



Central Regional Ethics Committee

Annual Report

December 2004 to December 2005

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This report provides an overview of the work of the Central Regional Ethics Committee from 1 December 2004 to 31 December 2005. The report was presented to the Central Regional Ethics Committee at its meeting on 14 March 2006.

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

Chairperson's Report

The Central Regional Ethics Committee came into being in December 2004, and 2005 represents the first full year of operation. For the committee, 2005 was a year of bedding in the changes brought by the reform of the ethical review process and learning how to work together as a new committee. Some of the faces on the committee were familiar, with people having worked together on previous health ethics committees from a number of other locations, other faces were new.

The work of an ethics committee is not an exact science. I appreciate that this is an issue of concern for researchers, who often come from disciplines that are concerned with measuring and quantifying. It raises issues about the role of consistency of decision-making within and between committees. Whilst in principle, I believe consistency is a desirable thing, there are some reasons why it might not be appropriate. It is important to remember that societal views change over time. There are some fundamentals upon which there is some consensus (the importance of informed consent being an example), but views about issues and scientific practices change over time. Scientific understanding about genetics and enviro-genomics is developing rapidly and raises ethical issues that are not easily or tidily addressed. We welcome greater public debate about these issues. Ideas about best practice also change over time. There can be variation because of particular local circumstances, local practices or experiences that affect what could be considered appropriate for that area. We also have to bear in mind that a Pākehā view of what is appropriate or beneficial might not be symmetrical with Māori beliefs and cultural practices. To summarise, the committee must assess applications in accordance with the guidance given in the Operational Standard for Ethics Committees. This provides a framework to guide us towards consistency. However, the desire for consistency must be balanced against particular local circumstances and should take into account changes in public perceptions and accepted practices.

Inevitably there have been some teething problems; many centring on the new requirement for a locality assessment. The previous process required that researchers have an appropriate person from the host organisation fill out a Part V declaration, which, in effect, signalled that the institution was aware of and supported the research being conducted. The new locality assessment procedure requires investigators to complete a form that is designed to assess the suitability of the researcher and the host organisation where the research is being conducted. However, a key issue that arises is that sometimes the host organisation is not where the research is being conducted. For example, a university might conduct research that takes place in community Plunket rooms in the lower North Island, with significant recruitment being done through Plunket. In this instance, what is the locality assessment needed for, and what purpose will it achieve? Although the university can attest

to the suitability of the researcher and the resources to conduct the project, an important element is missing – the requirement to provide evidence that Plunket is aware of and supports the research being conducted. The former Part V process covered this need to provide evidence of support. It seems that this limb is missing from the locality assessment process, and we would like to see it return. To date, we have been asking researchers in this type of situation to provide letters of support. We understand that the locality assessment process will be reviewed in the near future.

In 2005, we received two formal complaints to the committee about the way in which research was being conducted. These are detailed under Complaints below. A disappointing feature in at least two of these complaints has been the length of time it has taken to get a response from the organisation complained about. In one instance, the committee is still waiting for a response. It does leave the sense that perhaps the Operational Standard for Ethics Committees could be strengthened to encourage co-operation between researchers and ethics committees.

However, such complaints are the exception, and the committee has been impressed with the knowledge, professionalism and goodwill of the researchers who have submitted their research proposals over the last year. Many of these researchers are conducting a number of research projects, and the committee is fortunate to have the opportunity to get to know them as their research portfolio grows. The committee looks forward to seeing what these researchers contribute to the pool of knowledge, as evidenced in their progress reports and publications.

During the year, lectures and ethics presentations were given by the Chairperson, Deputy Chairperson and Joe Asghar. These were mainly contributions to undergraduate courses on research ethics including lectures to fifth-year medical students undertaking public health research projects, Diploma of Public Health students and students in the Department of General Practice in the Medical School. In addition, other members of the committee made themselves available to meet with researchers to facilitate resolution of ongoing ethical issues relating to the researchers' projects. The goodwill of committee members in undertaking this additional workload is acknowledged.

As Chairperson, I feel immensely grateful to have had the opportunity to work with the committee members. Each member contributes an invaluable skill and unique life experience to the work of the committee. To identify attributes that I believe particularly characterise the members of this committee, I would describe the members as being committed, intelligent yet pragmatic, blessed with a good sense of humour and above all, showing compassion for all involved in the research process. We have also been fortunate in retaining the invaluable skills and knowledge of Jan Ostnes and Claire Yendoll, the committee administrators. Claire and Jan worked for the former Wellington Ethics Committee and provide that important local regional knowledge, as well as being a familiar first port of call for researchers needing information. Some administrative difficulties were encountered during the changeover process, particularly with the introduction of a new database. All administrative problems have now been resolved, but database problems continue to be an issue.

Sally Cook of the Ministry of Health has also been most helpful in designing training programmes for new committee members and has co-ordinated the biannual chairperson's meeting at which the chairpersons of the committees discuss issues arising for the committees.

Thank you all.

Helen Colebrook
Chairperson

Committee Membership

Appointments

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

Chairperson

Helen Colebrook	BA, LLB, LLM (Hons)
Representation	Lay member
Member category	Lawyer
Gender	Female
Date of appointment	November 2004
Term of appointment	2 years
Retirement date	November 2006
Professional affiliations	Lawyer
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 NZ College of GPs
Iwi affiliations	None

Members

Mohamad Naseen (Joe) Asghar	BSc, MSc, MBA, FCPP, FRPharmS, Hon MFPH, MPS, Reg Pharm NZ
Representation	Non-lay member
Member category	Pharmacist/pharmacologist
Gender	Male
Date of appointment	November 2004
Term of appointment	2 years
Retirement date	November 2006
Professional affiliations	Pharmacy Industry Training Organisation, NZHPA
Iwi affiliations	None

Matire Harewood 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 Nga Puhi, Hapu Mahurehure, Ngati Rangi, Ngati Hine

Maureen Holdaway PhD
Representation Non-lay member
Member category Health researcher
Gender Female
Date of appointment November 2004
Term of appointment 2 years
Retirement date November 2006
Professional affiliations Massey University
Iwi affiliations Te Atihaunui-o-Paparangi Ngati Hauti

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

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

Andrea Needham Dip Tchg
Representation Lay member
Member category Community representative
Gender Female
Date of appointment November 2004
Term of appointment 2 years
Retirement date Resigned in February 2005
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	MB, ChB 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 DHB
Iwi affiliations	None
Anne Tuffin	MPhil (Education)
Representation	Lay member
Member category	Community representative
Gender	Female
Date of appointment	November 2004
Term of appointment	2 years
Retirement date	November 2006
Professional affiliations	Health promoter
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	Ngati Kahungunu

Change/s to membership

Andrea Needham resigned from the committee in February 2005. The following appointment was made by the Minister of Health in July 2005.

