managing mental illness	Dr Lisa Whitehead	1/09/2006	18/09/2006	Approved subject to conditions		Approved	19/10/2006	University of Otago	Nil		Research Manger Maori; Christchurch School of Medicine; Te Kai Hapai Tikanga Maori
URB/06/09/065	The impact of individuals supporting people diagnosed with bipolar affective disorder	Ms Virginia Maskill	1/09/2006	18/09/2006	Approved subject to conditions		Approved	5/11/2006	Christchurch School of Medicine and Health Sciences	Nil		Research Manager; Maori; Christchurch School of Medicine
URB/06/09/066/	A randomised controlled trial of pharmacists' visits versus usual blister pack care in the management of post-hospital discharge medication	Ms Kerri Miedema	4/09/2006	18/09/2006	Approved subject to conditions		Approved	6/12/2006	West Coast DHB	Nil	West Coast PHO	Maori Health for the West Coast DHB

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
URB/06/09/068	An observational prospective study of the diagnostic utility of Troponin I and Troponin T assays in the assessment of patients presenting to Christchurch Hospital with chest pain of possible cardiac origin	Dr Martin Than	5/09/2006	18/09/2006	Deferred	Further information required to make a decision	Approved	30/10/2006	Christchurch Hospital	Nil		
URB/06/09/069	Group therapy engagement/ retention of adolescents who have DSM IV substance dependence	Ms Bronwyn Pagey	5/09/2006	18/09/2006	Approved		Approved	26/09/2006		A		
URB/06/10/070	Can written advice provide a safe and timely alternative to a new patient assessment for selected referrals to haematology?	Dr Peter Ganly	25/09/2006	16/10/2006	Approved subject to conditions		Approved	15/12/2006	Christchurch Hospital	Nil		
URB/06/10/071	A retrospective chart review of the use of Interferon therapy in patients with multiple sclerosis in the Canterbury Region from 2000–2006	Dr Deborah Mason	27/09/2006	16/10/2006	Approved		Approved	20/10/2006		Nil		
URB/06/10/072	Audit to assess the quality and extent of venothromboemolic prophylaxis in general medical patients at Christchurch Hospital	Dr I Schonegevel	27/09/2006	16/10/2006	Ethical approval not required		Ethical approval not required		Christchurch Hospital	Nil		
URB/06/10/073	Clinical outcome in infants with antenatal renal dilatation, and mild postnatal renal dilatation	Dr Diane Leighton	28/09/2006	16/10/2006	Approved subject to conditions		Approved	1/12/2006	Christchurch Hospital	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/funder	Consultation undertaken
URB/06/10/074	Tissue bank: morphological review and immunophenotyping of invasive carcinoma of the breast with associated brain metastases	Dr Gavin Harris	29/09/2006	16/10/2006	Approved		Approved	20/10/2006	Christchurch Hospital	Nil		Christchurch School of Medicine Research Manager – Maori
URB/06/10/075	Processing of induced sputum for cell counts and oxidative stress biomarkers – a pilot study	Dr Michael Epton	29/09/2006	16/10/2006	Approved		Approved	20/10/2006	Christchurch School of Medicine and Health Sciences	A	Respiratory Research Group internal funding	Christchurch School of Medicine; Research Manager Maori
URB/06/10/076	The relationship between adult attention-deficit/hyperactivity disorder symptomatology and health-risk behaviours	Mairin Rose Taylor	2/10/2006	16/10/2006	Approved subject to conditions		Approved	6/12/2006		A		
URB/06/10/077	The influence of olfaction on swallowing-respiratory co-ordination and submental muscle contraction	Dr Maggie Lee Huckabee	2/10/2006	16/10/2006	Approved subject to conditions		Approved	18/11/2006	University of Canterbury Van der Veer Institute for Parkinson's and Brain Research	A	Summer studentship	Te Komiti Whakarite
URB/06/10/078	Tissue bank: Is there a molecular link between cancer and metabolic syndrome to explain ethnic disparities in cancer survival in New Zealand	Dr Gabi Dachs	2/10/2006	16/10/2006	Approved		Approved	20/10/2006	Christchurch School of Medicine and Health Sciences	Nil		Christchurch School of Medicine; Research Manager; Maori
URB/06/10/079	How does the supervisory process impact on mental health nurses' relationships with consumers?	Julie Mernick	2/10/2006	16/10/2006	Approved		Approved	20/10/2006	University of Auckland	Nil		Te Korowai Atawhai
URB/06/10/081	Are uterine Doppler measurement useful in the prediction and assessment of pre-eclampsia and intrauterine growth restriction in high-risk pregnancy?	Prof Pippa Kyle	4/10/2006	16/10/2006	Ethical approval not required		Ethical approval not required		Christchurch Women's Hospital	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/funder	Consultation undertaken
URB/06/10/082	Keratin bone graft replacement study	Dr Martin Than	4/10/2006	16/10/2006	Approved subject to conditions		Approved	15/01/2007		B	Keratec	
