

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

**Annual Report**

**January 2007 to December 2007**

Published in December 2008 by the  
Ministry of Health  
PO Box 5013, Wellington, New Zealand

ISBN 978-0-478-31860-9 (print)  
ISBN 978-0-478-31861-6 (online)  
HP 4716

This document is available on the New Zealand Health and Disability Ethics Committee's  
website: <http://www.ethicscommittees.health.govt.nz>

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# Chairperson's Report

This report provides an overview of the work of the Upper South A Regional Ethics Committee from January to December 2007. The report was presented to the Upper South A Regional Ethics Committee at its meeting on 21 April 2008.

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

The Upper South A Regional Ethics Committee met 11 times in 2007. Over the year, the committee processed 87 new applications. The committee experienced no membership changes. Jane Kerr took maternity leave from April to September inclusive. During her absence, Sharon English was involved in the meetings as expert advisor. Ellen McCrae took leave from May to July inclusive.

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

The committee reviewed 33 applications for expedited review. The time taken to approve these applications varied from one day to 86 days. The average time was 22 days.

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

Alieke Dierckx undertook the administration of the Upper South A Regional Ethics Committee in 2007.

Carolyn Mason  
Chairperson

# Committee Membership

## Appointments

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

### Chairperson

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

### Deputy Chairperson

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

### Members

<b>Carolynn Bull</b>	MA, LLB
Representation	Lay member
Member category	Lawyer
Gender	Female
Date of appointment	December 2006
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	–
Iwi affiliations	Kai Tahu

<b>John Horwood</b>	MSc (Hons)
Representation	Non-lay member
Member category	Biostatistician
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Statistical Association of New Zealand
Iwi affiliations	–
<b>Jane Kerr</b>	MChB, DRCOG, MPH
Representation	Non-lay member
Member category	Health researcher
Gender	Female
Date of appointment	March 2006
Term of appointment	3 years
Six-year maximum term	March 2012
Professional affiliations	–
Iwi affiliations	–
<b>Tom Marshall</b>	MA, Dip Clin Psych, MNZCC Psych
Representation	Non-lay member
Member category	Health researcher
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	April 2008
Professional affiliations	–
Iwi affiliations	–
<b>Ellen McCrae</b>	Bachelor of Pharmacy
Representation	Non-lay member
Member category	Pharmacist/pharmacologist
Gender	Female
Date of appointment	July 2005
Term of appointment	3 years
Six-year maximum term	July 2011
Professional affiliations	Pharmacy Council of New Zealand, Fellow of Pharmaceutical Society of New Zealand
Iwi affiliations	–
<b>Eddie Moke</b>	MBS
Representation	Lay member
Member category	Community representative
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	–
Iwi affiliations	Te Arawa, Ngai Tahu

**Nicky Murray**

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

**Liz Richards**

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

**Russell Scott**

	MBChB, FRACP, PhD
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	December 2006
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Royal Australasian College of Physicians
Iwi affiliations	–

**Deputy chairperson**

Alison Luckey, who was elected deputy chairperson at the Committee's inaugural meeting on 7 February 2005, remained as deputy chairperson throughout 2007.

**Community representative position**

Because of the appointed member being unable to take up the position, the committee had only one community representative in 2007.

## Members' attendance

Member	M/F	Lay/ non-lay	29 Jan	26 Feb	26 Mar	30 Apr	28 May	25 Jun	23 Jul	20 Aug	24 Sep	29 Oct	26 Nov	Total
Carolyn Mason (Ethicist)	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Alison Luckey (Health practitioner)	F	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Carolynn Bull* (Lawyer)	F	L	Y	Y	A	A	Y	Y	Y	Y	Y	Y	Y	9/11
John Horwood (Biostatistician)	M	NL	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	10/11
Jane Kerr (Health researcher)	F	NL	Y	Y	Y	Maternity leave						Y	Y	5/5
Tom Marshall (Health researcher)	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Ellen McCrae (Pharmacist)	F	NL	Y	Y	Y	Y	Leave			Y	Y	Y	Y	8/8
Edie Moke* (Community rep)	F	L	Y	Y	A	Y	Y	A	Y	Y	Y	Y	Y	9/11
Nicky Murray (Consumer rep)	F	L	Y	Y	Y	Y	Y	Y	A	A	Y	Y	Y	9/11
Liz Richards (Community rep)	F	L	Y	Y	Y	Y	A	Y	Y	Y	Y	A	Y	9/11
Russell Scott (Health practitioner)	M	NL	Y	Y	Y	A	Y	Y	Y	A	Y	Y	Y	9/11
Sharon English (Health practitioner expert advisor)	F	NL				Y	Y	Y	Y	A	Y			5/6
<b>No. of members present</b>			<b>11</b>	<b>11</b>	<b>9</b>	<b>8</b>	<b>8</b>	<b>8</b>	<b>8</b>	<b>7</b>	<b>10</b>	<b>10</b>	<b>11</b>	
<b>No. of applications</b>			<b>9</b>	<b>7</b>	<b>5</b>	<b>13</b>	<b>9</b>	<b>5</b>	<b>6</b>	<b>11</b>	<b>4</b>	<b>10</b>	<b>8</b>	<b>87</b>

\* = Māori member

Y = Present

A = Apology

## Training

### New member training

Training for new members took place on 23 May 2007 in Wellington. Nicky Murray attended from the Upper South A Regional Ethics Committee.

### Ongoing training

There was no ongoing training during 2007. A training session on applications for expedited review was held for chairpersons, deputy chairpersons and administrators on 27 April prior to the chairpersons' meeting.

## **Meeting of the Māori members**

A hui was held in Wellington on 13 June 2007. The following members of the Upper South A Regional Ethics Committee attended: Carolynn Bull and Edie Moke.