Jacqueline Renouf	MA (Sociology/Social work) 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
Iwi affiliations	None

Deputy Chairperson

The committee elected Jacqui Virtue as Deputy Chairperson at its inaugural meeting on 14 December 2004.

Members' attendance

Member	M/F	Lay/ non-lay	Dec 2004	Feb 2005	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	
Helen Colebrook (lawyer)	F	L	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	11/12	
Joe Asghar (pharmacist)	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12	
Matire Harwood* (biostatistician)	F	NL	Y	Y	A	A	Y	A	A	A	Y	Y	Y	Y	7/12	
Maureen Holdaway* (health researcher)	F	NL	Y	Y	Y	Y	Y	Y	Y	Y	A	A	Y	A	9/12	
Trevor James (community rep)	M	L	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	A	10/12	
John Kleinsman (ethicist)	M	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12	
Andrea Needham (community rep)	F	L	Y	Resigned											1/1	
Jacqueline Renouf (community rep)	F	L	New member						Y	Y	Y	Y	Y	Y	A	5/6
David Sinclair (health practitioner)	M	NL	Y	A	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	10/12	
Guy Taylor (health researcher)	M	NL	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	A	10/12	
Anne Tuffin (community rep)	F	L	Y	Y	Y	Y	Y	Y	Y	Leave of absence				Y	8/12	
Jacqui Virtue (health practitioner)	F	NL	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	11/12	
Dianne Wepa* (community rep)	F	L	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/12	
No. of members present			12	10	9	9	10	10	10	9	9	10	11	8		
No. of applications			11	8	4	9	12	13	6	11	8	5	8	17	112	

* = Māori member

Y = Present

A = Apology

Training

New member training

All members of the health and disabilities ethics committees, including those with previous experience were offered training in January and February 2005. The training was held in Auckland, Wellington and Christchurch. The following members of the Central Regional Ethics Committee attended the Wellington training: John Kleinsman, Helen Colebrook, Jacqui Virtue, Anne Tuffin, Guy Taylor, Joe Asghar, Trevor James, Dianne Wepa.

Ongoing training

While no ongoing training was offered to all committee members in 2005, the following meetings of specialist committee members were held.

Meeting of legal members and chairpersons

A meeting of the legal members and chairpersons was held on 23 June 2005 covering the role of the legal member, indemnity of members, compensation and research on people who are unable to consent themselves. The following member of the Central Regional Ethics Committee attended: Helen Colebrook.

Meeting of the Māori members

A meeting of the Māori members of the committees was held on 28 June 2005 and covered a number of topics including the role of the Māori member, consultation with Māori, the cultural section of the application form, tissue banking and recent changes to Right 7(10) of the Code of Health and Disability Services Consumers' Rights. The following member of the Central Regional Ethics Committee attended: Matire Harwood.

Chairpersons' meeting

Two meetings of the chairpersons of the multi-region and the regional ethics committees were held in 2005. Helen Colebrook attended the chairpersons' meetings on 14 April 2005 and 13/14 October 2005.

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. 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 patients/client notes or data, some student projects and studies specifically excluding Māori participants.
Number of applications returned through insufficient consultation on cultural issues	31
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 Island Communities Studies involving 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 two Māori members of the committee.

The committee has received a range of protocols that have either not considered Māori consultation or have perceived the requirement as an optional extra.

At the very least, all applicants are encouraged 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 12 scheduled meetings from December 2004 to December 2005.

Central Regional Ethics Committee statistics for December 2004–December 2005

Applications approved by full committee	82
Applications deferred as at time of report	03
Applications declined	00
Applications carried forward (approved subject to conditions)	13
Approval not required	10
Studies withdrawn by researcher	02
Studies terminated by sponsor	01
Studies transferred to Multi-region Ethics Committee	01
Total number of applications considered by the full committee	112
Applications considered under delegated authority (CPD)	16
Total number of applications received	128
Applications deferred and subsequently approved	6

Other committee statistics

Number of matters arising	5
Number of general business items	30
Number of amendments reviewed by committee	4
Number of amendments approved under CPD	31

Audit or matters not requiring ethical approval

Fourteen projects were confirmed as audits 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

No school science fair projects were reviewed.

Second opinions

There were no second opinions sought.

Complaints

The committee received two complaints in 2005. The details of these complaints are as follows.

At the March meeting, the committee received a complaint from an ESR researcher about the way feedback was given to participants in a study of blood serum dioxin levels of residents who lived near Paritutu in New Plymouth. The researcher expressed concern that the Institute of Environmental Science and Research Ltd (ESR) had given participant contact details to the Ministry of Health (which was sponsoring the research) without the express consent of the participants. In addition, the previous ethical approval given by the Taranaki Ethics Committee required that the local Health and Disability advocate be involved in determining how the feedback process should best be managed.

The complaint was raised with the ESR, and the Ministry of Health was advised that a complaint had been received. Unfortunately, due to staff leave and resignations at ESR, it took some time for the committee to receive a response to questions asked about the details of the complaint. In October, the committee received a response from ESR that indicated that the consent process for all participants in the study allowed for the participants' contact details to be given to the Ministry of Health. However, it was clear from ESR's response that a deliberate decision was made not to involve the Health and Disability advocate in discussions about providing feedback to participants. ESR justified this decision to the committee saying that:

'Several factors were involved in this decision including the scientific complexity and high degree of uncertainty around what the results meant, and the degree of public alarm and harm to participants that may possibly have occurred if advance information of the results became sensationalised in the media.'

The committee was, and is, concerned that ESR decided to ignore a condition that was placed upon the original ethical consent by the Taranaki committee. However, as the study had already been completed, the committee found that it had little recourse to deal with this situation. The committee reminded ESR formally that conditions attached to an approval are not optional extras to be ignored according to the personal convictions of the researchers involved. If researchers wish to deviate from the study protocol or any conditions placed on the ethical approval, the appropriate course of action is to seek the committee's approval to vary the conditions of the ethical approval.

The committee was disappointed that ESR chose to adopt the course of action that it did and that it took so long to get a response from ESR to questions. The final progress report submitted by ESR referred to the complaint, stating:

'It is difficult in terms of upholding ethical standards to conduct high profile research such as this when the commissioning agent is a government agency (that is, the Ministry of Health) that seeks to control the communication of results. It was a learning experience for all parties concerned, resulting in an understanding of the need for scientific independence on the part of ESR and the need for greater autonomy in future research of this kind.'

The committee is pleased to report, however, that ESR has now acknowledged that it has erred and has advised the committee that it has taken remedial action for the future. The committee noted that the Ministry of Health does not agree with the researcher's interpretation.

