



Multi-region Ethics Committee

Annual Report

January 2006 to December 2006

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Contents

Chairperson's Report	1
Committee Membership	2
Appointments	2
Members' attendance in 2006	6
Training	7
Approval by the Health Research Council	8
United States Department of Health & Human Services Registration	8
Response to Cultural Issues	9
Applications	10
Multi-region Ethics Committee statistics for January–December 2006	10
Other committee statistics	10
Audit or matters not requiring ethical approval	10
Innovative practice	10
Second opinions	11
Complaints	11
Issues for the Committee	12
Committee workload	12
Tissue banking	12
Guidelines for Chairperson's Delegation	13
Appendices	
Appendix 1: Applications Received January to December 2006	14
Appendix 2: Multi-region Ethics Committee Terms of Reference	43

Chairperson's Report

This report provides an overview of the work of the Multi-region Ethics Committee from January to December 2006. The report was presented to the Multi-region Ethics Committee at its meeting on 20 March 2007.

The report details applications received for ethical approval for the calendar year, the review of those applications and other work undertaken by the committee. In all, 185 applications were received by the committee and on average 15 applications were reviewed at each meeting. In the two months of October and November 2006, 30 applications were received each month and extra meetings were held. On these occasions, the committee co-opted additional medical expertise from regional ethics committees.

Most of the Multi-region Ethics Committee meetings were held at the Foundation of the Blind, Adelaide Rd, Wellington. In February, the committee convened in Dunedin, coinciding with the biennial Bioethics Conference and in May, the committee's meeting was held in Auckland as part of a successful outreach for the Auckland District Health Board. Five members of the committee met with researchers in an open meeting at Auckland Hospital.

There were two changes to the membership of the committee in 2006. In December, Dr Jane Koziol-McLain and Fiona McCrimmon completed their tenure on the ethics committee. Both members contributed a great deal of expertise to the committee's deliberations. With her nursing background, Dr Jane Koziol-McLain contributed expertise on clinical research and qualitative research. As the committee's legal expert, Fiona McCrimmon's contribution was invaluable. In 2007 Associate Professor Margaret Horsbrough replaced Dr Jane Koziol-McLain and Richman Wee replaced Fiona McCrimmon.

The committee appreciates the thorough and professional support given by its two administrators, Sue Fish and Michelle Judge.

The Multi-region Ethics Committee remains an effective committee staffed by highly motivated and capable members.

Sincerely

Martin Tolich
Chairperson

Committee Membership

Appointments

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

Chairperson

Martin Tolich	BA (Auck), MA (Auck), PhD (California, Davis)
Representation	Lay member
Member category	Ethicist
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2008
Professional affiliations	Programme co-ordinator, Sociology, Anthropology Department, Otago University
Iwi affiliations	None

Deputy Chairperson

Cynthia Darlington	BA (Class I), PhD (Sydney)
Representation	Non-lay member
Member category	Pharmacist/pharmacologist
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Department of Pharmacology and Toxicology, University of Otago; Editorial Board, CNS Editor, current opinion in investigational drugs
Iwi affiliations	None

Members

Maliaga Erick	Degree in Social Work, Graduate Certificate in Dual Diagnosis
Representation	Lay member
Member category	Consumer representative
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Auckland District Health Board
Iwi affiliations	Niuean

Jane Koziol-McLain	BSN (Loyola, Chicago), MS (Colorado), PhD (Colorado)
Representation	Non-lay member
Member category	Health researcher
Gender	Female
Date of appointment	November 2004
Term of appointment	2 years
Term completed	December 2006
Professional affiliations	Associate Professor, School of Nursing; Auckland University of Technology; Co-Director, Interdisciplinary Trauma Research Unit, Auckland University of Technology
Iwi affiliations	None
Barry Smith	BSc, MPhil (Auck), PhD (Essex); GradDipArts (Music) (Waik)
Representation	Lay member
Member category	Community representative, Māori
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	April 2008
Expertise	Research methods, research ethics, Māori research
Professional affiliations	National School of Performing Arts; Te Wānanga o Aotearoa ki Rotorua; Chairperson, Lakes District Health Board Research and Ethics Committee, Social Research Consultant
Iwi affiliations	Te Rarawa, Ngāti Kahu
Graham Mellso	MBChB(Otago), DPM, MD (Melb); Member of Royal College of Psychiatrists; Fellow of Royal Australian and New Zealand College of Psychiatrists
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Professional affiliations	Professor of Psychiatry, Waikato Clinical School, Faculty of Medical and Health Services, University of Auckland
Iwi affiliations	None
Sheila Williams	BSc (Hons)(Hull), PGDipSc (Otago), DSc (Otago)
Representation	Non-lay member
Member category	Biostatistician
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Professional affiliations	Department of Preventative and Social Medicine, University of Otago Medical School
Iwi affiliations	None