## **Chairpersons' meeting**

The following Chairpersons' meetings were held in 2007:

- 15 and 16 February: Carolyn Mason and Alison Luckey attended.
- 27 April 2007: Carolyn Mason and Alison Luckey attended.
- 25 and 26 October 2007: Carolyn Mason and Liz Richards attended.

## **Research community education**

During 2007, Carolyn Mason gave the following presentations.

- "Ethics committees" – students of a Health Science Bioethics course.
- "Ethics and relationships" – students of a Health Sciences Family Nursing course and students of a Forensic Genetics course.
- "Ethics and ethics committees" – students of Research Methodology Course, University of Otago, Department of Public Health and General Practice, Christchurch School of Medicine and Health Sciences.
- "Ethics committees and processes" – two different groups from the Centre of Postgraduate Nursing, University of Otago.

## **Meetings with researchers**

Various members from both Upper South A and Upper South B Regional Ethics Committees met with representatives at the Christchurch Clinical Studies Trust on 30 April 2007.

## **Approval by the Health Research Council**

The committee is approved by the Health Research Council until December 2010.

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

The Upper South A Regional Ethics Committee is registered with the United States Department of Health and Human Services. This registration enables the committee to review research funded by the United States Government. The registration number is IRB00004667 – Upper South A Regional Ethics Committee.

## Response to Cultural Issues

Number of applications deferred because Māori guidelines were not read	0
Number of applications for which consultation with Māori was considered appropriate	86
Number of applications returned through insufficient consultation on cultural issues	0 (Evidence of consultation required and carried out concurrently.)
Process the committee has for following through on consultation	Confirming written evidence of consultation is received, ensuring researchers implement suggestions.
Cases of unsatisfactory reasons for not including Māori	0
Mechanisms in place to facilitate consultation with Māori by researchers	Researchers have been given advice on whom to contact, as and when required. Researchers are encouraged to approach the administrator as soon as possible if there are difficulties in finding appropriate people to consult with.
Examples of Māori not being included in research	A study specific to one (non-Maori) family.

# Applications

The committee held 11 scheduled meetings from January to November 2007.

## Upper South A Regional Ethics Committee statistics for January–November 2007

<b>Applications reviewed by the full committee</b>	
Applications approved	75
Applications deferred and subsequently approved	2
Applications deferred as at time of report	2
Applications declined	0
Applications carried forward (approved subject to conditions)	6
Ethics committee approval not required	1
Studies withdrawn by researcher	0
Studies terminated by sponsor	1
Studies transferred to Multi-region Ethics Committee	0
<b>Total number of applications considered by the full committee</b>	<b>87</b>
<b>Expedited review applications</b>	
Expedited review applications approved	26
Expedited review applications declined review – ethics committee approval not required	8
Expedited review applications declined review – full application required	1
Expedited review applications carried forward (approved subject to conditions)	1
<b>Total number of expedited review applications reviewed</b>	<b>36</b>
<b>Total number of applications received</b>	<b>123</b>

## Other committee statistics

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

## Audit or matters not requiring ethics committee approval

Two projects were confirmed as audits or surveys not requiring ethical approval in accordance the Ethical Guidelines for Observational Studies, Observational Research, Audits and Related Activities, National Ethics Advisory Committee, December 2006.

## **Innovative practice**

No applications for innovative practice were received.

## **Second opinions**

No second opinions were sought.

## **Complaints**

No complaints were received.

## Guidelines for the Chairperson's Delegation

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

The Chairperson may approve under delegated authority:

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

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

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

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

# **Appendix 1: Upper South A Regional Ethics Committee Terms of Reference**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **Composition and membership**

### **Guiding principle**

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

### **Member numbers**

The number of members of the Upper South A REC should be 12.

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

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

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

## **Member categories**

The Upper South A REC's lay membership shall include:

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

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

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

## **Whole committee requirements**

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

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

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

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

## **Terms and conditions of appointment**

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

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

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

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

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

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

## **Chairperson and Deputy Chairperson**

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

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

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

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

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

### **General**

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

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

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

### **Conflicts of interest**

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

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

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

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

### **Confidentiality and information sharing**

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

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

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

### **Committee meetings**

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

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

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

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

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

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

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

### **Decision-making process**

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

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

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

### **Ethics committee actions**

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

## **Expert advice and consultation**

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

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

Advice may be sought from recognised experts with:

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

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

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

## **Second opinions and appeals**

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

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

## **Training for members**

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

## Reporting requirements

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

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

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

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

The annual report shall also include:

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

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

## Fees and allowances

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

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

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

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

## Appendix 2: Applications Received January–December 2007

Appendix 2 details the applications considered by the committee from January to December 2007. Four applications were considered in 'closed' meetings.