In June 2005, the committee received a complaint from the principal investigator of a study that he had been conducting on behalf of People First New Zealand Inc. He raised three main complaints, one being that he had been told that as a non-New Zealander he would have to have an ethics supervisor for the research he was conducting. He also complained that efforts were being made to distort his research findings, and that research participants were not going to be given appropriate feedback about the study. The committee looked into these concerns and was satisfied that there was no evidence to support the first two matters of complaint. As providing appropriate feedback was one of the conditions upon which ethical approval was granted, the committee sought reassurance that this condition was fulfilled by People First New Zealand Inc. People First New Zealand Inc confirmed that research participants were given feedback at a meeting held in August 2005.

In the course of looking into these issues, People First New Zealand Inc had advised the committee that the principal investigator's contract had expired and that they intended to appoint a new principal investigator to complete the study. The committee was satisfied with the credentials of the suggested replacement and approved the appointment of the new principal investigator.

Issues for the Committee

During 2005, an issue arose concerning duplication of research by two separate studies, one of which was approved by the Central Regional Ethics Committee and one by the Massey University Human Ethics Committee (MUHEC). The two research projects involved research on the same vulnerable study cohort. Clarification was sought from the Health Research Council on the status of the study approved by the MUHEC. The outcome was that the Central Regional Ethics Committee reviewed both studies, and the two principal investigators were asked to produce a joint information sheet and consent form for participants and also arrange to carry out only one blood test procedure on the study cohort.

The committee aims to promote excellence in research. During 2005, an intellectual property issue arose. A researcher alleged (in the study progress report) that unauthorised publication of part of the original research had occurred. The original entire research has not yet been published. The committee clarified with the publishing journal that original research would require evidence of ethical approval prior to publication.

Locality assessment

The locality assessment process required some adjustment in administrative procedures, and in some instances difficulties were experienced in receiving locality assessments. In addition, the administrators fielded a considerable number of queries concerning the purpose of the locality assessment and how a locality assessment should be completed.

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

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

Appendix 1: Applications received December 2004 to December 2005

This appendix details the applications considered by the committee from December 2004 to December 2005. One application was heard 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	Consultation undertaken
CEN/04/12/001	Diagnostic laparoscopy – patient understanding post-operatively	Dr Mark Omundsen	10/11/04	14/12/04	Approved subject to conditions		Completed	26/01/05	Capital & Coast DHB	NII		Jackie Davis, Māori Health Development Group
CEN/04/12/002	Facilitating a child emergency department: a participatory action research project	Ms Sharon Payne	10/11/04	14/12/04	Ethical approval not required	OSEC 134	Ethical approval not required			NII		
CEN/04/12/004	A Phase III Limited Institution Pilot Study of Acute Lymphoblastic Leukaemia for the Australian and New Zealand Children's Haematology and Oncology Group	Dr Anne Mitchell	10/11/04	14/12/04	Approved subject to conditions		Approved	23/12/04	Capital & Coast DHB	A		Colleen Wineera
CEN/04/12/005	A Phase 11 open label, single centre study to evaluate the post-immunisation kinetics after a fourth dose of MeNZB vaccine, in healthy adults who previously received three doses of MeNZB	Dr Stewart Reid	10/11/04	14/12/04	Approved subject to conditions		Approved	23/12/04		B	Chiron Srl, Italy	Te Ohu Rata O Aotearoa
CEN/04/12/006	Enhancing patient safety: nurses' role in safe administration of medicines	Dr Karen McBride-Henry	10/11/04	14/12/04	Approved subject to conditions		Approved	2/04/05	Capital & Coast District Health Board	NII		National Council of Māori Nurses
CEN/04/12/007	Medical students' experiences with patient consent to attend gynaecology theatre and for vaginal examination of anaesthetised patients (VE of AP)	Dr Juliet Broadmore	15/11/04	14/12/04	Ethical approval not required	OSEC 134	Ethical approval not required		Wellington School of Medicine & Health Sciences	NII		
CEN/04/12/008	A multi-centre, double-blind, randomised, placebo-controlled, parallel study of the safety and efficacy of TAK-559 compared to placebo in the treatment of patients with type 2 diabetes mellitus	Dr Jeremy Krebs	19/11/04	14/12/04	Approved subject to conditions		Withdrawn		Capital & Coast District Health Board	B	Takeda Global Research & Development Centre Inc	Māori Health Development Group
CEN/04/12/009	Predictive value of legionella serology in hospitalised patients	Dr Michelle Balm	19/11/04	14/12/04	Approved subject to conditions		Approved	22/12/04	Capital & Coast District Health Board	NII		Te Roopu Rangahau Hauora a Eru Pōmare
CEN/04/12/010	Study of rectal anatomy	Dr Sameer Memon	18/11/04	14/12/04	Approved subject to conditions		Approved	8/03/05	Capital & Coast District Health Board	A		Māori Health Unit, Wellington and Hutt hospitals

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
CEN/04/12/011	Single centre, randomised, double-blind, comparator study to demonstrate the superiority of salmeterol/fluticasone propionate combination diskus/accuhaler 50/100 mcg bd over fluticasone propionate diskus/accuhaler 200 mcg bd with respect to airway physiology in asthmatic children treated for six weeks	Dr Sarah Aldington	19/11/04	14/12/04	Approved subject to conditions		Approved	26/01/05	Medical Research Institute of New Zealand	B	GlaxoSmith Kline	Colleen Wineera, HE&R
CEN/05/02/001	Mast cell and skin cancers	Dr Sydney Ch'ng	20/01/05	8/02/05	Approved subject to conditions		Approved	3/02/05	Capital & Coast District Health Board	Nil		Kiuni Puketapu, Māori Health Advisor, Hutt Hospital
CEN/05/02/002	Primary Health Nursing Network Survey	Prof Marilyn Foureur	20/01/05	8/02/05	Ethical approval not required	OSEC 134	Ethical approval not required		Capital & Coast District Health Board	Nil		Kiuni Puketapu, Māori Health Advisor, Hutt Valley DHB
CEN/05/02/003	Investing in health: the continuum of care	Dr Jenny Carryer	20/01/05	8/02/05	Approved subject to conditions		Approved	14/04/05	MidCentral District Health Board	Nil		Rev Kahu Durie and Rev Tunu Walker
CEN/05/02/004	The mechanism of genetic change in metastatic progression of colon tumours to the liver	Dr Richard Stubbs	20/01/05	8/02/05	Approved subject to conditions		Approved	18/03/05	Wakefield Hospital	A		Mr Denis Simpson, Chairman, Wellington Council of Māori Elders
CEN/05/02/005	A nutritional status assessment of 11–14 year old competitive swimmers compared to age, gender and socioeconomic matched peers	Mr Tony Mottershead	20/01/05	8/02/05	Approved subject to conditions		Approved	4/03/05	Eastern Institute of Technology	A		CHOICES – Kahungunu Health Services (Te Rina Murphy – 06 878 7616)
CEN/05/02/006	Is there a link between maternal periodontal disease and the delivery of preterm low birth weight (PLBW) infants: a pilot study	Mrs Carolyn Coles	20/01/05	8/02/05	Approved subject to conditions		Approved	2/03/05	Capital & Coast District Health Board	Nil		Nga Tapuhi Whakawhanau
CEN/05/02/007	Nga Mokai Whanau Ora	Mr Denis O'Reilly	20/01/05	8/02/05	Deferred	Insufficient information for committee to make a decision	Deferred			Nil		Māori community health workers
CEN/05/02/008	Oral health-related quality of life among children receiving dental treatment under general anaesthetic at Wellington and Keneperu hospitals	Dr Penny Malden	20/01/05	8/02/05	Approved subject to conditions		Completed	4/03/05	Capital & Coast District Health Board	Nil		Te Roopu Rangahau Hauora a Eru Pomare, Te Ao Marama (New Zealand Māori Dental Association), Māori Health Unit, CCDHB
CEN/05/03/009	A qualitative exploration of registered nurses' experiences of consumer non-compliance with prescribed medication in mental health inpatient settings	Mrs Karin Nesdale	20/02/05	15/03/05	Approved subject to conditions		Approved	14/04/05	MidCentral District Health Board	Nil		Māori Mental Health Team