Christopher Wynne	MBChB (Otago); Fellow of the Royal Australia and New Zealand College of Radiologists; Fellow of the Chapter of Palliative Medicine, Royal Australasian College of Physicians
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Retirement date	July 2010
Professional affiliations	Clinical Director, Consultant Radiation Oncologist: Oncology Service, Christchurch Hospital; Oncologist, Canterbury Breastcare; Clinical Investigator, Christchurch Clinical Studies Trust
Iwi affiliations	None
Fiona McCrimmon	LLB (Hons)(Auck), MBChB (Otago)
Representation	Lay member
Member category	Lawyer
Gender	Female
Date of appointment	November 2004
Term of appointment	2 years
Term completed	December 2006
Professional affiliations	Member, New Zealand Law Society; Deputy Chairperson, Health Practitioners Disciplinary Tribunal; Member, Newborn Metabolic Screening Programme Advisory Committee; Principal, McCrimmon Law
Iwi affiliations	None
Carolyn Weston	Queen's Service Medal
Representation	Lay member
Member category	Consumer representative
Gender	Female
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Expertise	Disabilities, advocacy
Iwi affiliations	None
Georgina Johnson	Graduate Diploma Not for Profit Management (Unitec)
Representation	Lay member
Member category	Community representative, Māori
Gender	Female
Date of appointment	July 2005
Term of appointment	3 years
Six-year maximum term	July 2011
Professional affiliations	Executive member, National Association OSCAR; executive member, Tairāwhiti Youth Workers Collective; member, Māori Women's Welfare League
Iwi affiliations	Ngāti Porou, Ngāti Raukawa

Simon Jones	MBChB (Bristol), Dip FFP, RCOG, MRCOG, FRANZCOG
Representation	Non-lay member
Member category	Health researcher
Gender	Male
Date of appointment	July 2005
Term of appointment	3 years
Six-year maximum term	July 2011
Professional affiliations	Consultant gynaecologist, Christchurch Women's Hospital; specialist, The Oxford Clinic, Christchurch; senior clinical lecturer, University of Otago; Faculty of New Zealand Institute of Advanced Laparoscopic Surgery
Iwi affiliations	None

Membership changes

Fiona McCrimmon and Jane Koziol-McLain completed their terms in December 2006. Richman Wee and Margaret Horsburgh were appointed by the Minister of Health on 18 December 2006 and will commence in 2007.

Members' attendance in 2006

Member	M/F	Lay/ non- lay	24 Jan	13 Feb	21 Mar	18 Apr	16 May	20 Jun	18 Jul	22 Aug	19 Sep	17 Oct	31 Oct	21 Nov	29 Nov	12 Dec	Total	
Martin Tolich (ethicist)	M	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	14/14	
Cynthia Darlington (pharmacist/ pharmacologist)	F	N	A	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	12/14	
Maliaga Erick (consumer rep)	F	L	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	12/14	
Jane Koziol-McLain (health researcher)	F	N	Y	A	Y	A	Y	Y	T	Y	Y	Y	Y	Y	Y	A	11/14	
Barry Smith* (community rep)	M	L	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13/14	
Graham Mellsop (health practitioner)	M	N	A	Y	Y	T	A	Y	A	Y	Y	Y	Y	A	T	Y	10/14	
Sheila Williams (biostatistician)	F	N	Y	Y	Y	Y	Y	Y	Y	A	A	Y	Y	Y	Y	Y	12/14	
Christopher Wynne (health practitioner)	M	N	Y	Y	Y	Y	Y	Y	A	T	Y	E	T	Y	A	A	11/14	
Fiona McCrimmon (lawyer)	F	L	A	Y	T	A	T	Y	T	T	Y	Y	T	Y	A	T	11/14	
Carolyn Weston (consumer rep)	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	14/14	
Simon Jones (health researcher)	M	N	Y	A	Y	T	Y	Y	A	Y	A	D	A	Y	A	A	8/14	
Georgina Johnson* (community rep)	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	13/14	
Additional expertise																		
Elizabeth Spellacy	F	N	(HP member Northern Y REC)							Y								
David McGregor	M	N	(HP member Upper South B REC)													Y		
Mark Smith	M	N	(HP member Upper South B REC)													Y		
Alison Luckey	F	N	(HP member Upper South A REC)														Y	
No. of members present	5=M 7=F		9	10	11	9	11	12	9	11	10	11	10	11	7	9		
No. of applications			14	14	15	13	15	7	12	20	16	15	10	13	15	16	195	

* = Māori member

Y = Present

A = Apology

T = Teleconference

D = Delayed

E = Left early

Training

New member training

The following members attended training for new members held in Wellington on 1 April 2006: Georgina Johnson, Simon Jones.

Ongoing training

Ongoing training for all members was held in June 2006. The programme covered research with children, committee relationships, qualitative research and a discussion led by the National Ethics Advisory Committee on observational studies and intervention studies. For convenience, the one-day programme was run in three centres: Christchurch on 20 June, Auckland on 27 June and Wellington on 29 June.

The following members attended the one-day training programme: Martin Tolich, Cynthia Darlington, Barry Smith, Graham Mellsop, Sheila Williams, Georgina Johnson, Carolyn Weston, Jane Koziol-McLain, Chris Wynne.

Training regarding Using Cells from Established Human Embryonic Stem Cell Lines for Research was held on 15 August 2006. The following members attended the one-day training programme: Martin Tolich, Cynthia Darlington.