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
URA/07/01/001	Interferon-induced depression: risk factors, incidence and prevalence.	Dr Samuel Ritz	16/01/07	29/01/07	Approved		Approved	20/03/07	CDHB	A	Young investigators grant	Annette Finlay
URA/07/01/002	An audit into metastatic melanoma disease: treatments and response/survival.	Mr Steven Brown	19/12/06	29/01/07	Ethical approval not required	Ethical approval not required	Ethical approval not required		Christchurch Hospital	Nil		None – retrospective review only
URA/07/01/003	Attitudes towards frozen embryos.	Jan Barrett	5/01/07	29/01/07	Approved		Approved	28/03/07	The Fertility Centre	Nil	The Fertility Centre	Hana O'Regan, Jackie Freeman (ECART)
URA/07/01/004	Investigation into the micronutrient status for vitamin B1, B2, B6, B12, niacin, folate and vitamin D, in patients currently undergoing haemodialysis (HD) and continuous ambulatory peritoneal dialysis (CAPD).	Ms Kate Parrott	16/01/07	29/01/07	Approved		Completed	14/02/07	Christchurch Hospital	A	Christchurch Hospital, Christchurch School of Medicine	Annette Finlay
URA/07/01/006	Peroxioredoxin oxidation in severe infection.	Prof Stephen T Chambers	16/01/07	29/01/07	Approved		Approved	13/03/07	Christchurch Hospital	A	Internal funding	Elizabeth Cunningham
URA/07/01/007	Clinimetric studies of a new scale for Parkinson's disease.	Prof Tim Anderson	16/01/07	29/01/07	Approved		Approved	16/03/07	Christchurch Hospital	Nil	Internal	Elizabeth Cunningham
URA/07/01/008	Peripherally inserted central catheter (PICC)-related complications amongst oncology patients: retrospective review.	Ms Mary Fairhall	16/01/07	29/01/07	Approved		Approved	6/02/07	Christchurch Hospital	Nil		None undertaken – retrospective review only
URA/07/01/009	Free drug clearance and Michaelis-Menten pharmacokinetics of phenytoin in elderly versus young adults.	Mr Daniel Wright	16/01/07	29/01/07	Approved		Approved	20/02/07	Christchurch Hospital	A		Elizabeth Cunningham
URA/07/02/010	Apomorphine treatment for advanced Parkinson's disease – does it improve quality of life and not impair cognitive and motor performance?	Prof Tim Anderson	12/02/07	26/02/07	Approved		Approved	7/08/07	Christchurch Hospital	A	Farina Thompson Charitable Trust 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
URA/07/02/011	A randomised, double-blind, placebo-controlled study to assess the safety, tolerability, pharmacodynamics and pharmacokinetics of subcutaneous doses of ACV1 in patients with diabetic peripheral neuropathic pain or post herpetic neuralgia.	Dr Alison Luckey	13/02/07	26/02/07	Approved subject to conditions		Terminated	19/03/07	Primorus Clinical Trials Ltd St George's Hospital	B	Metabolic Pharmaceuticals Ltd	Peter Mason
URA/07/02/012	The role of sympathetic nerve response in Takotsubo cardiomyopathy.	Dr Zhi Hua (Michael) Zhang	13/02/07	26/02/07	Approved		Approved	24/04/07	Christchurch Hospital	A	NZ Heart Foundation, CMRF and Lotteries grant	Hector Matthews
URA/07/02/013	Focus groups to assess urgency associated with OAB.	Dr Sharon English	13/02/07	26/02/07	Approved		Approved	3/04/07	Canterbury Urology Research Trust	B	Oxford Outcomes	Peter Mason
URA/07/02/014	Focus groups and one-on-one interviews to assess patients' expectations, goal setting, goal attainment and satisfaction with OAB treatment.	Dr Sharon English	13/02/07	26/02/07	Approved		Approved	3/04/07	Canterbury Urology Research Trust	B	Oxford Outcomes	Peter Mason
URA/07/02/015	Neuropsychological functioning in young adults with bipolar disease (BP): contribution of attention-deficit/hyperactivity disorder (ADHD).	Mr Jason Alan Brown	13/02/07	26/02/07	Deferred		Approved	16/08/07	Canterbury DHB	A	University of Canterbury	Annette Finlay
URA/07/02/016	Comparison of rice bran oil margarine with Flora margarine and Flora Pro active margarine for lowering cholesterol.	Ms Sarah Eady	13/02/07	26/02/07	Approved		Approved	1/05/07	Canterbury DHB	B	Old Fashioned Foods	Annette Finlay
URA/07/03/017	Patterns of hearing loss during and following the removal of acoustic neuroma.	Mr P A Bird	5/03/07	26/03/07	Approved		Approved	22/05/07	Christchurch Hospital	A	No funding required	Te Komiti Whakarite
URA/07/03/018	Comparison of late-night salivary cortisol levels with standard screening tests for Cushing's syndrome in obese patients with type 2 diabetes.	Dr Eina Ellis	13/03/07	26/03/07	Approved		Approved	25/04/07	Christchurch Hospital	A	Christchurch Diabetes and Heart Research Trust	Annette Finlay
URA/07/03/019	Investigation of lapses of responsiveness via simultaneous functional-MRI and EEG.	Govinda Raj Poudel	13/03/07	26/03/07	Approved		Approved	26/06/07	Van der Veer Institute for Parkinson's and Brain Research	A	Van der Veer Institute, Hagley Radiology, Lottery Health Research, University of Otago Scholarship, Neurotechnology Scholarship	Elizabeth Cunningham
URA/07/03/020	A pilot study to develop programmes to support families after a suicide attempt.	Dr Annette Beutrais	13/03/07	26/03/07	Approved		Approved	10/04/07	Christchurch Hospital	A		Annette Finlay