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
CEN/05/03/010	A qualitative study of the effects of mental illness in adults on children	Mrs Josephine Kennedy	20/02/05	15/03/05	Approved subject to conditions		Approved	12/08/05	Supporting families in mental illness Wanganui	Nil		Te Hunga Piki Te Ora
CEN/05/03/011	Prevention of retinal inflammatory damage after cataract surgery	Dr Tony Wells	20/02/05	15/03/05	Deferred	Insufficient information on validity of research proposal OSEC 2.4	Approved	22/07/05	Wellington School of Medicine & Health Sciences	A		Te Runanga o Otakou (Inc) Ngai Tahu Research Consultation Committee
CEN/05/03/012	A randomised, open label, five-way crossover study to assess the systemic exposure of fluticasone propionate and salmeterol from Seretide/Advair 250HFA MDI without spacer and with AeroChamber-Max spacer and volumatic both in their washed and unwashed states in adult subjects with mild or intermittent asthma	Dr Dean Quinn	20/02/05	15/03/05	Approved subject to conditions		Completed	30/03/05	P3 Research	B	GlaxoSmith Kline	Colleen Wineera of HE&R
CEN/05/04/013	Exploring work satisfaction following a return to work programme post-back injury	Mrs Gretchen Simms	9/03/05	12/04/05	Approved subject to conditions		Approved	19/05/05	University of Otago, Wellington: ACC Manukau City, Auckland	Nil		Christine Rimene, University of Otago, Māori Health Advisor, MidCentral Health
CEN/05/04/014	A placebo-controlled trial of Zyractin, a chewable food supplement, for relief of symptoms of dyspepsia	Dr John Wyeth	20/03/05	12/04/05	Approved subject to conditions		Approved	10/11/05	Capital & Coast District Health Board	B	Vital Foods NZ Ltd	
CEN/05/04/015	Developing an effective intervention to reduce unintentional injury to pre-school children: factors that influence parental risk perception and mitigation	Jean Simpson	20/03/05	12/04/05	Approved subject to conditions		Approved	19/05/05	University of Otago	Nil		Manager, DHB Māori Health Unit
CEN/05/04/016	Health outcomes of former New Zealand timber workers exposed to pentachlorophenol	Dr Neil Pearce	20/03/05	12/04/05	Approved subject to conditions		Approved	29/06/05	Massey University	Nil		No consultation required
CEN/05/04/017	The psychosocial impact of an informational video on patient's recently diagnosed with Parkinson's Disease	Philip Osborn	20/03/05	12/04/05	Ethical approval not required	OSEC 134	Ethical approval not required			A		
CEN/05/04/018	Comparison of intraocular pressure readings between the Icare tonometer and the Goldmann tonometer	Dr Simon Nicholas	20/03/05	12/04/05	Approved subject to conditions		Approved	6/05/05	Capital & Coast District Health Board	A		No consultation required
CEN/05/04/019	Taranaki congenital hip dysplasia study	Dr James Myers	20/03/05	12/04/05	Approved subject to conditions		Approved	1/06/05	Taranaki Base Hospital	Nil		No consultation 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	Consultation undertaken
CEN/05/04/020	A randomised, double-blind, two-period, crossover study to investigate the effect of treatment with repeat doses of a PPAR gamma agonist on the allergen-induced late asthmatic response in subjects with mild asthma compared with repeat doses of placebo	Dr Dean Quinn	20/03/05	12/04/05	Approved subject to conditions		Approved	25/05/05	P3 Research	B	GlaxoSmith Kline	Colleen Wineera, HE&R Services
CEN/05/04/021	Undetected pathogenic infections in New Zealand women presenting for termination of pregnancy	Dr Beverley Lawton	21/03/05	12/04/05	Approved subject to conditions		Approved	17/06/05	Wellington School of Medicine & Health Sciences	A		Māori Health Directorate (MoH); Cheryl Goodyer, Manager, Whanau Care Services (CCDHB)
CEN/05/05/022	Intermediate and Long term results with thermo-expandable intraprostatic stents (Memokath) in managing Prostatic Bladder Outlet Obstruction (PBOO) with patient subjective and objective results	Dr Ahmad Al-Smaeraii	20/04/05	9/05/05	Approved subject to conditions		Approved subject to conditions		Palmerston North Hospital	A		Still outstanding
CEN/05/05/023	Osteoporosis screening in primary care is it achievable, acceptable to patients, and does it change patient management?	Dr F Ruiz	20/04/05	9/05/05	Approved subject to conditions		Approved	1/06/05	The doctors, Palmerston North	A		Kaumatua Council (South), Mr G Black
CEN/05/05/024	Stories within stories: stories clients tell us: what are they and how do mental health nurses use them?	Ms Anamaria Shanks	20/04/05	9/05/05	Approved subject to conditions		Approved	17/06/05	Victoria University of Wellington	A		Te Whare Marie, Māori Mental Health Service
CEN/05/05/025	Two-year survival after an ICU admission: Is the cause of death related to their ICU admission?	Ms Diane Mackle	20/04/05	9/05/05	Approved		Approved	18/05/05	Capital & Coast District Health Board	A		No consultation required
CEN/05/05/026	A brief intervention to reduce offending – the study of a faith-based programme	Mr Jeffrey Lees	20/04/05	9/05/05	Approved subject to conditions		Approved	1/07/05	Massey University	Nil		Turoa Haronga, Kaumatua, School of Psychology, Massey University
CEN/05/05/027	Nga Mokai Whanau Ora – Pilot Study	Ms Monique Mackenzie	20/04/05	9/05/05	Approved subject to conditions		Approved	17/06/05	Newtown Union Health Service	Nil		Community health workers, Newtown Union Health: key members of 'nga mokai' community
CEN/05/05/028	The efficacy of mechanical protection of the skin during radiation therapy: a trial to evaluate the benefits of a retention dressing in terms of patient comfort and acceptability	Ms Sue Edgecombe	22/04/05	9/05/05	Approved subject to conditions		Approved	29/06/05	Palmerston North Hospital	A		Local kaumatua at MidCentral Health Māori Health Unit
CEN/05/05/029	Assessment of staff understanding and use of the maternity care plan	Ms Annette Penny	27/04/05	9/05/05	Ethical approval not required	OSEC 134	Ethical approval not required		Capital & Coast District Health Board	Nil		Service and team leaders, consultants and midwifery advisor, Women's Health Service

