



Central Regional Ethics Committee

Annual Report

January 2006 to December 2006

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This report provides an overview of the work of the Central Regional Ethics Committee from 1 January 2006 to 31 December 2006. The report was presented to the Central Regional Ethics Committee at its meeting on 10 April 2007.

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

Chairperson's Report

It has been a privilege to serve as Chairperson for the Central Regional Ethics Committee following Helen Colebrook's resignation. In Helen's absence, legal expertise was available to the committee through the secondment of Jane Herschell. Her advice was sought on a number of occasions, most notably in correspondence with the Ombudsman over material sought under the Official Information Act 1982 and to which I refer elsewhere in the report (see 'Issues for the Committee'). Regrettably Dr David Sinclair also resigned late in the year due to his relocation to Auckland and we have greatly missed his expertise in epidemiology and experience of public health. He has since been appointed to the Northern X Regional Ethics Committee.

A considerable amount of time, at least from the Chairperson's point of view, has been devoted to issues related to the 2005 draft Annual Report, in which two complaints were mentioned. A transparent and fair process required that those involved were given opportunity to respond before the report was finalised. This process of consultation became more protracted than we would normally expect.

In my view, one issue facing ethics committees is the amount of new information that has to be digested and implemented as research and technology continually impact medical research. For instance, in the last quarter of the year, substantial reports were received on *Review of Applications for Established Human Embryonic Stem Cell Research*; also, from the Advisory Committee on Assisted Reproductive Technology, on *Use of Gametes and Embryos in Human Reproductive Research*; and there was a valuable discussion document from the Ministry of Health, *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes*. In about the same period, the National Ethics Advisory Committee presented its *Ethical Guidelines for Observational Studies*, and the first applications for expedited review appeared. Together these documents represent a lot of information, some of it quite specialised, for an ethics committee to absorb and apply well.

The committee's tasks would not be sustainable without the support it receives from its administrators, Claire Yendoll and Jan Ostnes, and the guidance and constructive advice provided by Sally Cook, National Co-ordinator.

Trevor James
Chairperson

Committee Membership

Appointments

The following members were appointed in November 2004 by the Minister of Health, pursuant to section 11 of the New Zealand Public Health and Disability Act 2000.

Chairperson (until June 2006)

Helen Colebrook	BA, LLB, LLM (Hons)
Representation	Lay member
Member category	Lawyer
Gender	Female
Date of appointment	November 2006
Term of appointment	3 years
Retirement date	November 2009
Professional affiliations	Lawyer
Iwi affiliations	None

Chairperson (from July 2006)

Trevor James	BA, BD, PhD (Lon)
Representation	Lay member
Member category	Community representative
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Retirement date	November 2007
Professional affiliations	Canon Theologian, Diocese of Waikato
Iwi affiliations	None

Deputy Chairperson

Jacqui Virtue	MBChB, FRNZCGP, DipGP
Representation	Non-lay member
Member category	Health professional
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Retirement date	November 2007
Professional affiliations	General Practitioner, Regional Director, General Practice Education Programme, Royal New Zealand College of General Practitioners
Iwi affiliations	None

Members

Mohamad Naseen (Joe) Asghar MSc, MBA, FCPP(UK), FRPharmS(UK), Hon FFPH(UK), MPS, Reg Pharm NZ

Representation Non-lay member
Member category Pharmacist
Gender Male
Date of appointment November 2006
Term of appointment 3 years
Retirement date November 2009
Professional affiliations Pharmacy Industry Training Organisation, New Zealand
HealthCare Pharmacists' Association
Iwi affiliations None

Matire Harwood

MBChB
Representation Non-lay member
Member category Biostatistician
Gender Female
Date of appointment November 2004
Term of appointment 3 years
Retirement date November 2007
Professional affiliations Medical practitioner, research fellow
Iwi affiliations Ngā Puhī, Hapū Mahurehure, Ngāti Rangi, Ngāti Hine

Maureen Holdaway

PhD
Representation Non-lay member
Member category Health researcher
Gender Female
Date of appointment November 2006
Term of appointment 2 years
Retirement date November 2008
Professional affiliations Massey University
Iwi affiliations Te Atihaunui-o-Paparangi, Ngāti Hauiti

John Kleinsman

MTheol, NZCE (Elec)
Representation Lay member
Member category Ethicist
Gender Male
Date of appointment November 2004
Term of appointment 3 years
Retirement date November 2007
Professional affiliations Researcher, the Nathaniel Centre; Lecturer, Wellington
Catholic Education Centre
Iwi affiliations None

Jacqueline Renouf	MA (1st class Hons), CQSW Dip Tch
Representation	Lay member
Member category	Community representative
Gender	Female
Date of appointment	July 2005
Term of appointment	3 years
Retirement date	July 2008
Professional affiliations	
Iwi affiliations	None
David Sinclair	MBChB, DComH, FAFPHM
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	November 2004
Term of appointment	2 years
Retirement date	November 2006
Professional affiliations	Public health medical specialist
Iwi affiliations	None
Guy Taylor	MBChB, MRCP(UK), FRACP, Dip MsM (Hons)
Representation	Non-lay member
Member category	Health researcher
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Retirement date	November 2007
Professional affiliations	Rheumatologist and clinical audit co-ordinator, Whanganui District Health Board
Iwi affiliations	None
Anne Tuffin	MPhil (Education)
Representation	Lay member
Member category	Community representative
Gender	Female
Date of appointment	November 2006
Term of appointment	3 years
Retirement date	November 2009
Professional affiliations	Health promoter/educator
Iwi affiliations	None

Dianne Wepa	BSW, CQSW, Pgrad Dip, MPhil, MANZASW
Representation	Lay member
Member category	Community representative
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Retirement date	November 2007
Professional affiliations	Senior Lecturer, Eastern Institute of Technology, Hawkes Bay
Iwi affiliations	Ngāti Kahungunu
Elaine Papps	RN, BA, Med (Distinction), PhD
Representation	Non-lay member
Member category	Health practitioner
Gender	Female
Date of appointment	December 2006
Term of appointment	3 years
Retirement date	December 2009
Professional affiliations	Director of Nursing, Hawke's Bay District Health Board
Iwi affiliations	None

Changes to membership

Helen Colebrook resigned as Chairperson of the committee in June 2006. Trevor James was appointed as Chairperson in July 2006. Jane Herschell provided legal expertise for the committee during Helen Colebrook's leave of absence from August to December. Dr David Sinclair resigned from the committee in September 2006. Dr Elaine Papps was appointed in December 2006. Members who were appointed until November 2006 agreed to continue on the committee until the new appointments were made.

Members' attendance in 2006

Member	M/F	Lay/ non-lay	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Helen Colebrook (lawyer)	F	L	Y	Y	Y	Y	Y	Leave of absence						5/5
Joe Asghar (pharmacist)	M	NL	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	10/11
Matire Harwood* (biostatistician)	F	NL	Y	Y	Y	Maternity leave			Y	A	Y	Y	Y	7/8
Maureen Holdaway* (health researcher)	F	NL	Y	A	Y	A	Y	Y	Y	Y	Y	Y	A	8/11
Trevor James (community rep)	M	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
John Kleinsman (ethicist)	M	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
David Sinclair (health practitioner)	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Resigned		9/9
Guy Taylor (health researcher)	M	NL	Y	Y	Y	Y	Y	A	A	Y	Y	Y	Y	9/11
Jacqui Virtue (health practitioner)	F	NL	Y	Y	Y	Y	Y	A	A	Y	Y	Y	Y	9/11
Dianne Wepa* (community rep)	F	L	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	10/11
Jacqueline Renouf (community rep)	F	L	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	10/11
Anne Tuffin (community rep)	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/11
Jane Herschell (lawyer)	F	L	Jane Herschell provided legal expertise while Helen Colebrook was overseas						Y	Y	Y	Y	Y	5/11
No. of members present			12	11	12	10	11	7	9	8	11	10	9	
No. of applications			12	9	12	8	17	15	6	5	8	16	7	115

* = Māori member

Y = Present

A = Apology

Training

New member training

New members of the health and disabilities ethics committees were offered training in April 2006. The training was held in Wellington. The following member of the Central Regional Ethics Committee attended the Wellington training: Jacqueline Renouf.