The following members attended the New Zealand Bioethics Conference in Dunedin from 10–12 February 2006: Martin Tolich, Barry Smith.

Meeting of the Māori members

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

Chairpersons' meetings

Three meetings of the chairpersons of the multi-region and regional ethics committees were held in 2006. Martin Tolich attended the chairpersons' meetings on 9 February 2006, 14–15 August 2006 and 5–6 September 2006. The September meeting included a discussion on tissue banking with Professor Campbell, previous Professor of Ethics in Medicine at the University of Bristol, United Kingdom, Chair of the Ethics and Governance Council of the UK Biobank and Vice-President of the Chair of the Retained Organs Commission, and currently Centennial Professor of Medical Ethics, Medical School of the National University of Singapore. Barry Smith also attended the meeting on 9 February 2006.

Approval by the Health Research Council

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

United States Department of Health & Human Services Registration

The Multi-region Ethics Committee is registered with the United States Department of Health & Human Services. This registration enables the committee to review research funded by the United States Government. The registration number is IRB00004663 – Multi-region 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	68% of applications received
Number of applications returned through insufficient consultation on cultural issues	30% of applications received
Process the committee has for following through on consultation	Required for ethical approval of most applications
Cases of unsatisfactory reasons for not including Māori	0
Mechanisms in place to facilitate consultation with Māori by researchers	The District Health Boards and some research organisations have processes in place to facilitate consultation
Examples of Māori not being included in research	2% of total applications received

A noticeable proportion of applications do not show evidence of satisfactory consultation with Māori. Furthermore, the result of consultation with Māori is generally not available at the time the application is submitted to the committee. Studies initiated outside New Zealand usually contain the statement that because the study was developed offshore, no prior Māori consultation can take place. However, it is frequently appropriate that engagement with Māori occur prior to the project beginning in Aotearoa. Where consultation has occurred, it is usually based around the need for cultural sensitivity and understanding, with less effort directed at research issues relating to Māori that may be implicated in the project.

There is a clear need for greater thought to matters regarding health outcomes for Māori. This need, to some extent, should be addressed with the re-vamping of the application form which will, in future, pose this question directly.

Barry Smith and Georgina Johnson

Applications

The committee held 12 scheduled meetings in 2006. Two additional meetings were held on 31 October and 29 November to consider applications that could not be reviewed at the scheduled meetings.

Multi-region Ethics Committee statistics for January–December 2006

Status at time of report	
Applications approved	154
Studies deferred on first review but subsequently approved	16
Studies deferred on first review and subsequently approved subject to conditions	4
Applications deferred	6
Applications declined	5
Applications carried forward (approved subject to conditions)	10
Approval not required	2
Withdrawn	7
Terminated	1
Total number of applications received	205
Applications considered under delegated authority (CPD)	7
Applications withdrawn prior to consideration	3
Total number of applications considered by the committee	195

Other committee statistics

Number of matters arising reviewed by the committee	32
Number of general business items considered by the committee	17
Number of amendments reviewed by committee	12
Number of amendments approved under CPD	1024

Audit or matters not requiring ethical approval

Two projects were confirmed by the committee as not requiring ethical approval.

Innovative practice

No innovative practice applications were received.

Second opinions

No second opinions were requested.

Complaints

1. The committee received a complaint from a person about their ineligibility for a study. The response from the researcher to the complainant was reviewed by the committee and considered satisfactory. The complainant was advised.
2. A prospective participant complained about a letter of invitation they received. The committee reviewed the researcher's response to the complainant and commended the researcher for the way in which they had dealt with the complaint.
3. The committee received a complaint from a researcher and from the Northern X Regional Ethics Committee about the way in which the Multi-region Ethics Committee considers compensation. The Northern X Regional Ethics Committee Chairperson, who is also that committee's legal member, teleconferenced with the Chairperson and the legal member of the Multi-region Ethics Committee to discuss the minimum compensation acceptable. A recommendation was made to modify the application form.

Issues for the Committee

Committee workload

The health professional members found it difficult to attend additional meetings required to review all applications received in October and November. To ensure sufficient expertise was represented, health practitioner members of regional ethics committee each attended one of the additional meetings. These members were: Elizabeth Spellacy, Northern Y Regional Ethics Committee; Alison Luckey, Upper South A Regional Ethics Committee; and Mark Smith and David McGregor, Upper South B Regional Ethics Committee.

Tissue banking

The Committee put in a submission to the Ministry of Health on the proposed guidelines for future, unspecified use of tissue.

Guidelines for Chairperson's Delegation

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

The Chairperson may approve under delegated authority the following:

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

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

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

At its meeting on 15 February 2005, the committee also agreed to delegate the authority to the Chairperson to approve add-on sites.

Appendix 1: Applications Received January to December 2006

Appendix 1 details the applications considered by the committee from January to December 2006. Eight applications were considered by the committee in 'closed' meetings.