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URA/07/03/021	Endometrial sampling and receptivity study.	Gloria Evelyn Evans	13/03/07	26/03/07	Approved		Approved	8/05/07	Christchurch Women's Hospital St George's Hospital	A	Enterprise scholarship	Cultural Committee at Christchurch Women's Hospital
URA/07/04/022	Enabling activity: facilitators and obstacles affecting people with disabilities participating in physical activities in the Nelson Marlborough region.	Dr Bjarne Vandeskog	17/04/07	30/04/07	Approved		Completed	28/05/07	Tasman Regional Sports Trust	Nil	Tasman Regional Sports Trust	Maori Regional Physical Activities Roopu; Maataa Waka; He Oranga Poutama; Kia Piki 4 Life
URA/07/04/023	Monitoring natural progression of dysphagic symptoms in stroke.	Dr Maggie Lee Huckabee	17/04/07	30/04/07	Approved subject to conditions		Approved	26/06/07	CDHB	Nil	Swallowing Rehab Research Lab	Te Komiti Whakarite
URA/07/04/024	Investigation of the health status of adolescents in rural Canterbury.	Dr Sue Bagshaw	17/04/07	30/04/07	Approved		Approved	3/07/07	Akaroa Area School Oxford Area School Rangiora High School	Nil	RCPHO	Onuku Runanga Incorporated Society – Tim Manawatu
URA/07/04/025	To investigate knowledge of an barriers to accessing healthcare services for a New Zealand west coast rural population.	Lynette Irene Dunlop	17/04/07	30/04/07	Approved		Completed	5/06/07	West Coast DHB	A	Scholarship funding	Gary Coughlan
URA/07/04/026	The implications of ageing with a physical disability.	Richard Peter Smaill	17/04/07	30/04/07	Approved		Approved	10/07/07	Christchurch Hospital	A	PhD funding from HRC	Elizabeth Cunningham
URA/07/04/027	The impact of clinical trials on intensive care nurses. What is their experience? A survey questionnaire to determine the impact of clinical trials on intensive care nurses as carers of patients enrolled in clinical trials and as implementers of trial protocols.	Ms Helen Johnson	17/04/07	30/04/07	Approved		Approved	22/05/07	Christchurch Hospital	Nil		Te Komiti Whakarite
URA/07/04/028	Is CNP/NTproCNP better than PSA as a marker of prostate cancer?	Prof Gary Nicholls	17/04/07	30/04/07	Deferred		Approved	26/06/07	Christchurch Hospital	A	Cardioendocrine Research Trust	Elizabeth Cunningham
URA/07/04/029	Refinement and validation of the Canterbury driving assessment tool (CanDAT) for screening and prediction of driving ability in healthy older drivers.	Petra A Hoggarth	17/04/07	30/04/07	Approved subject to conditions		Approved	3/07/07	Van der Veer Institute for Parkinson's and Brain Research	Nil	Christchurch Neurotechnology Research Programme, University of Canterbury	Elizabeth Cunningham
URA/07/04/030	An exploration of the relationship between culture and fatigue for people living with chronic obstructive pulmonary disease.	Ruth Haynes	17/04/07	30/04/07	Approved subject to conditions		Approved	19/06/07	Christchurch Hospital	Nil	CDHB Hospital Volunteers, Christchurch Hospital Nurses Study Fund	Elizabeth Cunningham
URA/07/04/032	Maturation of cortical auditory evoked potentials in children with normal hearing and hearing impairment.	Jennifer Walker	17/04/07	30/04/07	Approved		Approved	18/07/07	University of Canterbury Southern Cochlear Implant Programme	Nil	University of Canterbury	Te Komiti Whakarite

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URA/07/04/033	Clinical applicability of adaptive speech testing: a comparison of the time efficiency, accuracy and reliability of adaptive speech tests with conventional speech audiometry.	Brenna Sincock	17/04/07	30/04/07	Approved subject to conditions		Approved	12/06/07	University of Canterbury	A	University of Canterbury	Elizabeth Cunningham
URA/07/04/034	A randomised controlled trial to determine if heated humidification reduces the duration of oxygen therapy for infants with bronchiolitis.	Victoria Cullens	17/04/07	30/04/07	Approved		Approved	19/06/07	Christchurch Hospital	A	Fisher & Paykel equipment	Annette Finlay; Sandy Hunt
URA/07/05/035	Investigating cortical contribution to pre-motor planning of volitional and naive swallows using the Bereitschafts potential.	Ms Phoebe Macrae	14/05/07	28/05/07	Approved subject to conditions		Approved	26/06/07	Van der Veer Institute for Parkinson's and Brain Research	Nil	Swallowing Rehab Research budget	Dr Gail Gillon
URA/07/05/036	Coming to terms with serious mental illness.	Dr Anne Scott	15/05/07	28/05/07	Approved		Approved	19/08/07	MHERC Pacific Trust Te Awa o te Ora	Nil	Self-funded from university discretionary fund	Lynere Wilson – Bipolar Support Canterbury; Diane Gooch of SF Pegagus Bag; Geoff Bristowe of Te Awa o Te Ora and Maria Gianville of Pacific Trust Canterbury
URA/07/05/037	Why are skin cancers more aggressive in renal transplant patients?	Dr Katarzyna Mackenzie	15/05/07	28/05/07	Approved		Approved	25/07/07	CDHB	Nil	External grant funding for consumables – The Robert McClelland Trust	Elizabeth Cunningham
URA/07/05/038	Differences in patient's results and perception of the effort required while performing spirometry using different manoeuvres.	Dr Maureen Swanney	15/05/07	28/05/07	Approved		Approved	26/06/07	Christchurch Hospital	A	None	Te Komiti Whakarite
URA/07/05/039	Protect–pace study: the protection of the left ventricular function during right ventricular pacing. Does right ventricular high-septal pacing improve outcome compared with right ventricular apical pacing. Protocol version 1.10 dated 25/11/06.	Dr Ian Crozier	15/05/07	28/05/07	Approved		Approved	10/07/07	Christchurch Hospital	B	Medtronic Australasia Pty Ltd	Te Komiti Whakarite
URA/07/05/040	Spirit V – A clinical evaluation of the XIENCE V everolimus eluting coronary stent system in the treatment of patients with de novo coronary artery lesions. Protocol 05-369, version 6.0 dated 22/1/06.	Dr Dougal McClean	15/05/07	28/05/07	Approved		Approved	9/08/07	Christchurch Hospital	B	Abbott Laboratories	Te Komiti Whakarite
URA/07/05/041	Residual hearing levels post-surgery for the Southern cochlear implant programme – baseline levels.	Gurjoat S Vraich	15/05/07	28/05/07	Approved		Approved	3/09/07	University of Canterbury	Nil	University of Canterbury, Oticon Foundation Grant	Te Komiti Whakarite