Ongoing training

Ongoing training for all members was held in June 2006. For convenience, the one-day programme was run in three centres: Christchurch on 20 June, Auckland on 27 June and Wellington on 29 June. The following members from the Central Regional Ethics Committee attended this training: Trevor James, Jacqui Virtue, Jacqueline Renouf, David Sinclair, Maureen Holdaway, Guy Taylor and John Kleinsman. The two administrators attended the Wellington training day.

New Zealand Bioethics Conference

The New Zealand Bioethics Conference was held in Dunedin from 10–12 February. The following members of the Central Regional Ethics Committee attended: Helen Colebrook, Jacqui Virtue and John Kleinsman.

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 following members of the Central Regional Ethics Committee attended: Matire Harwood, Dianne Wepa and Maureen Holdaway.

Chairpersons' meetings

Three meetings of the chairpersons of the multi-region and the regional ethics committees were held in 2006. Helen Colebrook attended the chairpersons' meeting on 9 February 2006 and Trevor James attended the chairpersons' meeting on 5 and 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.

Training for review of applications using cells from established human embryonic stem cells lines for research purposes

This training session was held in Wellington on 15 August 2006. The following member of the Central Regional Ethics Committee attended: Jacqui Virtue (Deputy Chairperson).

Approval by the Health Research Council

The committee is approved by the Health Research Council until December 2007.

United States Department of Health and Human Services Registration

The Central 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: IRB00004666 – Central 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	Māori consultation is required for all studies except retrospective review of patient/client notes or data, some student projects and studies specifically excluding Māori participants.
Number of applications returned through insufficient consultation on cultural issues	35
Process the committee has for following through on consultation	Cultural issues are raised with the researcher. The committee requests the result of consultation and its proposed implementation before approval is given.
Cases of unsatisfactory reasons for not including Māori	0
Mechanisms in place to facilitate consultation with Māori by researchers	Researchers are referred to Capital & Coast District Health Board, Māori Health Development Unit. Other suitable organisations for referral may be suggested by the committee.
Examples of Māori not being included in research	Research conducted solely in Pacific communities may involve procedures that are culturally sensitive to Māori participants.

Most of the members of the Central Regional Ethics Committee share the responsibility in terms of matters pertaining to Māori so that it does not become the sole responsibility of the three Māori members.

The committee has received a range of protocols that still have not considered Māori consultation. A hui for Māori members of all the committees, which was held during the year, considered this component as part of Section F. A discussion document was circulated to all committees. The chairpersons' meeting has adopted the recommendations within the document.

We continue to encourage applicants to capture ethnicity data alongside other vital statistics so that the capacity for recording Māori participation rates in research is increased.

Dianne Wepa

Applications

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

Central Regional Ethics Committee statistics for January–December 2006

Applications approved by full committee	83
Applications deferred as at time of report	3
Applications declined	1
Applications carried forward (approved subject to conditions)	12
Approval not required	12
Studies withdrawn by researcher	2
Studies terminated by sponsor	0
Studies transferred to Multi-region Ethics Committee	2
Total number of applications considered by the full committee	115
Applications considered under delegated authority (CPD)	24
Total number of applications received	139
Applications deferred and subsequently approved	8

Other committee statistics

Number of matters arising	3
Number of general business items	40
Number of amendments reviewed by committee	3
Number of amendments approved under CPD	72

Audit or matters not requiring ethical approval

One project was confirmed as audit not requiring ethical approval in accordance with the section 4.1, page 26, of the Operational Standard for Ethics Committees, March 2002.

Innovative practice

No innovative practice applications were reviewed.

School science fair project

Seventeen school science fair projects were reviewed in 2006.

Second opinions

There were no second opinions sought.

Complaints

TRK/03/05/014 – The collection and analysis of blood serum in a selected population to investigate serum dioxin levels in residents who live, or have lived, near the former Ivon Watkins Dow chemical factory in Paritutu, New Plymouth

This complaint was reported in the 2005 Annual Report. However, it is worth noting that in December 2006 the Institute of Environmental Science and Research Ltd (ESR) advised the Central Regional Ethics Committee that it has:

invested a significant amount of time and effort to upgrade its policies, protocols and procedures – these activities are ongoing. For example, ESR has established an external working group to consider ethical and cultural issues associated with genetics to support our emerging health related research programmes.

Issues for the Committee

TRK/03/05/014 – The collection and analysis of blood serum in a selected population to investigate serum dioxin levels in residents who live, or have lived, near the former Ivon Watkins Dow chemical factory in Paritutu, New Plymouth

In 2005 this particular project was the subject of a complaint and in 2006 it was subject to an application to the Ombudsman by TV3 for access to a copy of Appendix O. Because the study involved a very small number of participants whose confidentiality might have been compromised by access to this information, the Central Regional Ethics Committee as well as ESR and the Ministry of Health opposed this application. Although the Ombudsman did not agree with the objections the committee raised, the issue underlines the tension between maintaining confidentiality and complying with requests for information obtained by application to the Official Information Act 1982 (OIA).

This is an issue for researchers and needs to be noted. ESR has referred to this in correspondence with the committee. It has specifically mentioned 'the tension between maintaining study participant confidentiality as prescribed by ethics committees and release of information via OIA processes etc that ESR continues to experience. Other research organisations would be equally conflicted in a similar situation'.

Guidelines for the Chairperson's Delegation

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

The Chairperson or Deputy Chairperson may approve under delegated authority the following:

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

The Chairperson may approve the 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 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 and by the Chairperson under chairperson's discretion from January to December 2006.

One application was considered in a 'closed' meeting.

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
CEN/06/02/001	An evaluation of a rural Mental Health Service in the Waimarino and Rangitikei regions of the Whanganui District Health Board	Mr Ronald Kinsey	12/12/2005	14/02/2006	Approved subject to conditions		Approved	7/04/2006	Good Health Wanganui	A	GHW Mental Health Service. Research grants.	Ngati Rangi Ohakune; Te Hunga Piki-Te-Ora Good Health Wanganui
CEN/06/02/002	Dioxin exposure levels and health effects in phenoxy herbicide production workers	Dr Neil Pearce	24/01/2006	14/02/2006	Deferred	Same study cohort as CEN/06/02/004 OSEC 2.6, 70	Approved	19/05/2006	Massey University	A	Health Research Council of NZ	Lis Ellison-Loschmann; Tania Slater (CPHR); Chris Cunningham (Research Centre for Maori Health and Development)
CEN/06/02/003	Intensive care nurses' perceptions of 'good' end-of-life care for patients who have had treatment withdrawn or withheld	Ms Catherine Hine	26/01/2006	14/02/2006	Approved subject to conditions		Approved	31/03/2006	Eastern Institute of Technology	Nil	Hawkes Bay Medical Research Foundation	Rapai Pohe; Maori Health; Hawkes Bay DHB
CEN/06/02/004	A serum study of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) in workers at the Dow AgroSciences (DAS) New Plymouth site at the time of manufacture of 2,4,5-T (1969-87)	David McBride	26/01/2006	14/02/2006	Deferred	Same study cohort as CEN/06/02/002 OSEC 2.6, 70	Approved	25/05/2006	University of Otago	A	The Dow Chemical Company	Ngai Tahu Research Committee; Te Whare Punanga Korero
CEN/06/02/005	Evaluation of the MidCentral District Health Board, Palliative Care Partnership between general practice and Arohanui Hospice	Ms Eileen McKinlay	26/01/2006	14/02/2006	Approved subject to conditions		Approved	8/03/2006	Wellington School of Medicine and Health Sciences	Nil	Mid Central Health District Health Board	Oriana Paewai; Maori Health Advisor; MidCentral 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
CEN/06/02/006	Older Maori and medication management, regulation and facilitation: characteristics, influences, indicators and attitudes of medication taking practice and behaviour in older Maori	Bevan Clayton-Smith	27/01/2006	14/02/2006	Approved subject to conditions		Approved	1/06/2006	Massey University	Nil	Application made to HRC	Brendan Stevenson; Te Hoe Nuku Roa; Marama Parore-Katene; Pharmac; Carole Fernandez Haami; Te Mauri o Rangitaane o Manawatu
CEN/06/02/007	An exploration of ideas about chlamydia testing: a qualitative research project involving focus groups with 16–24 years olds and health professionals	Dr Sally Rose	27/01/2006	14/02/2006	Approved subject to conditions		Approved	4/08/2006	Wellington School of Medicine and Health Sciences	Nil	University of Otago Research Grant	Christine Rimene; Ngai Tahu Research Consultation Committee
CEN/06/02/008	Determining the regional burden of chlamydia by auditing laboratory data	Dr Sally Rose	27/01/2006	14/02/2006	Approved subject to conditions		Approved subject to conditions	28/02/2007	Wellington School of Medicine and Health Sciences	A	University of Otago	
CEN/06/02/009	Cognitive behavioural therapy (CBT) in Aotearoa: CBT for depression with Maori tangata whaiora	Dr Simon Bennett	27/01/2006	14/02/2006	Approved subject to conditions		Approved	16/03/2006	Massey University	A	HRC	Te Whare Marie; C&CDHB; Oranga Hinengaro; HVDHB
CEN/06/02/010	The association of insulin-like growth factor with breast density	Ms Naomi Brewer	27/01/2006	14/02/2006	Approved subject to conditions		Withdrawn		Massey University	Nil	Application made to HRC	Dr Madeleine Wall; Dr Lis Ellison-Loschmann
CEN/06/02/011	Airway inflammation and irreversible lung function decline in asthmatic children	Prof Jeroen Douwes	27/01/2006	14/02/2006	Approved subject to conditions		Approved	31/03/2006	Massey University	A	Funding sought from HRC	Chris Cunningham; Lis Ellison Loschmann; Te Pumanawa Hauora; Massey University