URB/06/11/083	The prevalence and epidemiological factors in motor neurone disease in Canterbury – a retrospective study 1986–2006	Dr Mark Murphy	30/10/2006	13/11/2006	Approved		Approved	16/11/2006	Christchurch Hospital	Nil		
URB/06/11/084	Healthy eating, healthy ageing – a study to demonstrate the feasibility and effectiveness of nutritional screening and targeted nutrition interventions in community living older people identified to be at risk of poor nutrition	Sally Watson	30/10/2006	13/11/2006	Approved subject to conditions		Approved	8/12/2006	CDHB	Nil		Te Komiti Whakarite
URB/06/11/085	CARD15 mutations as genetic risk factors for cancer	Dr Rebecca Roberts	30/10/2006	13/11/2006	Approved subject to conditions		Approved	15/12/2006	Christchurch Hospital	Nil		Research Manager-Maori; Christchurch School of Medicine
URB/06/11/086	Audit of general practice diabetes case detection	Prof L Toop	30/10/2006	13/11/2006	Approved		Approved	16/11/2006		Nil		Maori Advisory Group; Pegasus Health
URB/06/11/087	The effect of topical negative pressure (TNP) therapy on the microbiology of lower limb ulcers; an observational pilot study	Mr Manar Khashram	1/11/2006	13/11/2006	Approved subject to conditions		Approved	27/11/2006		Nil		Te Komiti Whakarite
URB/06/11/088	SPRINT-LITE – extending tight control to the wards: a clinical practice improvement project	Dr Geoffrey Shaw	3/11/2006	13/11/2006	Approved subject to conditions		Approved	12/01/2007	Christchurch Hospital	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/funder	Consultation undertaken
URB/06/11/089	Impact of glycaemic control and insulin sensitivity in the ICU: an investigation of the effects of intensive care clinical treatments on insulin sensitivity and the impact of tight glycaemic control on SIRS/sepsis and gastric motility	Dr Geoffrey Shaw	3/11/2006	13/11/2006	Ethical approval not required		Ethical approval not required		Christchurch Hospital	Nil		
URB/06/12/090	Evaluation of the effectiveness of a formal community pharmacist review for people with diabetes who take hypoglycaemic medication on the West Coast of the South Island of New Zealand	Dr Carol Atmore	29/11/2006	11/12/2006	Approved subject to conditions		Approved	5/02/2007	West Coast DHB	Nil		West Coast PHO; Te Tatau Pounamu
URB/06/12/091	A study to determine the ability of plasma BNP signal peptide concentrations to act as a specific and early clinical biomarker of acute myocardial infarction: the "SP-AMI" study	Professor AM Richards	27/11/2006	11/12/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital	A		Elizabeth Cunningham
URB/06/12/092	A study to determine the amino acid structure of plasma BNP signal peptide as a specific and early clinical biomarker of acute myocardial infarction: the "SSS" study	Professor AM Richards	27/11/2006	11/12/2006	Approved subject to conditions		Approved	15/01/2007	Christchurch Hospital	A		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
URB/06/12/093	A study to determine the diagnostic test performance (sensitivity, specificity, negative predictive value, positive predictive value, accuracy and prognostic value) of BNP-SP measurement in detection of ACS (including those with ischemia short of infarction) within a population of 'all-comers' with chest discomfort: the "SP-ACE" study	Professor AM Richards	27/11/2006	11/12/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital	A		Elizabeth Cunningham
URB/06/12/094	Biomarkers risk-stratifying for adverse post-operative cardiac events: the "BRACE" study	Prof Mark Richards	27/11/2006	11/12/2006	Approved subject to conditions		Approved	12/02/2007	Christchurch Hospital	A		Elizabeth Cunningham
URB/06/12/095	Prediction of retention in a drug treatment therapeutic community: retrospective review	Prof Roger Mulder	29/11/2006	11/12/2006	Approved		Approved	18/12/2006	Odyssey House	Nil		
URB/06/12/096	Maintaining independence: predicting and preventing residential care admission	Claire Patricia Heppenstall	29/11/2006	11/12/2006	Approved subject to conditions		Approved	20/02/2007	Princess Margaret Hospital	Nil		Elizabeth Cunningham
URB/06/12/097	Presence of mycobacterium avium subsp paratuberculosis (MAP) in the peripheral blood of healthy Caucasians	Dr Rebecca Roberts	29/11/2006	11/12/2006	Approved subject to conditions		Approved	19/01/2007	Christchurch Hospital	Nil		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
URB/06/12/098	Physiological responses to acute hypobaric in normal volunteers, patients with chronic obstructive pulmonary disease (COPD) and patients with diffuse parenchymal lung disease (DPLD)	Mr Paul T Kelly	27/11/2006	11/12/2006	Approved subject to conditions		Approved	19/01/2007	Christchurch Hospital	A	Christchurch Hospital, Mt Hutt Skifield Co	Te Komiti Whakarite