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
MEC/06/01/001	A multicentre, randomised, double-blind, placebo-controlled trial of golimumab, a fully human anti-TNF monoclonal antibody, administered subcutaneously, in subjects with active rheumatoid arthritis despite methotrexate therapy	Dr Daniel Ching	24/11/2005	24/01/2006	Approved subject to conditions		Approved	22/02/2006	Auckland DHB Lakes District Health Board South Canterbury DHB	B	Centocor Inc	Mr B Wikitōa, local kaumatua liaison officer, Timaru Hospital
MEC/06/01/002	A long-term, open-label extension study to investigate the long-term safety of SYR110322 (SYR-322) in subjects with type 2 diabetes; Protocol No. SYR-322-OLE-012 (Amendment 3, dated 3 October 2006)	Prof Russell Scott	30/11/2005	24/01/2006	Approved subject to conditions		Approved	13/03/2006	Counties Manukau DHB Waitemata DHB Capital and Coast DHB Auckland DHB Canterbury DHB Christchurch Hospital Dunedin Hospital Waikato Hospital P3 Research Tauranga P3 Research Wellington	B	Takeda Global Research and Development Centre Inc	Māori Health Groups at all sites
MEC/06/01/003	A multicentre, randomised, double-blind, placebo-controlled trial of golimumab, a fully human anti-TNF monoclonal antibody, administered subcutaneously, in methotrexate-naïve subjects with active rheumatoid arthritis	Dr D Ching	11/11/2005	24/01/2006	Approved subject to conditions		Approved	24/02/2006	Timaru Hospital, North Shore Hospital, Middlemore Hospital	B	Centocor Inc	B Wikitōa, Kaumatua, Timaru Hospital; ADHB Māori Review Committee
MEC/06/01/004	A randomised, double-blind, placebo-controlled, parallel-group, multicentre study to evaluate the efficacy and safety of once-daily intranasal administration of GW685698X aqueous nasal spray 100 mcg for six weeks in adult and adolescent subjects 12 years of age and older with perennial allergic rhinitis (PAR)	Assoc Prof Peter Black	29/11/2005	24/01/2006	Approved subject to conditions		Approved	15/03/2006	University of Auckland	B	GlaxoSmith Kline	Māori representatives/groups from each site have been initially contacted

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
MEC/06/01/005	Evaluation of vocational rehabilitation under the Injury Prevention Rehabilitation and Compensation (IPRC) Act 2001	Dr Kath McPherson	6/01/2006	24/01/2006	Approved subject to conditions		Approved	6/03/2006	Accident Compensation Corporation (ACC)	Nil		Mrs Filomena Davies (AUT Maori Working Group) and Dr Mattie Harwood; ACC contribution; Mr Tapiana Sheldon being contacted for tikanga advice
MEC/06/01/006	A phase III, randomised, double blind, parallel-group study of the efficacy and safety of oral dabigatran etexilate (150 mg bid) compared to warfarin (INR 2.0–3.0) for six-month treatment of acute symptomatic venous thromboembolism, following initial treatment (5–10 days) with a parental anticoagulant approved for this indication; protocol no. 1160.53	Dr Sanjeev Chumilal	22/12/2005	24/01/2006	Approved subject to conditions		Approved	15/06/2006	North Shore Hospital Auckland City Hospital Middlemore Hospital Christchurch Hospital	B	Boehringer Ingelheim	Groups from each locality to be consulted; letters to be forwarded
MEC/06/01/007	Determinants of inequalities in breast cancer survival	Dr Mona Jeffreys	6/01/2006	24/01/2006	Deferred	Insufficient information for committee to make a decision	Deferred			Nil	Funded by Health Research Council and the Cancer Society	Māori health researchers; Kokiri Marae Health services; Manawatu Cancer Society
MEC/06/01/008	Maori women's access to the national cervical screening pathway and BreastScreen Aotearoa screening pathways	Ms Nicole Coupe	6/01/2006	24/01/2006	Approved subject to conditions		Approved	20/03/2006		A	Ministry of Health National Screening Unit	
MEC/06/01/009	A pivotal, multicentre, multinational, randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of TAK-242 in adults with severe sepsis	Dr Colin McArthur	6/01/2006	24/01/2006	Approved subject to conditions		Approved	4/05/2006	Auckland DHB Canterbury DHB Waikato DHB Counties Manukau DHB Bay of Plenty DHB	B	Takeda Global Research and Development Centre Inc	
MEC/06/01/010	Taxus olympta: a global taxus liberte registry programme to support worldwide commercialisation (IC and European launch phase)	Dr Gerry Devlin	6/01/2006		Withdrawn prior to meeting		Withdrawn		Waikato Hospital Ascot Hospital	B	Boston Scientific Corporation	
MEC/06/01/011	A phase 2, randomised, double-blind study to evaluate the safety, tolerability and immunogenicity of motavizumab (MEDI-524), a humanised enhanced potency monoclonal antibody against respiratory syncytial virus (RSV), and palivizumab when administered in the same season	Dr Arandomisedrian Trenholme	6/01/2006	24/01/2006	Approved subject to conditions		Approved	23/02/2006	Middlemore Hospital Christchurch Women's Hospital Waikato Hospital Palmerston North Hospital Dunedin Hospital	B	MedImmune Inc	