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
CEN/06/02/012	A multi-centre, randomised, double-blind, placebo-controlled, four-way incomplete block crossover study to examine efficacy, safety, tolerability, pharmacodynamics and pharmacokinetics of single and repeat administration of three inhaled doses (25, 100 and 400 ug) of GW642444	Dr Dean Quinn	27/01/2006	14/02/2006	Approved subject to conditions		Approved	5/04/2006	P3 Research Wellington	B	GlaxoSmith Kline	Colleen Wineera; HE&R Services
CEN/06/03/013	Physiological heat stress responses to cycling exercise in thermo neutral and warm environment at the same relative intensity of effort	Dr Andrew Edwards	15/02/2006	14/03/2006	Approved subject to conditions		Approved	3/05/2006	UCOL – select	A	UCOL	Te Atawhai Mataira; Director of Maori Liaison; UCOL
CEN/06/03/014	Perceived changes in quality of life related to stages of change for participants in a phase 11 cardiac rehabilitation exercise programme	Ms Wilma Tielemans	23/02/2006	14/03/2006	Approved subject to conditions		Approved	18/05/2006	Massey University – select	A	Massey University, Heart Foundation	Nick Roskrige; KaiArahi Maori to Pro Vice Chancellor; College of Sciences
CEN/06/03/015	What is the maximum rate that fructose co-ingested with maltodextrin can be oxidised during endurance exercise and how does this affect cycling performance?	Mr David Rowlands	23/02/2006	14/03/2006	Deferred	Relationship with sponsor unclear OSEC 2.4, 59. Compensation may need to be Declaration B	Approved	26/04/2006	Massey University	A	Gatorade	Prof Chris Cunningham; Director; Research Centre for Maori Health and Development; Massey University
CEN/06/03/016	Patient and physician perception of disease activity in psoriatic arthritis measured by visual analogue scale or global assessment (Wellington arm)	Dr William Taylor	23/02/2006	14/03/2006	Approved subject to conditions		Approved	5/04/2006	Wellington School of Medicine and Health Sciences – select –	Nil		Kuini Puketapu; Maori Health Unit; Hutt Valley 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
CEN/06/03/017	An analysis of leg length differences in cycling: the effect of correctional techniques on stroke mechanics	Mr Michael Mann	23/02/2006	14/03/2006	Approved subject to conditions		Approved	22/03/2006	UCOL	A	UCOL	Te Atawhai Mataira; Director of Maori Liaison; UCOL
CEN/06/03/018	The effect of monosodium urate (MSU) on the inflammatory response of blood-derived immune cells from gouty and non-gouty individuals	Dr Rebecca Grainger	23/02/2006	14/03/2006	Approved subject to conditions		Approved	12/05/2006	Malaghan Institute of Medical Research	A	Health Research Council	Prof Chris Cunningham; Te Pumanawa Hauora; Massey University
CEN/06/03/019	Experimental analysis of word production difficulties in Parkinson's disease	Mr Shaun Hayward	23/02/2006	14/03/2006	Approved subject to conditions		Approved	7/04/2006	Victoria University of Wellington Capital & Coast DHB	Nil	Victoria University of Wellington	Not required
CEN/06/03/020	A double blind, placebo controlled, repeat dose study to determine the effect of two doses of GSK256066 to protect against AMP challenge in the lung in mild steroid-naïve asthmatics	Dr Dean Quinn	24/02/2006	14/03/2006	Approved subject to conditions		Approved	7/06/2006	P3 Research Wellington	B	GlaxoSmith Kline	Colleen Wineera; HE&R Services
CEN/06/03/021	Comparison of cut and paste with sutured autograft pterygium excision surgery	Dr Reece Hall	24/02/2006	14/03/2006	Approved subject to conditions		Approved	7/04/2006	Capital & Coast DHB	A	Capital and Coast District Health Board	Riki Nia Nia; Director Maori Health Development; CCDHB
CEN/06/04/022	The use of mobile phones to compensate for organisational and memory impairment in people with acquired brain injury. Part 2: characteristics associated with successful electronic cognitive aids use.	Corne Mackie	15/03/2006	11/04/2006	Approved subject to conditions		Transferred to Multi-Region Ethics Committee	8/06/1906	Massey University	A	Massey University	Turoa Haronga, Kaumatua for Massey University

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
CEN/06/04/023	Young adults and decision-making about the Meningococcal B immunisation: a pilot study	Dr Marian Bland	21/03/2006	11/04/2006	Approved subject to conditions		Approved	1/06/2006	UCOL	Nil	UCOL and MidCentral DHB	MidCentral DHB Maori Adviser
CEN/06/04/024	Hawke's Bay District Health Board Mental Health and Addiction Service (MH&AS). Facilitating recovery by developing connectedness.	Alasdair Williamson	22/03/2006	4/11/2006	Deferred	Needs to be resubmitted	Approved	7/09/2006	Hawkes Bay DHB	Nil	HBDHB Mental Health and Addiction Service	Rapai Pohe; Service Manager; Maori Health HBDHB
CEN/06/04/025	Verbal and nonverbal inhibitory control in stroke patients	Darshani Kumareswaran	23/03/2006	4/11/2006	Approved subject to conditions		Approved	17/05/2006	Victoria University of Wellington	Nil	No funding required	Kuini Puketapu; Hutt Valley DHB Maori Health Unit
CEN/06/04/026	A pilot study of inhaled nicotine delivery in smokers	Professor Julian Crane	24/03/2006	11/04/2006	Approved subject to conditions		Approved	11/05/2006	Wellington School of Medicine and Health Sciences	A	HRC	Smoking Cessation Services at Kokiri Marae; Tu Kotahi Maori Asthma Trust; Maori Research Review Committee; University of Otago
CEN/06/04/027	Prediction of prosthetic use: functional and social outcomes following a unilateral lower limb amputation	Karen Michalanney	24/03/2006	11/04/2006	Approved subject to conditions		Approved	4/05/2006	Wellington School of Medicine and Health Sciences	Nil	Amputee Society of Wellington and Wairarapa regions	Mr Brian Thompson; Maori Cultural Advisor