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
CEN/05/05/030	Nursing culture in the 21st century: re-examining practice	Ms Joy Ann McClelland	27/04/05	9/05/05	Approved subject to conditions		Approved subject to conditions		Eastern Institute of Technology	Nil		EIT Kulia, Mrs Makere Paul-Hoetawa; EIT Kawa Whakaruruhau Co-ordinator, Ms Dianne Wepa
CEN/05/05/031	Study of blood samples from non-obese volunteers to aid in the search for a humoral factor causing insulin resistance in type 2 diabetes	Dr Richard Stubbs	27/04/05	9/05/05	Approved subject to conditions		Approved	15/07/05	Wakefield Hospital	A		Mr Denis Simpson, Te Kaunihera Kaumataua o te Whanganui a Tara
CEN/05/05/032	Research studies into obesity and diabetes: the effects of very low calorie diet versus gastric bypass surgery	Dr Richard Stubbs	27/04/05	9/05/05	Approved subject to conditions		Approved	15/07/05	Wakefield Hospital	A		Mr Denis Simpson, Te Kaunihera Kaumataua o te Whanganui a Tara
CEN/05/05/033	Pharmacogenomics of nicotine replacement therapy	Mr Rod Lea	27/04/05	9/05/05	Approved subject to conditions		Approved	29/06/05	ESR	A		John Whaanga, Ngati Rakaipaaka, Maui Hudson, Māori Development Manager ESR; Keriatu Stuart, Māori Researcher, Drug Foundation
CEN/05/06/034	Registered mental health professionals' perceptions of the experience of undergoing seclusion	Associate Professor Christine Alavi	15/05/05	13/06/05	Deferred	Safety issues of health professionals and consumers OSEC 2.5, 60	Withdrawn		Victoria University of Wellington	Nil		Kaumataua on the Rangatahi Unit
CEN/05/06/035	A comparative study of patients with non-specific syncope versus those with syncope of a known cause to identify their long-term clinical outcomes at 18 months	Dr Sisira Jayathissa	16/05/05	3/06/05	Approved subject to conditions		Approved	22/07/05	Hutt Valley District Health Board – select	Nil		Hutt Valley District Health Board Māori Health Unit
CEN/05/06/036	Evaluation of the lower north severe conduct disorder (SCD) programme	Ms Julie Warren	17/05/05	13/06/05	Ethical approval not required	OSEC 134	Ethical approval not required		Centre for Research Evaluation and Social Assessment	Nil		Various Māori members involved in the lower north severe conduct disorder programme
CEN/05/06/037	Patient understanding of pre-operative fasting	Dr Heidi Walker	17/05/05	13/06/05	Ethical approval not required	OSEC 134	Ethical approval not required		Capital & Coast District Health Board	Nil		Māori Health Unit, Capital and Coast District Health Board
CEN/05/06/038	Development of a clinical decision rule to aid the assessment of women presenting to the emergency department with early pregnancy bleeding	Dr Sandra Rattenbury	18/05/05	13/06/05	Approved subject to conditions		Approved	6/07/05	Hutt Valley District Health Board	Nil		Ms Kuni Puketapu, Māori Health Advisor, Hutt Valley District Health Board
CEN/05/06/039	Exploring barriers and solutions to improving child immunisation uptake by families identified as "hard to reach": a case study	Mrs Kathleen Lois Brown	19/05/05	13/06/05	Approved subject to conditions		Approved	15/07/05	Palmerston North Hospital	Nil		Del Te Oka, Health Manager, Te Wakahuia

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CEN/05/06/040	An exploration of men's past experience with acute surgical pain management	Larry Lindsay	20/05/05	13/06/05	Approved subject to conditions		Approved	15/07/05	Victoria University of Wellington	Nil		N/A
CEN/05/06/041	Proposal for the change of routine pre-medication for angiography	Jonele Cottle	21/05/05	13/06/05	Approved subject to conditions		Approved	1/07/05	Capital & Coast District Health Board	A		No consultation required
CEN/05/06/042	Review of aortic valve replacements performed at Wellington Hospital over the last 15 years: clinical outcomes and echocardiographic findings	Dr Graham McCrystal	22/05/05	13/06/05	Approved subject to conditions		Approved	1/07/05	Capital & Coast District Health Board	Nil		No consultation required
CEN/05/06/043	Challenging "Step 9" of the baby friendly hospital initiative (BFHI): the experiences of a group of young New Zealand mothers who breastfeed their babies and use, or have used, a pacifier or dummy	Noreen Roche	24/05/05	13/06/05	Approved subject to conditions		Approved subject to conditions		Capital & Coast District Health Board	Nil		Māori health worker, Carmen Parata
CEN/05/06/044	A cohort cancer mortality study of workers exposed to 2,3,7,8-Tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) during the manufacture of 2,4,5-T at the Dow AgroSciences (DAS) New Plymouth site	Dr David McBride	25/05/05	13/06/05	Deferred	Study group over-researched OSEC 70	Approved	16/09/05	University of Otago	A		Ngai Tahu research consultation committee
CEN/05/06/045	Implementing the rating scale for aggressive behaviours in the elderly (RAGE): can it make a difference to nursing management of aggressive behaviours in elderly patients with dementia	Bernadette Lidiard	25/05/05	13/06/05	Approved subject to conditions		Approved	15/07/05	Palmerston North Hospital	Nil		Te Whare Rapuora Māori Health Services
CEN/05/06/046	The application of a postural assessment tool and treatment approach for work-related musculoskeletal disorders in ultrasonographers: a pilot study	Geoffrey Coe	25/05/05	13/06/05	Approved subject to conditions		Approved	22/07/05	University of Otago	Nil		Riki Nia Nia, Māori Development Unit C&CDHB
CEN/05/07/047	Analysis of data from the Wellington regional retinal screening programme for people with diabetes managed by the Wellington Independent Practice Association (WIIPA)	Associate Professor Robert J Jacobs	24/06/05	11/07/05	Approved		Approved	18/07/05	University of Auckland	A		Mr Taku Parai, WIIPA Board
CEN/05/07/048	Living with chronic conditions: case study on people living with chronic conditions with associated depression	Ms Anne Goodhead	24/06/05	11/07/05	Approved subject to conditions		Approved	24/08/05	Victoria University of Wellington	Nil		Kirsten Smiler will undertake interviews with Māori
CEN/05/07/049	Efficacy of cognitive-based psychotherapy for clients who have sustained a traumatic brain injury (TBI)	Ms Muirel Christanson	24/06/05	11/07/05	Deferred	Methodology issues OSEC 53, minimisation of harm issues OSEC 61	Approved	22/09/05	Massey University	A		Kaumatuia Massey University