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URA/07/05/042	A multicentre, randomised, double-blind, placebo-controlled, parallel-group study of intravenous methylxanthine (MOA-728) for the treatment of post operative ileus. Protocol 6.0.01/03/07.	Prof F Frizelle	15/05/07	28/05/07	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital	B	Wyeth Research	Te Komiti Whakarite
URA/07/05/043	Pre-to-post cochlear implant surgery comparisons for speech and environmental sound perception.	Janna Arnephy	15/05/07	28/05/07	Approved		Approved	28/08/07	University of Canterbury	Nil	University of Canterbury, Oticon Foundation Grant	Te Komiti Whakarite
URA/07/06/044	Early intervention and quality of life of people with dementia and their family caregivers living in New Zealand.	Ms Franziska Gallrach	5/06/07	25/06/07	Approved subject to conditions		Approved	4/09/07	The Princess Margaret Hospital Alzheimer's Canterbury Telomessenger Solutions University of Canterbury	A	University of Canterbury Margaret Scott award	CDHB – Hector Matthews
URA/07/06/045	The impact of psychological distress, attachment style and relationship satisfaction on cancer patients and their partners.	Ms Hannah Blakely	10/06/07	25/06/07	Approved		Approved	11/09/07	Surgical Associates Urology Associates Canterbury Breastcare	Nil	Department of Psychology, University of Canterbury	Annette Finlay
URA/07/06/046	Intra-tympanic steroids for conservation of residual acoustic hearing after cochlear implantation.	Mr PA Bird	10/06/07	25/06/07	Approved		Approved	22/08/07	Christchurch Hospital	A	Deafness Research Foundation grant	Te Komiti Whakarite
URA/07/06/047	The intermediate phenotype conferred by heterozygosity for the TRPC1(P112Q) mutation in human cell lines from a New Zealand family with familial focal and segmental glomerulosclerosis (FSGS).	Assoc Prof Kelvin Lynn	12/06/07	25/06/07	Approved subject to conditions		Approved	17/07/07	Christchurch Hospital	A	Department of Nephrology Trust funds, National Institutes of Health, Diabetes, Digestive and Kidney Diseases research grants	Annette Finlay
URA/07/06/048	A prospective observational study of the diagnostic utility of the 'triage' multi-marker biochemical panel and myeloperoxidase and NGAL assays in the assessment of patients presenting to Christchurch Hospital with chest pain of possible cardiac origin.	Dr Martin Than	12/06/07	25/06/07	Approved		Approved	28/07/07	Christchurch Hospital	A	Cardio-endocrine research group, external financial contribution from Biosite	Te Komiti Whakarite
URA/07/07/049	Stroke rehabilitation in the community: Is perceived control influenced by location of the rehabilitation programme?	Dr Carl Hanger	3/07/07	23/07/07	Approved		Approved	4/09/07	The Princess Margaret Hospital	A	Summer studentship to cover costs of the interviewer. Transport costs subsidised by Health Care of the Elderly Education Trust	Elizabeth Cunningham
URA/07/07/050	Effects of hydrocortisone on emotion recognition and cognitive function.	Assoc Prof Lucy Johnston	10/07/07	23/07/07	Approved		Approved	30/10/07	Christchurch School of Medicine Canterbury University	A	Research grant from Department of Psychology, Canterbury University	Dannette Marie; Te Runanga o Nga Maata Waka

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URA/07/07/051	A randomised, double-blind, parallel group, international study to evaluate the safety and efficacy of Ocrelizumab compared to placebo in patients with active rheumatoid arthritis who have an inadequate response to at least one anti-TNF- $\alpha$ therapy. Protocol WA20495.	Dr Daniel Ching	10/07/07	23/07/07	Approved		Approved	22/09/07	Timaru Hospital	B	Roche Products (New Zealand) Ltd	Bruce Wikitua; Kaumatua Liaison; Health South Canterbury
URA/07/07/052	A phase 2 study of risk-adapted IV melphalan in patients with AL amyloidosis.	Dr S Gibbons	10/07/07	23/07/07	Approved		Approved	16/10/07	Christchurch Hospital	A	ALLG (Australasian Leukaemia and Lymphoma group) will contribute \$A800 per patient towards cost	Annette Finlay
URA/07/07/053	Anxiety responses in coping strategies of parents during the hospitalisation of their child.	Ms Virginia Jones	10/07/07	23/07/07	Approved		Approved	30/10/07	Canterbury DHB	Nil	Self funded	Elizabeth Cunningham
URA/07/07/054	Genetic endometrial receptivity during the window of implantation (WOI).	Gloria Evelyn Evans	10/07/07	23/07/07	Approved subject to conditions		Approved	18/09/07	The Fertility Centre	A	Enterprise Scholarship	Elizabeth Cunningham
URA/07/08/055	Demonstrate changes in breath analytes in healthy volunteers using a new online breath sampling device and a new breath trace gas spectrum analytical algorithm.	Dr Randall Allardyce	7/08/07	20/08/07	Approved		Approved	20/11/07	Christchurch Hospital	B	Syft Technologies	None undertaken. Participants are already identified and do not include Maori.
URA/07/08/056	Improved magnetic resonance imaging (MRI) of blood vessels using multiple receiver coils and a support constraint.	Assoc Prof Philip J Bones	7/08/07	20/08/07	Approved subject to conditions		Approved subject to conditions			A	Accrued research funds	Annette Finlay
URA/07/08/057	Serum levels of bupivacaine associated with the rectus catheter system of continuous postoperative analgesia for major abdominal surgery.	Dr Philip Cornish	7/08/07	20/08/07	Approved subject to conditions		Approved subject to conditions			A	Parent institution	Maori consultation has been requested.
URA/07/08/058	Using primary epithelial cells to understand the role of H pylori outer membrane vesicles in gastric disease.	Dr Jacqui Keenan	7/08/07	20/08/07	Approved		Approved	16/09/07	Christchurch Hospital	A	Robert McClelland Trust	Elizabeth Cunningham
URA/07/08/059	Anxiety and coping strategies in emergency nurses.	Ms Heather Josland	7/08/07	20/08/07	Approved		Approved	16/09/07	Christchurch Hospital	Nil	CPIT School of Nursing Higher Qualification Fund	Elizabeth Cunningham