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
CEN/06/04/028	A randomised, double blind, placebo-controlled, parallel group, multicentre study to evaluate the efficacy and safety of GW685698X 200 mcg twice daily, GW685698X 200 mcg and 400 mcg once daily in the morning, and GW685698X 200 mcg and 400 mcg once daily in the evening compared with placebo for eight weeks in adolescent and adult subjects (12 years of age and older) with persistent asthma	Dr Dean Quinn	24/03/2006	11/04/2006	Deferred	Needs of adolescent participants not addressed OSEC 258	Transferred to Northern Y Ethics Committee	16/06/2006	P3 Research Wellington	B	GlaxoSmith Kline	Colleen Wineera, HE&R Services
CEN/06/04/029	Application of goal planning to the rehabilitation of people with acquired brain injury (ABI): a qualitative investigation	Dr William Levack	24/03/2006	11/04/2006	Approved subject to conditions		Approved	23/06/2006	Wellington School of Medicine and Health Sciences	A	Wgtn School of Med and Health Sciences	Dr Matire Harwood; MRINZ
CEN/06/04/030	Quantification of open wounds in patients using a hand-held laser scanner	Dr Rachelle Love	24/03/2006	11/04/2006	Approved subject to conditions		Approved	18/05/2006	Hutt Valley DHB	A	N/A	Hutt Valley DHB Kaitiaki Maori staff
CEN/06/04/031	Frequency of affected items from the World Health Organization classification of functioning, disability and health (ICF) in people with psoriatic arthritis (Wellington arm)	Dr William Taylor	28/03/2006	4/11/2006	Approved subject to conditions		Approved	5/07/2006	Wellington School of Medicine and Health Sciences	A	Grant from Group for Research and Assessment of Psoriasis and Psoriatic Arthritis	Maori Health Unit; Hutt Valley DHB
CEN/06/04/032	WHY survey (Wellbeing and Health of Youth). Population-based health and well being survey of Hawke's Bay Year 13 (Form 7) students and alternative education students	Sandy Keen	28/03/2006	11/04/2006	Deferred	Inadequate arrangements for participants' confidentiality and inadequate questionnaire OSEC 2.3 and 2.4	Withdrawn		Hawkes Bay DHB	Nil	Hawkes Bay DHB, MoH	Hawkes Bay DHB Maori Health Unit

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
CEN/06/04/033	Is C-Flex™ superior to standard continuous positive airway pressure in the treatment of moderate to severe obstructive sleep apnoea? Randomised controlled trial to assess marginal benefit in terms of patient compliance, sleepiness, psychomotor function and symptoms	Dr Angela Campbell	29/03/2006	11/04/2006	Deferred	No information sheet and consent form provided	Approved	19/05/2006	Wellsleep	A	To be advised	University of Otago Maori Research Review Committee; Ngai Tahu Research Consultation Committee
CEN/06/05/034	Do child asthmatics benefit from referral for specialist follow up from the emergency department	Ms Clare Pepper	24/04/2006	5/09/2006	Deferred	Insufficient information provided particularly on study design	Deferred		Capital & Coast DHB	Nil		Riki Nia Nia; Director; Maori Health Unit; CCDHB
CEN/06/05/035	The experiences of a group of rangatahi Maori with psychosis during the Tuakiri o te Tangata programme	Ms Menetta TeAonui	24/04/2006	9/05/2006	Approved subject to conditions		Approved subject to conditions		Lower North Island Severe Conduct Disorder Programme	Nil	Self-funded	CCDHB Early Intervention Service; Kuni Shepherd and Janine Olasa; Kai Manaaki; EIS
CEN/06/05/036	Medication administration via feeding tubes by patients and/or their carers – a qualitative study	Ms Lorraine Welman	24/04/2006	9/05/2006	Approved subject to conditions		Approved	10/08/2006	School of Pharmacy, University of Otago	Nil		Te Whare Rapuora – Maori Health Unit; Te Puawai Maori Women's Welfare League; Mid Central Health Kui/Kaumatua Ropu
CEN/06/05/037	In chronic obstructive pulmonary disease, what thoracic dimensions make the chest look 'hyperinflated' and how do these relate to measurable lung volumes?	Dr David Jones	24/04/2006	9/05/2006	Approved subject to conditions		Approved	27/10/2006	Capital & Coast DHB	Nil		Colleen Wineera; HE&R Services Ltd

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
CEN/06/05/038	Leading change: nursing staff perceptions of morale, job satisfaction and patient care on a hospital medical ward	Dr Jenny Carryer	24/04/2006	9/05/2006	Ethical approval not required	OSEC 4.0, 138	Ethical approval not required		MidCentral DHB	Nil		DHB Kaiwhakaruru Hauoria Maori Advisor
CEN/06/05/039	Pilot study of oral fluid collection in active and passive marijuana smokers	Dr Stuart Dickson	24/04/2006	9/05/2006	Approved subject to conditions		Approved	5/07/2006	ESR	A	ACC	Riki Nia Nia; Maori Health Development Unit; CCDHB
CEN/06/05/040	Nursing staff satisfaction with the acute pain management service in a surgical ward setting: a pilot study	Ms Erica Gleeson	24/04/2006	9/05/2006	Ethical approval not required	OSEC 4.0, 138	Ethical approval not required		MidCentral DHB	Nil	MidCentral Health, Anaesthetic Department	
CEN/06/05/041	The effects of massage on children	Ms Jill Morgan	24/04/2006	9/05/2006	Approved subject to conditions		Approved	8/06/2006	Eastern Institute of Technology	Nil	Therapeutic Massage Association	Dianne Wepa; EIT
CEN/06/06/042	Development of a health service specific asset planning methodology model: case study of MidCentral District Health Board Child and Adolescent Oral Health Service	Mr John Manderson	26/05/2006	13/06/2006	Ethical approval not required	OSEC 4.0, 138)	Ethical approval not required		MidCentral DHB	Nil	N/A	
CEN/06/06/043	Evaluative audit following the increased dose in syntocinon (medication) given for the management for third stage labour at MidCentral Health	Ms Leona Dann	26/05/2006	13/06/2006	Approved	Retrospective review of records	Approved	16/06/2006	Massey University MidCentral DHB	Nil		Retrospective review of records only
CEN/06/06/044	The lived experience of supporting a family member with an intellectual disability who is dying in a community setting: an interpretive analysis of family member's accounts	Ms Susan Marlow	26/05/2006	13/06/2006	Approved subject to conditions		Approved	13/07/2006	Victoria University of Wellington	Nil	Research grant from Nursing Education and Research Foundation	Whanau Support Worker; Te Omanga Hospice; Lower Hutt

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CEN/06/06/045	MidCentral Health (MCH) nursing staff's understanding of, and attitudes towards the organisation's professional development and recognition programme (PDRP)	Prof Jenny Carryer	26/05/2006	13/06/2006	Ethical approval not required	OSEC 4.0, 138	Ethical approval not required		MidCentral DHB	Nil	Internally-funded nursing budget	
CEN/06/06/046	Constraint induced movement therapy in a paediatric setting – children with hemiplegic cerebral palsy (a pilot study)	Ms Khami Hatcher	26/05/2006	13/06/2006	Approved subject to conditions		Approved	13/07/2006	Hawkes Bay DHB	A	HBDHB	Querida Whatuira-Strickland; Whakawateatia; HBDHB
CEN/06/06/047	A randomised clinical trial of venepuncture versus heel stick for blood sampling in term newborn babies	Dr Harshad Patel	26/05/2006	13/06/2006	Approved subject to conditions		Approved	3/08/2006	Capital & Coast DHB	A	N/A	Mr Riki Nia Nia; Maori Health Development Unit; CCDHB
CEN/06/06/048	The inter-relationship between exposure to music and noise induced hearing loss	Mr Sargunamoorthy Sivaraj	26/05/2006	13/06/2006	Approved subject to conditions		Approved	4/08/2006	Capital & Coast DHB	A	PhD student funds	Riki Nia Nia; Maori Health Unit; CCDHB
CEN/06/06/049	In search of improved standards of care: a qualitative study of adolescent experiences in mental health	Ms Peggy Dupuis	26/05/2006	13/06/2006	Approved subject to conditions		Approved	14/09/2006	MidCentral DHB	A	N/A	Oranga Hinengaro; Maori Child; Adolescent and Family Mental Health Service
CEN/06/06/050	Will clinical pilates decrease pain and improve function in chronic low back pain sufferers? A pilot study	Ms Lee-Anne Taylor	26/05/2006	13/06/2006	Approved subject to conditions		Approved	5/07/2006	Eastern Institute of Technology	A	No additional funding required	Rapai Pohe; Maori Health Unit; Aramanu Mitchell; Ngati Kahungunu Iwi
CEN/06/06/051	An exploration of the sexuality needs of women with enduring mental illness	Ms Joanna Davison	26/05/2006	13/06/2006	Approved subject to conditions		Approved	13/07/2006	Whitireia Community Polytechnic	Nil	Graduate Research fund, School of Health Sciences	Areta Koopu; Rua Moko; CCDHB
CEN/06/06/052	A retrospective audit of the use of intravenous fentanyl in labour in the maternity unit in Wanganui	Ms Robyn McDougal	26/05/2006	13/06/2006	Approved	Retrospective review of records	Approved	16/06/2006	Massey University	Nil		