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
MEC/06/01/012	An open label multicentre study to assess the efficacy and safety of B-domain deleted recombinant factor VIII (BDDrFVIII, ReFacto AF) in patients with hemophilia A undergoing elective major surgery	Dr Mark Smith	6/01/2006	24/01/2006	Approved subject to conditions		Approved	14/03/2006	Canterbury DHB Auckland DHB	B	Wyeth Research	
MEC/06/01/013	Evaluation of South Canterbury Health Board and MidCentral District Health Board mental health services	Mr Jim Hales	6/01/2006		Withdrawn prior to meeting		Withdrawn			Nil	Funded by the Ministry of Health	
MEC/06/01/014	Validation of urine tests for cancer	Dr Parry Guilford	6/01/2006	24/01/2006	Approved subject to conditions	No response received	Withdrawn		Canterbury DHB ProMed Urology	Nil		
MEC/06/01/015	Reception screening for mental illness in New Zealand Prisons: a prospective study	Dr Ceri Evans	6/01/2006	24/01/2006	Deferred	Insufficient information for committee to make a decision	Approved	1/06/2006	Hillmorton Hospital (Christchurch Men's Prison) Mason Clinic (Auckland Central Remand Prison)	Nil		Christchurch; Te Korowai Atawhai; Auckland; Te Taumata o Meihana
MEC/06/01/016	The effect of pre-hospital antibiotics on mortality in meningococcal disease	Dr Amanda Kvalsvig	6/01/2006	24/01/2006	Approved		Approved	31/01/2006	Wellington School of Medicine and Health Sciences	Nil		
MEC/06/01/017	Future revascularisation evaluation in patients with diabetes mellitus: optimal management of multivessel disease	Dr Gerard Devlin	6/01/2006	21/03/2006	Approved subject to conditions		Approved	10/05/2006	Waikato Hospital Christchurch Hospital Wellington Hospital	A	National Heart Lung and Blood Institute through Mount Sinai School of Medicine	Waikato DHB Kaumata Kaunihera rep group and Manager of Te Puna Oranga; Auckland Maori rep group
MEC/06/02/001	Effectiveness trial of wrist-extended operated key-pinch glove for people with tetraplegia	Mr Marcus King	10/01/2006	13/02/2006	Approved subject to conditions		Approved	15/05/2006	Burwood Spinal Unit Auckland Spinal Unit	Nil		
MEC/06/02/002	Toward a health behaviour lifestyle typology of pregnancy	Jayne Krisjanous	6/01/2006	13/02/2006	Deferred	Due to concerns about validity of research proposal (Op Std 53 iii)	Approved	3/05/2006		Nil	Funded by a grant of \$5000 available to VUW PhD students	
MEC/06/02/003	Gene expression in rheumatoid arthritis	Dr Paul A Hessian	18/01/2006	13/02/2006	Approved subject to conditions		Approved	14/07/2006	Christchurch School of Medicine and Health Sciences Wellington School of Medicine and Health Sciences Dunedin School of Medicine	A	Health Research Council of New Zealand; Lottery Health	

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
MEC/06/02/004	2006/07 New Zealand Health Survey	Dr Barry Borman	19/01/2006	13/02/2006	Approved		Approved	17/02/2006	Ministry of Health	Nil	Ministry of Health's New Zealand Health Monitor budget, managed by Public Health Intelligence	Consultation undertaken with stakeholder groups
MEC/06/02/005	An open-label, multicentre study to assess the efficacy and safety of biostate in patients with Von Willebrand's disease (VWD)	Dr Mark P Smith	19/01/2006	13/02/2006	Approved subject to conditions		Approved	26/05/2006	Canterbury DHB Waikato Haematology Dept Auckland City Hospital Capital & Coast DHB	B	CSL Ltd	Respective DHB Māori consultation committees
MEC/06/02/006	The use of mobile phones to compensate for organisational and memory impairment in people with acquired brain injury; Part 1: Methods people use for assisting with remembering	Ms Corne Mackie	20/01/2006	13/02/2006	Approved subject to conditions		Approved	3/05/2006	Brain Injury Association Ranworth Healthcare Ltd Massey University	A	No funder named	
MEC/06/02/007	ENOS: a prospective international, multicentre, randomised, parallel-group, blinded controlled, collaborative, factorial, trial to investigate the safety and efficacy of treatment with transdermal glyceryl trinitrate, a nitric oxide donor, and of stopping or continuing prior antihypertensive therapy in patients with acute stroke	Dr John Gommans	25/01/2006	13/02/2006	Approved subject to conditions		Approved	20/03/2006	Hawke's Bay DHB Auckland DHB Counties Manukau DHB Waitemata DHB Capital and Coast DHB Hutt Valley DHB Otago District Health Board	A	UK and Singapore government research grants through the University of Nottingham, the Hypertension trust and the Medical Research Council of the UK	
MEC/06/02/008	A clinical trial comparing cangrelor to clopidogrel in subjects who require percutaneous coronary intervention	Prof Harvey D White	26/01/2006	13/02/2006	Approved subject to conditions		Approved	31/03/2006	Auckland City Hospital Wellington Hospital Waikato Hospital Christchurch Hospital Dunedin Hospital Middlemore Hospital Greenlane Clinical Centre	B	The Medicines Company, USA	
MEC/06/02/010	Te Tomokanga, acceptable child/adolescent mental health services for New Zealand Maori	Kahu McClintock	26/01/2006	13/02/2006	Approved subject to conditions		Approved	6/03/2006	Waikato Child and Adolescent Mental Health Service, Waikato DHB Kaumata Kaunihera, Waikato DHB Te Au o Hinetai CAMHS, Lakes DHB Group Special Education Head Office CYF Head Office	Nil		