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URA/07/08/060	Investigation of triggering methods for motor evoked potentials of the anterior hypo-mandibular muscle group.	Mr Sebastian Doeltgen	7/08/07	20/08/07	Approved		Approved	13/11/07	Van der Veer Institute for Parkinson's and Brain Research	Nil	University of Canterbury Department of Communication Disorders and the UC Swallowing Rehabilitation Research Lab	Marilyn Farrell; Te Komiti Whakarite
URA/07/08/061	Influence of catheter diameter on measurement of resting and deglutitive manometric pressures at the upper oesophageal sphincter.	Dr Maggie Lee Huckabee	7/08/07	20/08/07	Approved		Approved	23/10/07	Christchurch Hospital	Nil	CSMHS, Department of Gastroenterology	Te Komiti Whakarite – Marilyn Farrell
URA/07/08/063	Primary chemotherapy with temozolomide vs radiotherapy in patients with low grade gliomas after stratification for genetic 1p loss: a phase 3 study.	Dr Melissa James	7/08/07	20/08/07	Approved		Approved	11/12/07	Christchurch Hospital	B	EORTC	Te Komiti Whakarite
URA/07/08/064	Pilot project to determine the acceptability of "Hemosure" faecal occult blood test kit among the general population.	Dr Peter Moody	7/08/07	20/08/07	Approved		Approved	15/02/08		A	Rotary Club	Marilyn Farrell
URA/07/08/065	Toxicity comparison of smoking hand-rolled cigarettes versus factory-made cigarettes.	Dr Murray Laugesen	7/08/07	20/08/07	Approved subject to conditions		Approved	9/10/07	Christchurch School of Medicine	Nil	Health Sponsorship Council, Cancer Society, Health NZ Ltd	Elizabeth Cunningham
URA/07/09/066	Cognitive debriefing interviews to evaluate selected urgency measures associated with OAB. Protocol C-1090 26/07/07.	Dr Sharon English	28/08/07	24/09/07	Approved		Approved	30/10/07	CURT Medical Trials Trust Board	A	Oxford Outcomes	Peter Mason
URA/07/09/067	Baseline survey for the Nelson Marlborough District Health Board's (DHB) Nutrition and Physical Activity Plan (NPA).	Dr Rob McNeill	1/09/07	24/09/07	Approved subject to conditions		Approved	4/02/08		Nil	NMDHB	NM Iwi Health Board
URA/07/09/068	An exploration of older people's perceptions of elder abuse, and the identification of elder abuse in the emergency department setting.	Ms Dianne Hudson	4/09/07	24/09/07	Approved		Approved	25/11/07	Christchurch Hospital	Nil	Researcher's private funds	Elizabeth Cunningham
URA/07/09/069	Abortion in Christchurch, New Zealand: Actors, Networks and Organisation.	Ms Leitia Meadows	4/09/07	24/09/07	Approved		Approved	30/10/07	Lyndhurst Hospital	A		Doris Warren; Te Komiti Whakarite
URA/07/10/070	Effects of non-event related electrical stimulation on motor evoked potentials of the anterior hypo-mandibular muscle group.	Mr Sebastian Doeltgen	9/10/07	27/10/07	Approved		Approved	11/12/07	Van der Veer Institute for Parkinson's and Brain Research	A	University of Canterbury Department of Communication Disorders, University of Canterbury Swallowing Rehab Research Lab	Marilyn Farrell

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URA/07/10/071	Evaluation of the Can Quit Practice, smoking cessation training for dental practitioners.	Ms Allison Bennett	9/10/07	27/10/07	Approved		Approved	27/11/07	Cancer Society of New Zealand Nelson Marlborough District Health Board	Nil	Tobacco Control Health Promotion budget held by NMDHB Public Health Service	NMDHB Iwi Health Board
URA/07/10/072	Evaluation of a framework for community mobility: what skills predict independent walking?	Ms Sue Lord	9/10/07	27/10/07	Approved		Approved	17/12/07	Nelson Marlborough District Health Board	A		Ngai Tahu Research Consultation Committee
URA/07/10/073	The contribution of attention to complex gait after stroke: a prospective study.	Ms Sue Lord	9/10/07	27/10/07	Approved		Approved	16/12/07	Nelson Marlborough District Health Board	Nil	NZ Lottery Grants Board	Mark Brunton – Facilitator Research Division – Ngai Tahu
URA/07/10/074	Working models of attachment, illness perceptions, and health outcomes in couples experiencing type 2 diabetes: the mediating role of support-seeking and support-giving process.	Ms Louella B Orillaza	9/10/07	27/10/07	Approved		Approved	7/01/08	University of Canterbury	A	Department of Psychology, University of Canterbury	Marilyn Farrell
URA/07/10/075	Breast cancer stem cells: hypoxia and angiogenesis.	Assoc Prof Bridget Robinson	9/10/07	27/10/07	Approved		Approved	21/11/07		Nil	Genesis Oncology Trust	Tissue bank application; none required
URA/07/10/076	The Canterbury Wegener's Granulomatosis (and WG like diseases) observational study.	Dr Lisa Stamp	9/10/07	27/10/07	Approved		Approved	11/12/07	CDHB	A	Canterbury Rheumatology, Immunology Research Trust, Lotteries Health NZ, Vasculitis Foundation of America	Elizabeth Cunningham
URA/07/10/078	Intratympanic and intravenous delivery of dexamethasone to cochlear perilymph.	Mr PA Bird	11/10/07	27/10/07	Approved subject to conditions		Approved subject to conditions			A	Deafness Research Foundation	Pending
URA/07/10/079	Investigation of the effectiveness of carbonated beverages in clearing soft food bolus obstructions of the oesophagus.	Dr Katherine Southwell	11/10/07	27/10/07	Approved		Approved	4/12/07		A	Otolaryngology Trust Fund	Marilyn Farrell
URA/07/11/080	Investigation into the effect of a nutritional supplement on attention and mood in a clinical sample of adults with ADHD and mood instability: open label pilot study.	Dr Julia Rucklidge	9/11/07	26/11/07	Approved		Approved	19/02/08	University of Canterbury	A	Department of Psychology, University of Canterbury, Synergy Group	Marilyn Farrell