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CEN/06/06/053	Tackling the chlamydia epidemic in New Zealand youth: an RCT in primary care	Dr Beverley Lawton	26/05/2006	13/06/2006	Approved subject to conditions		Approved	26/07/2006	Wellington School of Medicine and Health Sciences	Nil	Applied to HRC	Christine Rimene; Ngai Tahu Research Consultation Committee; Ria Earp; Maori Health Directorate; MoH
CEN/06/06/054	The test-retest reliability and inter-rater reliability amongst final year physiotherapy students of the Australian Therapy Outcome Measures (AusTOMs) for Physiotherapy in a New Zealand rehabilitation setting	Geoffrey Coe	26/05/2006	13/06/2006	Approved subject to conditions		Approved subject to conditions		School of Physiotherapy	A	Stationery will be paid for by the investigators	Lynda Kirkman; Kaitiaki with Taeoria Tinana
CEN/06/06/055	The inter-rater reliability and test-retest reliability of a novel isometric strength measure amongst physiotherapy students, based on the concept of movement impairment syndromes of the shoulder region on people with musculoskeletal disorders of the upper limb	Geoffrey Coe	26/05/2006	13/06/2006	Approved subject to conditions		Approved subject to conditions		School of Physiotherapy	A	Cost of stationery will be met by researcher	Lynda Kirkman; Kaitiaki with Taeora Tinana
CEN/06/06/056	Effects of whole body vibration on delayed onset muscle soreness after downhill running	Dr Suzanne Broadbent	26/05/2006	13/06/2006	Approved subject to conditions		Approved	26/07/2006	Massey University	A	Vibragym platform donated by Vibragym Inc. Other funds from Massey University	Nick Roskruge; Maori adviser; Massey University
CEN/06/06/057	An evaluation of the effects of staff education on the management of patients who require 1:1 observation	Ms Angela Dick	26/05/2006	13/06/2006	Approved	Retrospective review of records only	Approved	16/06/2006	MidCentral DHB	Nil	Retrospective review of records	

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CEN/06/06/058	A community based health needs assessment of the oral health needs of Maori mothers enrolled with a Wellington-based Maori health provider	Ms Charrissa Makowharemahihi	26/05/2006	13/06/2006	Approved subject to conditions		Approved	5/07/2006	Wellington School of Medicine and Health Sciences	Nil	Researcher's own funds	Bridget Robson; Eru Pomare Centre
CEN/06/07/059	Adolescent oral health and oral health care: a health services research investigation	Dr Lyndie Foster Page	23/06/2006	11/07/2006	Approved subject to conditions		Approved	27/07/2006	Taranaki Base Hospital	Nil	Grant from Maurice & Phyllis Paykel Trust	Hayden Wano; Tui Ora Ltd; Taranaki; Sam Bishara; Te Puni Kokiri Taranaki; Greg White Te Whare Punga Korero
CEN/06/07/060	An investigation into the perceived value of music therapy interventions in an acute adolescent mental health setting	Andrew Tutty	23/06/2006	11/07/2006	Approved subject to conditions		Approved	14/09/2006	Massey University	A	Own funds	Mere Hammond; Rangatahi Unit; Kenepuru Hospital
CEN/06/07/061	Collection of tumour tissue from brain tumour patients for preliminary studies into dendritic-cell based therapy	Ian Hermans	23/06/2006	11/07/2006	Approved subject to conditions		Approved	31/08/2006	Malaghan Institute of Medical Research	Nil	HRC Sir Charles Hercus Senior Research Fellowship Application to Cancer Society	Riki Nia Nia; Maori Health Unit; CCDHB
CEN/06/07/062	Increasing understanding of factors that impact upon the quality of life of elderly women with multiple chronic illness	Pauline Lowe	23/06/2006	11/07/2006	Approved subject to conditions		Approved	1/09/2006	Capital & Coast DHB	Nil	Application to Nurses and Midwives Scholarship Fund	Darrin Parata; Runanga office; Te Ati Awa Ki Whakarongotai Inc; Kapiti
CEN/06/07/063	Child-parent wellbeing in a paediatric ward: the role music therapy can play in supporting children and their parents facing the challenge of hospitalisation	Carolyn Ayson	23/06/2006	11/07/2006	Approved subject to conditions		Approved	3/08/2006	Massey University	A	Own and institution resources	Maori Health Adviser; Hutt Valley District Health Board

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CEN/06/07/064	Peri-natal mental health policy: young mothers' formal mental health support during pregnancy	Jane Parsons	23/06/2006	11/07/2006	Approved subject to conditions		Approved	14/09/2006	Massey University	A	Graduate Research Fund, Massey University	Research Supervisor; Massey University; Service Leader Child Adolescent and Family Mental Health; maternal mental health specialists
CEN/06/07/065	Identifying characteristics of patients admitted to Hutt Hospital medical service with cellulitis and their suitability for treatment at home	Saira Dayal	23/06/2006	11/07/2006	Approved subject to conditions		Approved	27/07/2006	Hutt Valley DHB	Nil	Funding and Planning, Hutt Valley DHB	Kuini Puketapu, Maori Health Advisor, HVDHB
CEN/06/07/066	The nature, incidence and frequency of injecting behaviour amongst participants in the lower North Island methadone programmes	Dr Graeme Judson	23/06/2006	11/07/2006	Approved subject to conditions		Approved	11/08/2006	Wairarapa DHB	A	Researcher's CME Fund	Stephanie Turner; Maori Health; Wairarapa DHB
CEN/06/07/067	Investigation of the validity of the distress and impact thermometer in the New Zealand population	Cheryl Wooley	23/06/2006	11/07/2006	Approved subject to conditions		Approved	10/08/2006	Massey University	Nil	Application to Mid Central Health	Simon Bennet; Lisa Charrington; Ruroa Haronga; John Waldon; Oriana Paewae (Maori Health Unit)
CEN/06/07/068	The effect of a physical exercise programme on the morphological, psycho-emotional and coronary risk profiles of staff members at a tertiary institution	Sonja Dreyer	23/06/2006	11/07/2006	Approved subject to conditions		Approved	26/07/2006	UCOL	A	UCOL research grant	Te Arawhai Mataira; UCOL
CEN/06/07/069	An acceptability study of sinus and a novel nicotine pouch substitute in New Zealand smokers	Professor Julian Crane	23/06/2006	11/07/2006	Approved subject to conditions		Approved	19/10/2006	Wellington School of Medicine and Health Sciences	A	Grant from Asthma and Respiratory Foundation of NZ	Ngai Tahu Research Consultation Committee; Sharon Reid; Kokiri Marae
CEN/06/07/070	Evaluation of Dialectical Behaviour Therapy Programme	Melanie Simons	23/06/2006	11/07/2006	Approved		Approved	20/07/2006	Massey University	A	University funding allocation	Turoa Haronga; Midcentral Health Mental Health Service