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CEN/05/07/050	A randomised, double blind, placebo-controlled, double dummy, crossover, dose ascending study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of single inhaled doses of nebulised GSK656398 and tiotropium bromide (18 µg via DPI) in COPD patients	Dr Marion Leighton	24/06/05	11/07/05	Approved subject to conditions		Terminated before approval finalised	22/09/05	P3 Research	B	GlaxoSmith Kline	Colleen Wineera, HE&R
CEN/05/07/051	An exploratory study to identify substance use disorders in a prison population using a diagnostic assessment interview; comparing violent to non-violent prisoners	Ms Amanda Jones	24/06/05	11/07/05	Approved subject to conditions		Approved	8/12/05	Massey University	A		Mr Bill Simpson, Regional Māori Advisor, Wellington Regional Prisons, Kaumatua Council (Upoko-O-Te-Ika) Wellington
CEN/05/07/052	General practice enrolment, utilisation and disease management 2001 to 2005	Dr Deborah McLeod	24/06/05	11/07/05	Approved subject to conditions		Approved	22/12/05	Wellington School of Medicine & Health Sciences	Nil		Ms Donna Cormack, Eru Pomare Māori Health Research Unit: Ms Bridget Robson, Eru Pomare Unit
CEN/05/08/053	Information system support for clinical decision-making in primary health care: case studies of New Zealand primary health organisations	Ms Judith Engelbrecht	20/07/05	8/08/05	Approved subject to conditions		Approved	9/11/05	Massey University, Palmerston North	Nil		Te Pumanawa Hauora
CEN/05/08/054	The role of seated immobility in the development of venous thrombo-embolism and pulmonary embolism	Dr Sarah Aldington	20/07/05	8/08/05	Deferred	Methodology issues, OSEC 53	Approved	21/09/05	Medical Research Institute of New Zealand	A		Colleen Wineera, HE&R
CEN/05/08/055	The experience and needs of patients waiting for coronary artery bypass surgery	Martin Grethe	20/07/05	8/08/05	Deferred	No information sheet and consent form provided OSEC 2.2	Approved	1/09/05	Massey University	Nil		Riki Nia Nia, Māori Health Unit, C&CDHB
CEN/05/08/056	Pregnant pauses: making sense of the experience of moral agency in the era of prenatal genetic testing	Ms Sarah Donovan	20/07/05	8/08/05	Approved subject to conditions		Approved	1/09/05	Victoria University of Wellington	Nil		Tai Walker, Māori Research Advisor, HRSR, VUW
CEN/05/08/057	Flexible diuretic medication dosing by heart failure patients in New Zealand nurse-led heart failure clinics; exploring patients' decision-making processes and perceptions of efficacy	Ms Brigitte Lindsay	24/07/05	8/08/05	Approved subject to conditions		Approved	2/09/05	Hutt Valley District Health Board	Nil		Kuini Puketapu, Hutt Valley DHB Māori Advisor
CEN/05/08/058	Randomised adolescent pedometer trial (RAP T); pedometers as motivational tools for increasing physical activity in adolescents with type 1 diabetes	Ms Kirsty Newton	24/07/05	8/08/05	Approved subject to conditions		Approved subject to conditions		Hutt Valley District Health Board, Capital & Coast District Health Board, MidCentral Health DHB	A		Stephen Ihaka, VUW

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CEN/05/08/059	What practising nurses understand by the term evidence-based practice and how it shapes their clinical decision-making	Ms Myra Wilson	22/07/05	8/08/05	Approved subject to conditions		Approved	1/09/05	Massey University	Nil		No consultation required
CEN/05/08/060	What are the experiences of nurses involved in the assessment of competency in clinical practice via the portfolio process?	Ms Mary Johnson	22/07/05	8/08/05	Approved subject to conditions		Approved	2/09/05	Massey University	Nil		Director of Nursing Wakefield Hospital
CEN/05/08/061	Technical reliability and accuracy of home polysomnography	Dr Angela Campbell	22/07/05	8/08/05	Approved subject to conditions		Approved	1/09/05	Wellsleep	A		Christine Rimene, Ngai Tahu Māori Health Research Unit, University of Otago; Kara Mihaere, Ngati Kahungunu Ki Wairoa and Rangitane
CEN/05/08/062	Retrospective specimen reclassification in the era of c-kit/CD117 immunohistochemical staining	Dr Matthew Henderson	22/07/05	8/08/05	Approved subject to conditions		Approved	22/09/05	Capital & Coast District Health Board	A		No consultation required
CEN/05/08/063	A comparison of optic nerve compliance in those with glaucoma and those without glaucoma	Dr Tony Wells	25/07/05	8/08/05	Approved subject to conditions		Approved	23/12/05	Capital & Coast District Health Board	A		Christine Rimene, University of Otago Research Division
CEN/05/09/064	Diagnostic sensitivity in assessment of benign paroxysmal positional vertigo	Dr Stuart Mossman	24/08/05	12/09/05	Approved subject to conditions		Approved subject to conditions		Capital & Coast District Health Board	A		Still outstanding
CEN/05/09/065	Venous and arterial blood gas results in intensive care patients	Dr Heidi Walker	24/08/05	12/09/05	Approved subject to conditions		Approved subject to conditions		Capital & Coast District Health Board	A		Riki Nia Nia, Māori Health Unit, CCDHB
CEN/05/09/066	The experiences of 75–85-year-old people, of being nursed in an acute care environment	Kerry Walsh	24/08/05	12/09/05	Approved subject to conditions		Approved	27/10/05	Capital & Coast District Health Board	Nil		Māori participant excluded
CEN/05/09/067	Quantifying the time intervals of patient flow for patients admitted in hospital through a New Zealand emergency department: a descriptive study	Iona Bichan	26/08/05	12/09/05	Ethical approval not required	OSEC 134	Ethical approval not required		Massey University, Pallmerston North	Nil		
CEN/05/09/068	Meaningful moments in music therapy improvisation	Fiona Shaw	26/08/05	12/09/05	Approved subject to conditions		Approved	28/09/05	Wellington Early Intervention Trust	Nil		No consultation required
CEN/05/09/069	From random and chaotic beating to more organised, meaningful forms: does the use of rhythm in music therapy facilitate such changes for clients with complex needs and how does this occur?	Judith Cooper	26/08/05	12/09/05	Approved subject to conditions		Approved	30/09/05	Massey University	Nil		No consultation required
CEN/05/09/070	Reliability of diagnoses of schizophrenia in Māori and non-Māori pilot study	Dr Tai Kake	26/08/05	12/09/05	Approved subject to conditions		Approved	24/11/05	Wellington School of Medicine and Health Sciences, Capital & Coast District Health Board	A		Hirana McKenzie, Transcultural Mental Health Services, C&CDHB