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URA/07/11/081	A worldwide, double blind, randomised, placebo controlled study of MK-0524A 2g co-administered with intensive LDL-C lowering therapy compared to intensive LDL-C lowering therapy alone on carotid artery intima-media thickness in patients with heterozygous familial hypercholesterolemia. Protocol MK-0524A 05/07/07.	Prof Russell Scott	13/11/07	26/11/07	Approved subject to conditions		Approved	8/02/08	Christchurch Hospital Hagley Radiology	B	Merck Sharpe & Dohme	Marilyn Farrell
URA/07/11/082	Understanding nurses' prioritisation of the patient need for care within and between patient situations while nursing several patients concurrently in hospital wards.	Sarah Elizabeth Lake	12/11/07	26/11/07	Approved subject to conditions		Approved subject to conditions		Neison Marlborough District Health Board	Nil	PhD scholarship from Victoria University of Wellington	Nicola Ehau
URA/07/11/083	The Kotuku experience – mental health consumers as providers in crisis intervention.	Jan Flinn	13/11/07	26/11/07	Approved subject to conditions		Approved	19/02/08	Health Action Trust	Nil		Nicola Ehau
URA/07/11/084	Understanding clinician and consumer perspectives of obesity: expanding knowledge of the causation and treatment of obesity.	Prof Doug Sellman	13/11/07	26/11/07	Approved		Approved	15/02/08	By Ethics Committee	A		Elizabeth Cunningham
URA/07/11/085	Nursing roles in parental support: a cross-cultural comparison between neonatal intensive care units (NICU) in New Zealand and Japan.	Emiko Ichijima	13/11/07	26/11/07	Approved		Approved	19/02/08	Christchurch Women's Hospital	A		Hector Matthews; Maori & Pacific Health; CDHB
URA/07/11/086	The effects of amantadine and anticholinergics on cognition and eye movements in Parkinson's disease.	Charlotte Graham	13/11/07	26/11/07	Approved		Approved	6/01/08		A	Prof Anderson's existing research resources	Elizabeth Cunningham
URA/07/11/087	A phase 2, 12-week, double-blind, dose-finding, placebo-controlled study to assess the efficacy and safety of a range of SCH 420814 doses (1 mg BID, 2 mg BID, 5 mg BID and possibly 10 mg BID) in subjects with moderate to severe Parkinson's disease experiencing motor fluctuations and dyskinesias, P04501 Amd #3.	Prof T Anderson	13/11/07	26/11/07	Approved subject to conditions		Approved	8/02/08	Van der Veer Institute for Parkinson's and Brain Research	B	Schering-Plough P/L	Elizabeth Cunningham

## Studies approved by the Chairperson under delegated authority

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URA07/01/CPD	Hip fracture mortality in Timaru – should we change our management strategy? Retrospective review.	Dr Scott Newburn	13/12/06				Ethical approval not required			A		None – observational research
URA07/02/EXP	An audit of the management of patients acutely admitted to Christchurch Hospital with chronic obstructive pulmonary disease (COPD).	Dr Roland Meyer	6/02/07				Approved	9/02/07		Nil		None – observational research
URA07/03/EXP	A prospective audit of opportunities for alternative health pathways in patients presenting acutely to Christchurch Hospital.	Dr Martin Than	6/02/07				Approved	8/02/07		A		None – observational research
URA07/04/EXP	Translation, linguistic validation and concept confirmation of a hot flushes symptom measure.	Dr Ray Kirk	7/02/07				Approved	3/04/07		A		None – observational research
URA07/05/EXP	The health effects of population mixing in New Zealand – observational research.	Laura Miller	20/02/07				Approved	20/02/07	University of Canterbury	A		None – observational research
URA07/06/EXP	How does a patient understanding their doctor affect patient healthcare satisfaction?	Mr Jason Wong	20/03/07				Approved	21/03/07	Christchurch Hospital	A		None – observational research
URA07/07/EXP	Oxycodone audit: its use in Christchurch Hospital.	Mr Paul Hallot	27/03/07				Ethical approval not required		Christchurch Hospital	A		None – observational research
URA07/08/EXP	Free drug clearance of phenytoin in elderly versus young adults.	Mr Daniel Wright	27/03/07				Approved	3/04/07	Christchurch Hospital	A		None – observational research
URA07/09/EXP	Starting insulin classes – an efficient and effective method of delivering group education.	Ms Marion Greenslade	9/06/07				Ethical approval not required			Nil		None – observational research
URA07/09/EXP	Retrospective audit of after hours care at Oxford Community Health Centre.	Colleen Wilkinson	9/04/07				Ethical approval not required			A		None – observational research
URA07/10/EXP	Mental health nurses' explanatory frameworks.	Dr Marie Crowe	9/06/07				Approved	3/07/07		Nil		None – observational research
URA07/11/EXP	Lay understanding of type 2 diabetes.	Arjeela Marie Kumar	9/06/07				Completed	3/07/07		A		None – observational research
URA07/12/EXP	Whole body bone scan research study.	Mr Ross McGurk	10/06/07				Completed	5/07/07		A		None – observational research