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CEN/06/07/071	β-Adrenoceptor polymorphisms and the risk of asthma mortality: a case-control study	Dr Rod A Lea	23/06/2006	11/07/2006	Approved subject to conditions		Approved	7/09/2006	ESR	Nil	N/A	Colleen Wineera; H&E Services
CEN/06/07/072	Analysing inter-agency activity – a case study examining the relationship between a health and education state sector that provides services for children with special needs	Carlene Receveur	23/06/2006	11/07/2006	Ethical approval not required		Ethical approval not required		Hawkes Bay DHB	Nil	N/A	
CEN/06/07/073	The adolescent cancer experience	Dr Anne Mitchell	26/06/2006	11/07/2006	Deferred	Committee not happy with researchers being present at focus groups OSEC, Appendix 5, 336	Approved	21/09/2006	Capital & Coast DHB	Nil	Child Cancer Foundation	Colleen Wineera; HE&R Services
CEN/06/08/074	South Wairarapa Kaumatua aged 49 plus health care needs analysis study	Mr Joe Howells	21/07/2006	8/08/2006	Declined	Previous participants' right to decline should be respected	Declined		Wairarapa Community PHO	Nil	DHB	Marae Committee; Te Hauora and Whaiora Whanui
CEN/06/08/075	The prevalence of cervical dysplasia and the management of abnormal cervical smears in a New Zealand general practice	Dr Nadine Nicolaai	21/07/2006	8/08/2006	Approved	Retrospective review of patient data only	Approved	10/08/2006	National Cervical Screening Programme -select-	Nil	Retrospective review of records only	
CEN/06/08/076	The diagnosis of pars interarticularis stress fractures in the lumbar spine – the association between patient symptoms and findings on scintigraphy	Chris Gregg	21/07/2006	8/08/2006	Approved subject to conditions		Approved	25/08/2006	Wakefield Hospital Pacific Radiology	A	Internally funded	University of Otago; Maori consultation committee
CEN/06/08/077	Dioxin exposure levels and health effects in fire fighters	Prof Neil Pearce	21/07/2006	8/08/2006	Approved subject to conditions		Approved subject to conditions	22/12/2006	Massey University	A	New Zealand Fire Service	Grant Knuckey; Te Atiawa iwi

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CEN/06/08/078	Experiences of patients participating in specialist nurse-managed heart failure clinics: an exploratory study	Ms Judy Dewar	21/07/2006	8/08/2006	Deferred	Application inadequate. Questionnaire needs rewriting	Approved	19/10/2006	Hutt Valley DHB	Nil	Hutt Hospital Heart Trust	Kuini Puketapu; Maori Health Unit; HVDHB; Christine Pihama; Coronary Care Unit Maori Health
CEN/06/08/079	Does therapy with an inhaled combination of corticosteroids and long-acting beta-agonists improve clinical outcome in asthma?	Dr Kyle Perrin	21/07/2006	8/08/2006	Approved subject to conditions		Approved	7/09/2006	Medical Research Institute of New Zealand	A	Glaxo Smith Kline	Colleen Wineera; HE&R Services
CEN/06/09/080	Does Gentamycin prophylaxis at the time of removal of urinary catheter prevent infection in patients after total joint arthroplasty? A prospective randomised study	Dr Arvind Puri	24/08/2006	12/09/2006	Approved subject to conditions		Approved subject to conditions		Taranaki Base Hospital	Nil		Still awaited
CEN/06/09/081	Survey of rheumatology outpatients to determine their means of obtaining, and preferred content of, information about arthritis	Dr Andrew Harrison	24/08/2006	12/09/2006	Approved subject to conditions		Approved subject to conditions	13/10/2006	Hutt Hospital	A	Wellington Regional Rheumatology Unit research fund	Maori Health Unit; Hutt Valley DHB
CEN/06/09/082	How can midlife nurses be supported to deliver bedside care in the acute clinical services until retirement?	Ms Caroline Dodsworth	24/08/2006	12/09/2006	Ethical approval not required	Operational Standard for Ethics Committees 4.0, 138	Ethical approval not required		MidCentral DHB	Nil	PN Medical Trust Scholarship	None
CEN/06/09/083	A study of individual variations in the rate and volume of saliva produced stimulated by chewing of model system snack bars	Ms Sandra Kim	29/08/2006	12/09/2006	Approved subject to conditions		Approved	25/10/2006	Crop and Food Research	Nil	Funded by FORST	
CEN/06/09/084	Management of venous thrombo-embolism in Hutt Hospital	Dr Joanne Holden	29/08/2006	12/09/2006	Approved subject to conditions		Approved	2/11/2006	Hutt Valley DHB Kowhai Health Ropata Medical Centre	Nil		Kuini Puketapu; Maori Health Advisor; Hutt Valley DHB

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CEN/06/10/085	A cultural approach to music therapy in New Zealand: a Maori perspective	Dennis Kahui	22/09/2006	10/10/2006	Approved subject to conditions		Approved	10/11/2006	Massey University	Nil	Self-funded	Regional rangatahi adolescent inpatient services
CEN/06/10/086	Children and young person's nurse eczema clinic evaluation	Dr Karen McBride-Henry	22/09/2006	10/10/2006	Deferred	Inadequate application (OSEC 2.4.57). Wrong questionnaire and Maori support letter supplied.	Approved	30/11/2006	Capital & Coast DHB	Nil	Grant from Graduate School of Nursing, Midwifery and Health	Riki Niania; Maori Health Unit; C&CDHB; Dr Kathryn Adams; Clinical Services Research Centre; C&CDHB
CEN/06/10/087	A comparison of monocular near and distance vision in amblyopia	Ms Ellen Adrichem	22/09/2006	10/10/2006	Approved subject to conditions		Approved	20/10/2006	Good Health Wanganui	A	No additional funding required	
CEN/06/10/088	Effect of Quetiapine on generalised anxiety disorder – open label trial	Dr Sohail Sheikh	22/09/2006	10/10/2006	Deferred	Vulnerable study group (OSEC 65,69iv) issues not adequately addressed	Deferred		Hawkes Bay DHB	A	Hawkes Bay Medical Research Foundation (applied for) Astra Zeneca	Rapai Pohe; Te Whanga Hauora Maori; HBDHB
CEN/06/10/090	Study of life satisfaction of older persons on dialysis	Dr Krishan Madhan	22/09/2006	10/10/2006	Approved subject to conditions		Approved	6/12/2006	Taranaki Base Hospital	A	Application to Taranaki Medical Foundation	Senior Adviser for Maori Health; Taranaki DHB
CEN/06/10/091	Reflections and analysis to improve clinical practice: a student music therapist's clinical practice	Ms Catherine Wilkinson	22/09/2006	10/10/2006	Ethical approval not required	(OSEC 4.0, 138)	Ethical approval not required		Capital & Coast DHB	A	Own funding	Maori liaison person; Child Development Team; Kenepuru Hospital
CEN/06/10/092	The Orelle ABC exercise programme and training aid (the Orelle Programme) phase two before and after trial on pelvic floor function	Ms Carol Armitage	22/09/2006	10/10/2006	Approved subject to conditions		Approved subject to conditions		Massey University	A	Ora3 Ltd	Te Waka Huia Highbury Health Centre; Maori Advisor kai areahi Maori Massey University
CEN/06/11/093	Family perception of services and supports in childhood cerebral palsy	Dr Rachel Fletcher	27/10/2006	14/11/2006	Ethical approval not required		Ethical approval not required		Capital & Coast DHB	Nil		