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CEN/05/09/071	Dioxin exposure levels and health effects in phenoxy herbicide production workers	Professor Neil Pearce	6/09/05	12/09/05	Approved		Approved	30/09/05	Massey University	Nil		No consultation required
CEN/05/10/072	Rakaipaaka Health and Ancestry Study	Ms Helena Barwick	23/09/05	10/10/05	Received		Transferred to M/C committee		ESR	A		Ngati Rakaipaaka
CEN/05/10/073	To assess the adequacy of secondary preventative strategies, including medical therapy, comorbid condition management and lifestyle measures following previous coronary artery bypass surgery	Dr Laura Davidson	26/09/05	10/10/05	Approved subject to conditions		Approved	26/05/06	Capital & Coast District Health Board	A		Colleen Wineera, Māori Health Unit, Wellington Hospital
CEN/05/10/074	A multi-site qualitative investigation of staff perceptions of end-of-life care pre and post the implementation of an integrated care pathway for the care of the dying patient	Dr Jean Clark	26/09/05	10/10/05	Approved subject to conditions		Approved	10/11/05	MidCentral Health DHB	Nil		Māori Health Unit, Te Whare Rapuora
CEN/05/10/075	The 'exclusion' of autism: how does music therapy aid the psychological, social and educational difficulties confronted by children with autism in a special education setting?	Ms Rebecca Travaglia	26/09/05	10/10/05	Approved subject to conditions		Approved	27/10/05	Massey University	Nil		No consultation required
CEN/05/10/076	Documenting a music therapy programme in a forensic setting	Ms Anna Hill	26/09/05	10/10/05	Approved subject to conditions		Approved	27/10/05	Massey University	Nil		Kaamanaki on study site
CEN/05/11/077	Incidence and risk factors for musculoskeletal pain in the general adult New Zealand population	Dr William Taylor	17/10/05	14/11/05	Approved subject to conditions		Approved	23/11/05	Wellington School of Medicine and Health Sciences	Nil		Christine Rimene, Māori Research, University of Otago
CEN/05/11/078	A optometrist-led survey of pupil ruff status in the Wellington region	Dr Anthony Wells	17/10/05	14/11/05	Deferred	Methodology issues OSEC 53, Minimisation of harm issues OSEC 2.5	Approved	22/02/06	Wellington School of Medicine and Health Sciences	A		Christine Rimene, Māori Research, University of Otago
CEN/05/11/079	A randomised study on the effects of adult literacy on health care outcomes	Dr Carl Eagleton	17/10/05	14/11/05	Approved subject to conditions		Approved	2/12/05	Capital & Coast District Health Board	A		Riki Nia Nia, Māori Health Unit, CCDHB
CEN/05/11/080	A critical discourse analysis of evil	Greig Olsen	17/10/05	14/11/05	Deferred	Retrospective review form not considered appropriate, committee required full application	Deferred		Mental Health Services	Nil		
CEN/05/11/081	Reporting of clinical implications of clinical glaucoma findings	Dr Anthony Wells	17/10/05	14/11/05	Ethical approval not required	OSEC 134	Ethical approval not required		Massey University	Nil		Dr Nick Roskrug, Kaiaorahi Māori

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CEN/05/11/082	Health risks of roof-collected rainwater study	Stan Abbott	18/10/05	14/11/05	Approved subject to conditions		Approved	17/11/05	Massey University	Nil		Dr Nick Roskrug, Kaiairahi Māori
CEN/05/11/083	A multi-centre three-year longitudinal prospective study to identify novel endpoints and compare these with forced expiratory volume in one second (FEV1) for their ability to measure and predict COPD severity and its progression over time	Dr Dean Quinn	21/10/05	14/11/05	Approved subject to conditions		Approved	23/12/05	P3 Research	B	GlaxoSmith Kline	Colleen Wineera, HE&R Services
CEN/05/11/084	Survey of positive treponemal serology in the Wellington area	Dr Jane McDonald	21/10/05	14/11/05	Approved subject to conditions		Approved	23/12/05	Wellington IPA Sexual Health Clinic	Nil		No consultation required
CEN/05/12/085	Gender differences in adaptation to a phase 2 cardiac exercise rehabilitation programme	Dr Suzanne Broadbent	14/11/05	12/12/05	Approved subject to conditions		Approved	30/01/06	Massey University	A		Nick Roskrug, Kaiairahi Māori, College of Sciences
CEN/05/12/086	Building a professional learning community	Mrs Patricia Russell	17/11/05	12/12/05	Ethical approval not required	OSEC 134	Ethical approval not required			Nil		No consultation required
CEN/05/12/087	Outcome evaluation of the lower north severe conduct disorder (SCD) programme	Bennett Friedmann	18/11/05	12/12/05	Approved subject to conditions		Approved	9/02/06	Victoria University	Nil		Various different Māori stakeholders who are part of the lower north SCD programme
CEN/05/12/088	Prosthesis suspension and energy cost in amputee walking	Dr Alan Walmsley	24/11/05	12/12/05	Approved subject to conditions		Approved subject to conditions		Massey University	A		Consultation undertaken but no evidence provided
CEN/05/12/089	The influence of moderate dehydration on thermoregulatory match-play variables and sport specific fitness in recreationally active multiple sprint sport players	Dr Andrew Edwards	24/11/05	12/12/05	Approved subject to conditions		Approved	10/02/06	UCOL	A		Te Atawhai Mataira, Director of Māori Liaison, UCOL
CEN/05/12/090	The lung macrophage: crucial to asthma pathology	Dr Christine Van Dalen	24/11/05	12/12/05	Approved subject to conditions		Approved	2/03/06	Massey University	A		Chris Cunningham, Te Punimanawa Hauora, Massey University
CEN/05/12/091	To evaluate the introduction of the Liverpool Care Pathway for the terminally ill/ying phase in an aged care facility within the New Zealand context	Ms Kate Gellatly	24/11/05	12/12/05	Approved subject to conditions		Approved	30/01/06	Te Omanga Hospice	Nil		Gala August, Māori Whanau Liaison Officer, Te Omanga Hospice
CEN/05/12/092	An evaluation of fathers' experiences of attending mental health appointments with their child	Ms Michelle Lomas	24/11/05	12/12/05	Approved subject to conditions		Approved subject to conditions		Massey University	Nil		School of Psychology Kaumatua, Mr Turoa Haronga (awaiting letter)