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
MEC/06/02/011	New Zealand Sexual and Reproductive Health Survey	Dr Barry Borman	26/01/2006	18/04/2006	Deferred	Due to insufficient info to make a decision; resubmission of a pilot study required	Approved	22/05/2006	Ministry of Health	Nil	Funded by Ministry of Health	
MEC/06/02/012	Does combination therapy with inhaled corticosteroids improve clinical outcomes in asthma?	Dr John Gillies	27/01/2006	13/02/2006	Deferred	Due to concerns about validity (Op Std 53 iii)	Deferred			A	GlaxoSmithKline	
MEC/06/02/013	Assessment of the influence of timing of post-lumpectomy radiation therapy (RT) on local recurrence in early breast cancer	Dr Graham Stevens	27/01/2006	18/04/2006	Approved		Approved	18/04/2006	University of Auckland Waikato Hospital Palmerston North Hospital Christchurch Hospital Dunedin Hospital Auckland City Hospital	Nil		Local Māori reps to be consulted at each locality
MEC/06/02/014	A randomised, controlled trial to evaluate the safety and efficacy of the Zomaxx drug eluting coronary stent system as compared to the taxus paclitaxel-eluting stent in de novo coronary artery lesions	Dr John Ormiston	27/01/2006	13/02/2006	Approved subject to conditions		Approved	29/03/2006	Auckland City Hospital Christchurch Hospital	A	Mental Health Research and Development Strategy	
MEC/06/02/015	Alcohol and other drug outcome treatment outcome measures; Part II: preliminary work towards validating a draft instrument	Dr Gail Robinson	27/01/2006	13/02/2006	Deferred	Scientific validity	Approved	22/02/2007		A	Funded by Ministry of Health via Mental Health Research and Development Strategy	
MEC/06/02/016	Psychology clinic research database	Dr Duncan Babbage	27/01/2006	13/02/2006	Declined	Due to concerns about validity (Op Std 53iii)	Declined			Nil	Funded by Massey University Psychology Clinic	
MEC/06/03/019	The role of resiliency in responding to blood borne viral and sexually transmitted infections in indigenous communities	Dr Clive Aspin	23/02/2006	21/03/2006	Deferred	Insufficient information	Approved	22/05/2006	University of Auckland	Nil	Funded by Health Research Council of New Zealand	
MEC/06/03/020	International childhood liver tumours strategy group SIOPEL 5 (HCC-1) trial on the hepatocellular carcinoma family of tumours in children/ adolescents and young adults	Dr Jane Skeen	24/02/2006	21/03/2006	Approved subject to conditions		Approved	25/08/2006	Starship Hospital Christchurch Hospital	A	Child Cancer Foundation; Trust funds; DHB funding	

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
MEC/06/03/021	Liraglutide effect and action in diabetes (LEAD-2): metabolic and glycaemic control after once daily administration of liraglutide in combination with metformin versus metformin and glibenclamide combination therapy in subjects with type 2 diabetes; a six-month double-blind, double-dummy, randomised, active controlled, parallel-group, multicentre, multinational trial with an 18 months trial extension period (study no. NN2211-1572)	Dr Simon Young	27/02/2006	21/03/2006	Approved subject to conditions		Approved	23/05/2006	Christchurch Hospital North Shore Hospital Auckland City Hospital	B	Novo Nordisk A/S Denmark	
MEC/06/03/022	A randomised, double-blind, placebo controlled, multicenter Phase III study of denosumab on prolonging bone metastasis-free survival in men with hormone-refractory prostate cancer	Mr Frank Kueppers	28/02/2006	21/03/2006	Approved subject to conditions		Approved	31/05/2006	Urology Research Trust ProMed Urology Cardinal Points Research Trust Ltd Auckland City Hospital Urology Associates	B	Amgen Inc.	Mr Peter Mason; Māori Perspective Group; DoL
MEC/06/03/023	Development of the international classification of functioning disability and health (ICF) core sets for individuals with spinal cord injuries (SCI) – identification of the most frequent problems of functional health	Anne Sinnott	28/02/2006	21/03/2006	Approved subject to conditions		Approved	3/07/2006	Burwood Spinal Unit Auckland Spinal Unit -select-	Nil	Burwood Academy of Independent Living; researcher has been offered co-ordinator role for the W Pacific, funded by the Swiss Paraplegic Foundation, University of Otago, New Zealand Spinal Trust, and Burwood Spinal Unit	
MEC/06/03/024	Observational, non-interventional one arm, global surveillance study of clinical outcomes in renal allograft recipients switched at least six months after renal transplantation to long-term immunosuppressive therapy with cellcept or who have started cellcept therapy at transplantation; protocol M55025	Assoc Prof Richard Robson	1/03/2006	21/03/2006	Approved subject to conditions		Approved	2/05/2006	Christchurch Hospital Wellington Hospital	B	Hoffman-La Roche	
MEC/06/03/025	Development of a self-assessed consumer outcome measure for Aotearoa/New Zealand	Sarah Gordon	1/03/2006	21/03/2006	Approved subject to conditions		Approved	26/04/2006		Nil		