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CEN/06/11/094	Mountain biking injuries in two New Zealand events – a cross sectional survey	Dr Jenny Visser	27/10/2006	14/11/2006	Approved subject to conditions		Approved	22/12/2006	Wellington School of Medicine & Health Sciences	Nil	Department higher fees budget	Univ of Otago Maori consultation committee
CEN/06/11/095	The experience of adolescents living with a stoma – a narrative inquiry	Susan Garthwaite	27/10/2006	14/11/2006	Approved subject to conditions		Approved	20/12/2006	Hutt Valley DHB	Nil	Self-funded	Maori Health Unit; Hutt Valley DHB
CEN/06/11/096	Improving the view from both sides of the fence: staff perception of patient discharge from intensive care unit to ward-based care	Dr Karen McBride-Henry	27/10/2006	14/11/2006	Ethical approval not required		Ethical approval not required		Capital & Coast DHB	Nil	ICU Research Fund, ANZ Intensive Care Society	Colleen Wineera; H E & R Services
CEN/06/11/097	Collection of pre-screening data for use in future clinical trials	Dr Dean Quinn	27/10/2006	14/11/2006	Ethical approval not required		Ethical approval not required		P3 Research Wellington	A	P3 research	Colleen Wineera; H E & R Services
CEN/06/11/098	Exploring health perceptions and health provider choices in people with musculoskeletal pain	Melanie Brown	27/10/2006	14/11/2006	Approved		Approved	17/11/2006	Wellington School of Medicine & Health Sciences	Nil	HRC Disability Research Placement Programme	Ngai Tahu Research Consultation Committee
CEN/06/11/099	Community perspectives of community participation in primary health care: a case study in New Zealand	Lesley Batten	27/10/2006	14/11/2006	Approved subject to conditions		Approved	14/12/2006	Whanganui Regional Primary Health Organisation	Nil	Ministry of Health Primary Health Care Nursing Scholarship Massey University Doctoral Scholarship Massey University Graduate Research Fund	Maureen Holdaway; Director Taumata Hauora Trust
CEN/06/11/100	Determination of basic level of sialyltransferases SAT I and SAT IV in human blood obtained from healthy adults	Dr Ulrike Hubl	27/10/2006	14/11/2006	Approved subject to conditions		Approved	14/12/2006	Industrial Research Ltd	A	Internally funded	Not required

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
CEN/06/11/101	Comparison of high flow versus titrated oxygen therapy in the emergency department management of respiratory disorders	Prof Richard Beasley	27/10/2006	14/11/2006	Approved subject to conditions		Approved	18/01/2007	Wellington Hospital	A	Applications currently being submitted	Colleen Wineera; HE&R Services
CEN/06/11/102	Effect of supplementary oxygen on myocardial ischaemia during exercise testing	Dr Mark Simmonds	27/10/2006	14/11/2006	Approved subject to conditions		Approved subject to conditions	28/02/2007	Wellington Hospital	A	No extra funding required	Colleen Wineera; HE&R Services
CEN/06/11/103	Comparison of high flow versus titrated oxygen therapy in the emergency department management of ST elevation myocardial infarction	Dr Mark Simmonds	27/10/2006	14/11/2006	Approved subject to conditions		Approved subject to conditions	28/02/2007	Wellington Hospital Hutt Valley DHB	A	Funding applied from HRC	Colleen Wineera; HE&R Services
CEN/06/11/104	Investigation of the effect of atorvastatin on lipids and inflammation in chronic renal failure	Dr Scott Harding	27/10/2006	14/11/2006	Approved subject to conditions		Approved	1/02/2007	Malaghan Institute of Medical Research	A	Application to Wellington Medical Research Foundation Inc	Colleen Wineera; HE&R Services Ltd
CEN/06/11/105	SIDS genetic pilot study – systematic genome-wide identification of common gene variants predisposing to SIDS	Prof Richard Beasley	27/10/2006	14/11/2006	Deferred	Needs to be resubmitted (OSEC 2.3, 49)	Deferred		ESR	Nil	To be sought	Colleen Wineera; Matire Harwood
CEN/06/11/106	Strategies to promote healthier food purchases: a supermarket intervention trial	Dr Cliona Ni Mhurchu	27/10/2006	14/11/2006	Ethical approval not required		Ethical approval not required		Wellington School of Medicine & Health Sciences	Nil	HRC A form provided but not required	Te Hotu Manawa Maori
CEN/06/11/107	Assessing the provision of medical termination of pregnancy in the first trimester	Kim Lund	30/10/2006	14/11/2006	Approved subject to conditions		Approved	8/12/2006	Capital & Coast DHB	Nil	Istar Ltd	Colleen Wineera; HE&R Services; Riki Nia Nia; CCDHB
CEN/06/11/108	An evaluation study: the effectiveness of a slow stream rehabilitation service	Naomi Tate	30/10/2006	14/11/2006	Ethical approval not required		Ethical approval not required		MidCentral DHB	Nil	Wellington Masonic Villages Trust	Form A provided but not required

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
CEN/06/12/109	Implications for treatment: methadone maintenance treatment (MMT) clients who concurrently take Benzodiazepine (BZD) medication	Katherine Clark	24/11/2006	12/12/2006	Approved subject to conditions		Approved	26/01/2007	Capital & Coast DHB	Nil	University of Otago Masters research fund	Riki Nia Nia; Maori Health Development Unit; CCDHB
CEN/06/12/110	Safety and efficacy of pentoxifylline in the treatment of necrotising enterocolitis in preterm neonates: a randomised, placebo controlled pilot trial	Dr Sanjay Patole	24/11/2006	12/12/2006	Approved subject to conditions		Approved subject to conditions		Capital & Coast DHB	A	Raine Foundation, Western Australia	Mr Riki Nia Nia; Maori Health Development Unit; CCDHB
CEN/06/12/111	A qualitative exploration of the person living with type 2 diabetes in Wanganui, their understanding, perception and ability to self manage their condition	Janice Handley	24/11/2006	12/12/2006	Approved subject to conditions		Approved subject to conditions	21/02/2007	Whanganui Regional Primary Health Organisation	Nil	Diabetes NZ General Practice Trust	Dr Heather Gifford; Maori members of WRPHO Diabetes Governance Group
CEN/06/12/112	Service research and improvement project: Midcentral Health's after hours emergency mental health services	Jo Innes	24/11/2006	12/12/2006	Approved subject to conditions		Approved	14/02/2007	MidCentral DHB	Nil	Funding Division, Midcentral DHB	
CEN/06/12/113	A randomised, double blind, two-way crossover study, to examine the safety, tolerability, pharmacokinetics and pharmacodynamics of a single inhaled administration of GW685698X (800µg) with and without magnesium stearate, in mild/moderate asthmatic patients	Dr Dean Quinn	24/11/2006	12/12/2006	Approved subject to conditions		Approved	20/12/2006	P3 Research Wellington	B	GlaxoSmith Kline	Colleen Wineera; HE&R Services

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
CEN/06/12/114	Assessment of bone mineral density around a femoral revision stem using dual-energy X-ray zbsorptiometry (DEXA)	Prof Geoffrey Horne	27/11/2006	12/12/2006	Approved subject to conditions		Approved subject to conditions		Capital & Coast DHB Pacific Radiology	A	Zimmer Inc	Laurayne Mariu Peck; Orthopaedic Department CCDHB; supported by Maori Health Unit; Wellington Hospital
CEN/06/12/115	The use of exhaled nitric oxide in the practical management of childhood asthma: pilot study	Dr Thorsten Stanley	27/11/2006	12/12/2006	Approved subject to conditions		Approved	18/01/2007	Capital & Coast DHB	A	Asthma and Respiratory Foundation of New Zealand Grant	Mr Riki Nia Nia; CCDHB; Ms Christine Rimene; Ngai Tahu Research Council

Application considered in 'closed' meeting

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
CEN/06/10/089	RML 785 fluticasone/salmeterol bronchodilation and bronchoprotection clinical equivalence study. A randomised, 30-week, double-blind, double dummy, crossover trial comparing the bronchodilation and bronchoprotection of two fluticasone propionate 50 mcg / salmeterol xinafoate 25 mcg per actuation HFA metered dose inhalers administered for two 12-week treatment periods following a three-week run in phase with a three-week washout phase between treatments in adult patients with stable chronic mild to moderate asthma.	Prof Carl Burgess	22/09/2006	10/10/2006	Approved subject to conditions	Considered in closed meeting	Approved	26/01/2007	Wellington School of Medicine and Health Sciences	B	REX Medical Ltd	Riki Niania; Maori Health Unit; C&CDHB