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
URA07/13/EXP	Neurodevelopmental outcomes of children born very preterm at age nine years.	A/P L Woodward	18/04/07				Approved	14/07/07		A		Te Komiti Whakarite; Doris Warren
URA07/14/EXP	The changing trends of percutaneous gastrostomy feeding tubes: a retrospective review at Christchurch Hospital from 2002 to 2006.	Dr Amanda Landers	1/07/07				Approved	31/07/07		A		None – observational research
URA07/15/EXP	Depression, romantic relationships and therapy: changes in romantic relationships during individual psychotherapy for major depression.	Dr Kumari Fernando	10/07/07				Approved	26/07/07		A		None – observational research
URA07/16/EXP	Can antioxidants from white blood cells prevent heart disease? Measurement of serum neopterin levels.	Dr S Giese	1/08/07				Approved	2/08/07		A		None – observational research
URA07/17/EXP	Outcome of raised nuchal translucency risk assessments over a three-year period in Christchurch.	Prof Pippa Kyle	7/08/07				Ethical approval not required			A		None – observational research
URA07/18/EXP	The processes that improve or impede accurate retrieval of information from memory.	Mrs Joyce Alberts	7/08/07				Approved	30/09/07		A		None – observational research
URA07/19/EXP	An audit of needs co-ordination referrals to examine whether differences exist in the use of support services for clients with a coexisting mental health and substance use disorder in contrast to those without a coexisting disorder.	Ms Liane Davison	21/08/07				Ethical approval not required			A		None – observational research
URA07/20/EXP	Major abdominal surgery patient satisfaction survey.	Ms Kim Macfarlane	28/08/07				Approved	18/09/07		A		None – observational research
URA07/21/EXP	Needs assessment to design simulation training to help junior medical staff manage acutely unwell patients.	Mr John Thwaites	31/08/07				Approved	18/09/07		A		None – observational research
URA07/22/EXP	Pumanawa Atawhai evaluation project.	Dr Ria Schroder	1/09/07				Approved	6/01/08		A		None – observational research
URA07/23/EXP	Epidemiology of staphylococcus aureus blood stream infection in Canterbury, New Zealand.	Dr Paul J Huggan	1/09/07				Approved	13/12/07		A		None – observational research
URA07/24/EXP	Presentation, incidence and outcome of infections caused by fusobacterium species in Canterbury, New Zealand, 2002–07.	Dr Paul J Huggan	1/09/07				Approved	8/10/07		A		None – observational research

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
URA07/25/EXP	Promoting mental health for children under five years – a case study of a nurturing programme in Aranui community.	Oseyi Ewhrudjakpor	11/10/07				Ethical approval not required			A		None – observational research
URA07/26/EXP	Outcomes for patients presenting with chest pain who are not initially diagnosed with an acute coronary syndrome.	Ms Caroline Ulrich	11/10/07				Approved	17/11/07		A		None – observational research
URA07/27/EXP	A descriptive study of nurse practitioners in New Zealand; who are they and what do they do?	Ms Mary Jo Gagan	14/10/07				Approved	5/02/08		A		None – observational research
URA07/28/EXP	A pilot study to investigate the impact of a clinical librarian service on the decision making of resident doctors and the quality of information they provide to patients.	Margaret Paterson	4/11/07				Approved	20/11/07		A		None – observational research
URA07/29/EXP	2D hand-held dynamometer evaluation.	Mr Marcus King	6/11/07				Declined			A		None – observational research
URA07/30/EXP	Brain injury patient interactions study.	Mr Julian Verkaaik	6/11/07				Approved	22/12/07		A		None – observational research
URA07/31/EXP	Studies of suicide, self harm and related issues using New Zealand national databases.	Dr Annette Beautrais	9/11/07				Received			A		None – observational research
URA07/32/EXP	The impact of decreasing use of gastric decontamination on increasing trends of self-harm behaviour in the Christchurch Hospital emergency department.	Dr Annette Beautrais	9/11/07				Approved	12/11/07		A		None – observational research
URA07/33/EXP	Bereavement support after suicide: appraisal and acceptability amongst families.	Dr Annette Beautrais	9/11/07				Approved	17/01/07		A		None – observational research
URA07/34/EXP	US Department of Housing Healthy Homes Technical Study.	Caroline Shorter	11/11/07				Ethical approval not required			A		None – observational research
URA07/35/EXP	Recurrent staphylococcus aureus bloodstream infection – a case series.	Dr Paul Huggan	8/12/07				Approved	18/12/07		A		None – observational research

## Applications considered in 'closed' meetings

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
URA/07/01/005	Randomised, open label, six-sequence, three-period cross-over study to investigate the relative bioavailability of three oral formulations of RO4607381 in healthy subjects.	Assoc Prof Richard Robson	16/01/07	29/01/07	Approved		Closed	23/02/07	Christchurch Clinical Studies Trust	B	F Hoffmann-La Roche Inc	Mr and Mrs J McManus
URA/07/04/031	A phase II study to assess the safety, tolerability, and efficacy of MK-0822 (Cathepsin-K inhibitor) in the treatment of women with breast cancer and established bone metastases (MBD).	Dr Chris Wynne	17/04/07	30/04/07	Approved		Approved	5/06/07	Christchurch Clinical Studies Trust	B	Merck Sharp and Dohme	Mr and Mrs J McManus
URA/07/08/062	Safety, tolerability, pharmacokinetics and pharmacodynamics of LY2405319 after multiple subcutaneous injections in subjects with type 2 diabetes. Protocol #11K-MC-GLUD.	Assoc Prof Richard Robson	26/08/07	20/08/07	Approved		Approved	26/09/07	Christchurch Clinical Studies Trust	B	Chorus LRL	Mr and Mrs J McManus
URA/07/10/077	Randomised, ascending, single-dose, double-blinded, placebo-controlled study to assess the safety, tolerability, pharmacodynamics and pharmacokinetics of subcutaneous and intravenous administration of AMG-195 in healthy subjects. Protocol 20070163.	Dr Chris Wynne	9/10/07	29/10/07	Approved subject to conditions		Approved subject to conditions		Christchurch Clinical Studies Trust	B	Amgen Inc	Mr and Mrs J McManus – pending