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
MEC/06/03/026	The Maori community heart study	Suzanne Pitama	2/03/2006	21/03/2006	Deferred	Design of study	Approved	29/09/2006	He Oranga Pounamu Wairoa Taiwhenua	Nil	Health Research Council of New Zealand	Wairoa PHD; Ngati Kahungunu Iwi Inc; Ngati Kahungunu (Wairoa Taiwhenua) Inc; Christchurch School of Medicine; He Oranga Pounamu; Hawkes Bay District Health Board; Manawhenua ki Waitaha
MEC/06/03/027	People's attitude towards medication compliance and devices to improve compliance	Natalie Gaud	2/03/2006	21/03/2006	Approved subject to conditions		Approved	3/05/2006		Nil	Douglas Packaging Ltd, suppliers of Medico Packaging	
MEC/06/03/028	Physical and emotional health outcomes for women following significant primary post partum haemorrhage (PPH); a multicentre prospective cohort study	Prof David Ellwood	3/03/2006	21/03/2006	Approved subject to conditions		Approved	4/07/2006	National Women's Hospital Christchurch Women's Hospital Middlemore Hospital North Shore Hospital Waikare Hospital	Nil	Funded by a grant from the ACT Health and Medical Research Program with supp funding from WHA	
MEC/06/03/029	A randomised, double-blind, placebo controlled parallel-group fixed and flexible SLV308 dose arm study to assess efficacy and safety of SLV 308 monotherapy in the treatment of patients with early stage Parkinson's disease; protocol no. S308.3.001; protocol date: 2 February 2006; protocol amendment 02 dated 24 July 2006	Prof Tim Anderson	3/03/2006	18/04/2006	Approved subject to conditions		Approved	12/05/2006	Van der Veer Institute for Parkinson's and Brain Research Wellington Hospital	B	Solvay Pharmaceuticals	
MEC/06/03/030	A phase III, randomised, multicentre, double-blind parallel-group, active controlled study to evaluate the efficacy and safety of oral dabigatran etexilate compared to warfarin (INR 2.0-3.0) for the secondary prevention of venous thromboembolism. RE-MEDY (secondary VTE prevention); protocol no. 1160.47	Dr Sanjeev Chunnial	3/03/2006	21/03/2006	Approved subject to conditions		Approved	6/06/2006	North Shore Hospital Auckland City Hospital Middlemore Hospital Christchurch Hospital	B	Boehringer Ingelheim	
MEC/06/03/031	A prospective, multicentre, non-randomised, direct stenting registry of the Conor CoStar Pacifixel-eluting coronary stent system in participants with de novo lesions of the native coronary arteries (CoStar II continued Access Direct Stent Registry – DSR)	Dr Mark Webster	3/03/2006	21/03/2006	Approved subject to conditions		Approved	21/04/2006	Auckland City Hospital Christchurch Hospital, Riccarton Avenue	B	Conor Medsystems Inc, USA	