Applications considered under chairperson's delegated authority

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
CEN/06/01/CPD	How aware of cardiovascular factors are patients attending their first cardiology outpatient appointment?	Dr Stewart Mann	2/02/2006		Approved subject to conditions		Approved	8/06/2006	Wellington School of Medicine		Wellington School of Medicine	University of Otago Maori Advisory Research Group
CEN/06/02/CPD	Symptoms of acute myocardial infarction (AMI) and time to presentation at the emergency department of a regional hospital (CPD)	Judy Searle	2/02/2006				Approved	17/02/2006	Eastern Institute of Technology	Nil	HB Medical Research Foundation, Heart Foundation, Cardiac Society	Rapai Pohe; Maori Health Unit
CEN/06/03/CPD	Development of a diagnostic clinical prediction rule for patellofemoral pain syndrome	Ms Cheryl Hefford	24/02/2006				Approved	17/03/2006	Victoria University of Wellington	Nil	Student project	Not required for summer student project – record review only
CEN/06/04/CPD	Nutrition resource development for coronary artery bypass graft and valve replacement patients	Ms Sally Studholme	20/03/2006				Approved	5/04/2006	Capital & Coast DHB	Nil	Student project	Not required for summer student project
CEN/06/05/CPD	Induction of labour in women of advanced age with prolonged pregnancies	Dr Dushyant Maharaj	9/05/2006				Completed	17/05/2006	Wellington School of Medicine and Health Sciences	Nil	Summer Studentship No. 06/	Not required; retrospective review of records only
CEN/06/06/CPD	A review of DVT prophylaxis post surgery	Ms Janice Young	12/06/2006				Approved	15/06/2006	Capital & Coast DHB	Nil		Not required; retrospective review of records only
CEN/06/07/CPD	Effect of repeated movement on a patient with low back pain – a case study	Russell Dalton	22/08/2006				Approved	7/09/2006	University of Otago	Nil	Student project	Not required for summer student project
CEN/06/08/CPD	The assessment of the use of pharmacological treatments in patients admitted with chronic obstructive pulmonary disease (COPD)	Dr Tristram Ingham	15/09/2006				Approved	27/09/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project	Not required for summer student project – record review only

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
CEN/06/09/CPD	Characteristics of atrial fibrillation associated with successful cardioversion	Ann-Marie Stevenson	18/09/2006				Approved	27/09/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project	Ngai Tahu Research Consultation Committee
CEN/06/10/CPD	Monitoring of QT interval – how important is methadone dose?	Brent Hyslop	5/10/2006				Approved	19/10/2006	Wellington School of Medicine & Health Sciences	Nil	Summer student project	Ngai Tahu Research Consultation Committee
CEN/06/11/CPD	Events precipitating pensioner's move to residential homes	Helen Viggers	11/10/2006				Approved	3/11/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project	He Kainga Oranga
CEN/06/12/CPD	Walking around the neighbourhood: a social network intervention – pilot study to test pedometer, computer map and questionnaire use and experience	Ms Chiara La Rotonda	6/11/2006				Approved	10/11/2006	Wellington School of Medicine & Health Sciences	Nil	Student project	Not required for summer student project
CEN/06/13/CPD	Proposal for usability testing of GE Aesys anaesthetic machine	Dr Paul Dalley	2/11/2006				Approved	10/11/2006	Capital & Coast DHB	Nil		Not required – CPD study only
CEN/06/14/CPD	Survey on sleep deprivation and post partum mood disturbance	Alasdair Williamson	16/11/2006				Approved	22/11/2006	Hawkes Bay DHB	Nil		Not required, anonymous questionnaire
CEN/06/15/CPD	Beta-glucan content of individual bedding items	Jennifer Heyes	10/11/2006				Approved	22/11/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project	Not required for summer student project
CEN/06/16/CPD	Medical education in the community: a survey of New Zealand general practices	Ruth Lum	1/11/2006				Approved	22/11/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project	Not required for summer student project
CEN/06/17/CPD	Pacific youth health perspectives	Ana Fonua	15/11/2006				Approved	22/11/2006	Massey University	Nil	Summer student project	Not required for summer student project

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
CEN/06/18/CPD	Managing pregnant women on the methadone programme	Calvin Chan	7/11/2006				Approved	22/11/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project	Not required for summer student project
CEN/06/19/CPD	Development and piloting of a primary health care nursing practice documentation tool	Kathy Holloway	10/11/2006				Approved	22/11/2006	Whitireia Community Polytechnic	Nil	CPD Project	CPD project developed in conjunction with Carmen Timu-Parata
CEN/06/20/CPD	Review of sudden infant death in the Wellington region 1996–2005	Alistair Escott	22/11/2006				Approved	6/12/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project	Record review only; consultation not required
CEN/06/21/CPD	Skin prick allergy testing in children and infants – assessing a potentially more reliable and less uncomfortable method using an auto injector	Dr Thorsten Stanley	27/11/2006				Approved	8/12/2006	Wellington School of Medicine and Health Sciences	A	Summer student project	Not required
CEN/06/22/CPD	Hip abductor muscle weakness following hip replacement surgery	Dr Supratim Mukherjee	8/12/2006				Approved	14/12/2006	MidCentral DHB	Nil	Retrospective review of records only	Not required for retrospective record review
CEN/06/23/CPD	Arterial pulse wave velocity: validation of sphygmocor pulse wave tonometry in Wellington	Dr John Delahunt	8/12/2006				Approved	14/12/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project	Mr Riki Nia Nia; Maori Health Unit; WSM&HS
CEN/06/24/CPD	Orchidopexy audit	Prof Kevin Pringle	27/11/2006				Approved	20/12/2006	Wellington School of Medicine and Health Sciences	Nil	Summer student project for Samer Hermiz	Not required
CEN/06/25/CPD	Observational study on nausea and anti-emetic prescription in Wellington ED	Geoff Spencer	20/12/2006				Approved	20/12/2006	Emergency Department, Wellington Hospital	Nil	Geoff Spencer	Not required for summer student project

Appendix 2: Central Regional Ethics Committee Terms of Reference

Public authority of the Central Regional Ethics Committee

The Central Regional Ethics Committee (Central 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 Central REC.

Authority of the Central Regional Ethics Committee

The Central REC shall have responsibility for ethics committee review of health and disability research and innovative practice occurring in the following District Health Board regions:

- Taranaki
- Whanganui
- MidCentral
- Hawke's Bay
- Capital & Coast
- Wairarapa
- Hutt Valley.

The Central REC is responsible for any health and disability research that is currently being undertaken in the above District Health Board 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 Central REC.

Relations with other public sector organisations

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

The Central 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 Central Regional Ethics Committee

The primary role of the Central 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 Central 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 Central REC is to ensure that the Central 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 Central 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 layperson 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 Central REC's lay membership shall include:

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

The Central 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 Central 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 Central REC are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

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

Members should possess an attitude that is accepting of the values of other professions and community perspectives, and it is important for the committee 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, Central 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 Central REC as equal individuals of sound judgement, relevant experience and adequate training in ethical review.

Terms and conditions of appointment

Members of the Central 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 Central 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 Central 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 Central REC. Those persons shall not be eligible for appointment to the Central 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 Central 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 Central 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 Central REC shall continue in office until their successor comes into office. Any member of the Central REC may at any time resign as a member by advising the Minister of Health in writing.

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

The Central REC shall appoint a non-lay member as Deputy Chairperson.

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

General

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

Conflicts of interest

Central 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 Central REC and its members and will ensure Central REC retains public confidence.

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

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

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

Confidentiality and information sharing

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

Within the Central 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 Central 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 Central REC to be open to the public. Meetings of the Central REC should therefore be:

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

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

Decision-making process

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

In relation to research involving Māori, it is important that Māori expertise be available to ensure that all issues are appropriately considered. Where it is not possible for Māori members to attend a Central 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 Central 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 Central REC members believes there is insufficient expertise on the Central 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 Central REC's decision on a proposal.

Second opinions and appeals

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

The decisions of the Central 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 Central 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 Central REC, including any change in the Central REC's membership or other substantive changes the Central 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 Central REC members, and a statement on processes for orientation and training of new Central REC members should be included
- ii. a list of complaints received by the Central 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 Central REC in making a decision on any particular protocol(s), and any questions on policy or other matters the Central REC referred to the National Ethics Advisory Committee or the Health Research Council Ethics Committee for comment or guidance.

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

Servicing of the Central Regional Ethics Committee

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