URB/06/12/099	Subclinical thyrotoxicosis in an outpatient population – Audit of presentation plus clinical and biochemical outcome	Dr Belinda Robb	29/11/2006	11/12/2006	Approved subject to conditions		Approved	12/02/2007	Christchurch Hospital	A		
URB/06/12/100	Stable primary care depression: maintenance versus gradual withdrawal of fluoxetine	Dr Dee Mangin	29/11/2006	11/12/2006	Approved subject to conditions		Approved subject to conditions			Nil	HRC	Elizabeth Cunningham
URB/06/12/101	Investigation into the effect of a nutritional supplement on mood and function in a clinical sample of young adolescents with bipolar disorder: naturalistic clinical case series ABAB patient preference design	Dr Julia Rucklidge	18/12/2006	11/12/2006	Declined	Safety of participants	Declined		Bipolar Support Canterbury	A		Annette Finlay

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
URB/06/03/020	A single-centre, single-dose randomised, open-label, three-way cross-over study with a washout period of at least seven days to investigate the relative bioavailability of RO4588161 following oral administration in healthy subjects	Assoc Prof Richard Robson	27/02/2006	20/03/2006	Approved subject to conditions		Approved	31/03/2006	Ethics Committee	B	Roche Palo Alton	Mr and Mrs John McManus
URB/06/05/034	A placebo-controlled, randomised, double-blind, sequential, single dose escalation study to evaluate the safety, tolerability, and pharmacokinetics of intravenous infusion and subcutaneous injection of AMG 379 in healthy adults	Dr Chris Wynne	1/05/2006	15/05/2006	Approved subject to conditions		Approved	30/05/2006	Christchurch Clinical Studies Trust	B	Amgen Inc	Mr and Mrs John McManus
URB/06/06/052	A multi-centre, double-blind, double dummy, placebo-controlled, parallel panel study to assess the safety, tolerability and glucose lowering efficacy of MK-0893 in patients with type 2 diabetes mellitus	Prof Russell Scott	6/06/2006	19/06/2006	Approved subject to conditions		Approved	21/07/2006		B	Merck Sharp and Dohme	
URB/06/07/055	A multi-centre, single dose, open label study to investigate the effect of severe hepatic impairment on the pharmacokinetics of RO0503821	Assoc Prof Richard Robson	3/07/2006	19/07/2006	Approved subject to conditions		Approved	21/07/2006	Christchurch Clinical Studies Trust	B	F Hoffmann-La Roche Inc	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/funder	Consultation undertaken
URB/06/07/056	Assessment of the bioavailability of opened 200 mg saquinavir capsules suspended in two different vehicles combined with ritonavir to unopened 200 mg saquinavir capsules combined with ritonavir	Dr Chris Wynne	3/07/2006	19/07/2006	Approved subject to conditions		Approved	21/07/2006	Christchurch Clinical Studies Trust	B	F Hoffmann-La Roche Inc	Mr and Mrs John McManus
URB/06/07/057	Assessment of the palatability of opened 200 mg Invirase capsules suspended in various vehicles	Dr Chris Wynne	3/07/2006	19/07/2006	Approved subject to conditions		Approved	21/07/2006	Christchurch Clinical Studies Trust	B	F Hoffmann-La Roche Inc	Mr and Mrs John McManus
URB/06/08/059	A single-centre, single-ascending dose, randomised, double-blind, placebo-controlled, parallel-group study with an open label active control arm of peginterferon α -2a (Pegasys®) 180 ug to investigate the pharmacokinetics, pharmacodynamics, safety, and tolerability of RO5014583 following subcutaneous administration in healthy volunteers	Assoc Prof Richard Robson	7/08/2006	25/08/2006	Approved subject to conditions		Approved	31/08/2006	Christchurch Clinical Studies Trust	B	Hoffman-La Roche	Mr and Mrs John McManus
URB/06/09/067	A multiple-centre, observer-blinded, randomised, placebo-controlled, single and multiple ascending dose study to investigate the pharmacokinetics, pharmacodynamics, safety, tolerability, and food effect of RO5024048 in healthy volunteers and in patients with chronic HCV infection of Genotype 1	Assoc Prof Richard Robson	4/09/2006	18/09/2006	Approved subject to conditions		Approved	13/10/2006	Christchurch Clinical Studies Trust	B	Pharmasset Inc	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/funder	Consultation undertaken
URB/06/10/080	A single-centre, single-ascending dose, randomised, observer-blinded, placebo-controlled, parallel study to investigate the safety, tolerability and pharmacokinetics of RO4926219 following oral administration in healthy subjects	Dr Chris Wynne	3/10/2006	19/10/2006	Approved subject to conditions		Approved subject to conditions	27/10/2006	Christchurch Clinical Studies Trust	B	Roche Palo Alto LLC	Mr and Mrs John McManus

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 Upper South B 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.