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CEN/05/12/093	A randomised, double-blind study of treatment with a known anti-inflammatory (prednisolone) to evaluate novel endpoints in patients with chronic obstructive pulmonary disease (COPD)	Dr Dean Quinn	24/11/05	12/12/05	Approved subject to conditions		Approved	9/02/06	P3 Research	B	GlaxoSmith Kline	Colleen Wineera, HE&R Services
CEN/05/12/094	Periodontal disease, systemic inflammation, and impaired glucose metabolism	Mr Will Dransfield	24/11/05	12/12/05	Approved subject to conditions		Approved subject to conditions		Capital & Coast District Health Board	A		Māori Health Advisor, Hutt Hospital (awaiting letter)
CEN/05/12/095	Safety assessment of two popular legal party drugs: BZP and BZP+TFMPP	Dr Brent Caldwell	24/11/05	12/12/05	Deferred	Minimisation of harm to participants OSEC 61	Deferred		Medical Research Institute of New Zealand	A		Colleen Wineera
CEN/05/12/096	Tracking health care interactions: patient-professional communication	Dr Kevin Dew	28/11/05	12/12/05	Approved subject to conditions		Approved subject to conditions		Wellington School of Medicine and Health Sciences	Nil		Ngai Tahu Research Consultation Committee
CEN/05/12/097	Effects of 'back migration' on atopic markers and asthma symptoms in Tokelauans: a pilot study	Dr Robert Siebers	28/11/05	12/12/05	Approved subject to conditions		Approved subject to conditions		Wellington School of Medicine and Health Sciences	A		Te Runanga o Otakou (Inc), Tu Kotahi (Māori Asthma Trust)
CEN/05/12/098	To determine the prevalence of malnutrition among in-centre haemodialysis patients at MidCentral Health using the subjective global assessment (SGA) tool	Dr Robert Siebers	28/11/05	12/12/05	Approved subject to conditions		Approved	3/02/06	Palmerston North Hospital	A		No consultation undertaken
CEN/05/12/099	A new model of service delivery for children and families living with childhood type 1 diabetes	Louise Farmer	28/11/05	12/12/05	Approved subject to conditions		Approved subject to conditions		Hutt Valley District Health Board	Nil		Kiuni Puketapu, Māori Health Advisor, HVDHB
CEN/05/12/100	Developing an effective intervention to reduce unintentional injury to pre-school children: factors that influence parental risk perception and mitigation	Jean Simpson	28/11/05	12/12/05	Approved subject to conditions		Approved subject to conditions		University of Otago Medical School	Nil		Te Taiwhenua o Heretaunga, Te Kupenga Hauori, Choices, Ngati Kahungunu Iwi Trust
CEN/05/12/101	A pilot study of a randomised controlled trial of an occupational therapy intervention to prevent work disability in people with newly-diagnosed rheumatoid arthritis	Dr William Taylor	29/11/05	12/12/05	Approved subject to conditions		Approved	27/01/06	Hutt Valley District Health Board	Nil		Christine Rimene, Facilitator, Māori Research, University of Otago

Studies approved by the Chairperson under delegated authority

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
CEN/05/01/CPD	An assessment of procedure-related information recalled by patients about to undergo coronary angiography or angioplasty (student project)	Dr Stewart Mann	7/01/05				Approved	2/03/05	Wellington School of Medicine and Health Sciences	Nil		Christine Rimene, Facilitator Research Maori, University of Otago
CEN/05/02/CPD	Screening tests for respiratory studies	Dr Sarah Aldington	4/02/05				Approved	9/02/05	P3 Research	Nil		No consultation required
CEN/05/03/CPD	Assessing response to the free heart check campaign in Maori and Pacific men over 35: what are the barriers to care?	Adnan Bilgrami	23/02/05				Completed	23/03/05		Nil		Satisfactory consultation undertaken
CEN/05/04/CPD	COPD pre-screening tests	Dr Shaun Holt	2/05/05				Approved	4/05/05	P3 Research	Nil		No consultation required
CEN/05/05/CPD	Neurorehabilitation physiotherapy	Ms Ruth Cutfield	19/05/05				Approved	19/05/05	Capital & Coast District Health Board	Nil		No consultation required
CEN/05/06/CPD	Relationship between prematurity and previous termination of pregnancy	Dr Rachel Fletcher	30/07/05				Approved	3/08/05		Nil		No consultation required
CEN/05/07/CPD	Unequal treatment – a feasibility study of pain management in A&E Department	Brendon Little	24/08/05				Approved	24/08/05	Wellington School of Medicine and Health Sciences	Nil		Donna Cormack, Eru Pomare Centre
CEN/05/08/CPD	Long term results of a z-plastic release of Dupuytren's contracture	Vishal Pai	26/08/05				Approved	1/09/05	Wellington School of Medicine and Health Sciences	Nil		No consultation required
CEN/05/09/CPD	Evaluation of the Doctors' Health Advisory Service	Ms Helena Barwick	2/09/05				Approved	22/09/05		Nil		No consultation required
CEN/05/10/CPD	The use of waterproof lined plasters in immobilisation of children's upper limb fractures	Dr Andrew Matthews	5/09/05				Approved	12/10/05	Capital & Coast District Health Board	A		No consultation required
CEN/05/11/CPD	Experimental analysis of word production difficulties in Parkinson's disease: a pilot study	Dr Shaun Hayward	27/09/05				Approved	12/10/05	Wellington School of Medicine and Health Sciences	Nil		No consultation required
CEN/05/12/CPD	Infant atopic eczema/dermatitis – what happens after the allergy clinic?	Ms Linda Zhou	1/11/05				Approved	10/11/05	Wellington School of Medicine and Health Sciences	Nil		No consultation required
CEN/05/13/CPD	Diabetes, insulin and driving: the New Zealand experience	Damon Bell	14/11/05				Approved	16/11/05		Nil		No consultation required
CEN/05/14/CPD	Indoor allergen spray study	Caroline Phung	2/11/05				Approved	17/11/05		Nil		No consultation required
CEN/05/15/CPD	What determines bowel function after right hemicolectomy for cancer	Tom Knobloch	11/11/05				Approved	25/11/05	Wellington School of Medicine and Health Sciences	Nil		No consultation required
CEN/05/16/CPD	StepS skin test pressure study	Dr Tristram Ingham	28/11/05				Approved	25/11/05	Wellington School of Medicine and Health Sciences	A		No consultation required

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.