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
MEC/06/03/032	A double-blind, prospective, randomised comparison of MitoQ tablets and placebo tablets for the treatment of patients with Friedreich ataxia	Dr Richard Roxburgh	3/03/2006	18/04/2006	Approved subject to conditions		Approved	8/06/2006	Murdoch Children's Research Institute Monash Medical Centre	B	Antipodean Pharmaceuticals	
MEC/06/03/033	A double-blind, prospective, randomised comparison of two doses of MitoQ and placebo for the treatment of patients with Parkinson's disease	Dr Barry Snow	3/03/2006	21/03/2006	Approved subject to conditions		Approved	10/05/2006	Whangarei Hospital Waikato Hospital Tauranga Medical Research Trust Hawke's Bay DHB Palmerston North Hospital Wellington Hospital Nelson Hospital Van der Veer Institute for Parkinson's and Brain Research Dunedin Hospital Auckland City Hospital	B	Antipodean Pharmaceuticals	
MEC/06/04/034	Studying the genetics of keratoconus	Prof Stephen Robertson	6/03/2006	18/04/2006	Approved subject to conditions		Approved	31/07/2006	University of Otago	A	Dunedin School of Medicine	Ngai Tahu Research Consultative Committee; letter attached
MEC/06/04/035	The prevalence of Raynaud's phenomenon among laboratory workers exposed to organic solvents	Prof Stephen Robertson	30/03/2006	18/04/2006	Approved subject to conditions		Approved	4/05/2006		Nil	Applying for funding from Arthritis Foundation	
MEC/06/04/036	Initial observational study on the iron status of New Zealand blood donors	Dr Krishna Badami	30/03/2006	18/04/2006	Approved subject to conditions		Approved	24/07/2006	New Zealand Blood Service, Christchurch New Zealand Blood Service, Hamilton	Nil		
MEC/06/04/037	Assessment of wear time of one piece closed ostomy pouches constructed with barrier PL-0337; various faceplate designs using ostomate volunteers	Dr Nigel Gilchrist	31/03/2006	18/04/2006	Approved		Approved	18/04/2006	CGM Research Trust P3 Research Tauranga Middlemore Hospital	B	Hollister Inc	Mr Pete Mason; Janet McLean of Maori Health Planning and Funding; Maori Health 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
MEC/06/04/038	A phase II trial in patients with previously untreated acute promyelocytic leukaemia to evaluate the effects of (i) adding arsenic trioxide to all-trans retinoic acid and idarubicin for remission induction, and (ii) adding arsenic trioxide to all-trans retinoic acid as consolidation	Dr Peter Browett	31/03/2006	18/04/2006	Approved subject to conditions		Approved	18/08/2006	Auckland DHB MidCentral DHB Capital and Coast DHB Otago DHB Canterbury DHB	A	Pharmalab Australia (supplier of As2O3 for free)	Mata Forbes – Maori Research Review Komiti of ADHB; Te Komiti Whakarite – Canterbury DHB; Maori Health Services – MidCentral DHB; Manu Whenua Health Working Party for Ngai Tahu – Otago/Southernland; Te Runanga O Awarua; Waihopai Runaka; Hokonui Runanga; Oraka-Aparima Runanga – Southernland
MEC/06/04/039	Nurse workforce and patient outcomes	Prof Jenny Carryer	31/03/2006	18/04/2006	Approved		Approved	18/04/2006		Nil		
MEC/06/04/040	C0524T11 – randomised, double-blind, placebo-controlled trial of Golimumab, a fully human anti-TNF α monoclonal antibody, administered subcutaneously, in subjects with active rheumatoid arthritis and previously treated with biologic anti-TNF α agent(s)	Dr Daniel Ching	3/04/2006	18/04/2006	Approved subject to conditions		Approved	26/05/2006	South Canterbury DHB Waitemata DHB Lakes District Health Board	B	Centocor Inc	Mr B Wikitoo, Timaru Hosp
MEC/06/04/041	A multicentre study using the chemotherapy combination of bi-monthly capecitabine and oxaliplatin, with the addition of avastin, in patients with advanced colorectal cancer	Dr Anne O'Donnell	3/04/2006	18/04/2006	Approved		Approved	26/05/2006	Capital and Coast DHB Auckland DHB MidCentral DHB Canterbury DHB	A	Roche Pharmaceuticals	Auckland: Maori Health Research Review Committee; Waikato: Kaumatua Counsel; etc; PN: Te Whare Rauapuora; Wellington: Colleen W/nera; Christchurch: Te Komiti Whakarite to be consulted; Dunedin: Manawhenua Working Party
MEC/06/04/042	Spirituality in New Zealand end-of-life cancer care	Dr Anne O'Donnell	4/04/2006	18/04/2006	Approved subject to conditions		Approved	23/05/2006	North Shore Hospice Mary Potter Hospice Nurse Maude Association	Nil	PI's PhD scholarship	Ngai Tahu Maori Health Research Unit; Te Komiti Rakahau ki Kai Tahu
MEC/06/05/043	Outcomes of massage therapy (MT): a multidimensional approach from a self-regulatory perspective	Ms Karen Malone	21/04/2006	16/05/2006	Deferred	Scientific validity	Withdrawn		The New Zealand College of Massage	A	The New Zealand College of Massage	

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
MEC/06/05/044	The incidence of lateral epicondylitis in airtrainer pilots	WGCDR Peter Hurly	27/04/2006	16/05/2006	Approved subject to conditions		Approved	5/07/2006		Nil	Funded by RNZAF	
MEC/06/05/045	Should we stay or should we go: a discourse analysis of decision making by women and midwives with regard to transfer to secondary or tertiary care from rural maternity facilities in New Zealand Aotearoa	Ms Jean Patterson	26/04/2006	16/05/2006	Deferred	Design of study	Approved	27/10/2006	All New Zealand DHBs	Nil		
MEC/06/05/046	Risk-targeted study of avian influenza zoonosis	Dr Q Sue Huang	26/04/2006	16/05/2006	Approved subject to conditions		Approved	10/07/2006	Institute of Environmental Science and Research, Porirua Investigation and Diagnostic Centre, Upper Hutt AgResearch Ltd, Upper Hutt	A	ESR, MAF	
MEC/06/05/047	A multicentre randomised, double-blind, placebo and active controlled study to evaluate the safety and efficacy of the addition of Sitagliptin 100 mg once daily in patients with type 2 diabetes with inadequate glycaemic control on metformin monotherapy	Dr Jocelyne Benatar	26/04/2006	16/05/2006	Approved subject to conditions		Approved	15/06/2006	Auckland City Hospital Hawke's Bay DHB Christchurch Hospital	B	Merck Sharp and Dohme	
MEC/06/05/048	New Zealand heart failure registry	Dr Gerard Devlin	28/04/2006	16/05/2006	Approved subject to conditions		Approved	13/07/2006	Waikato Hospital Middlemore Hospital Christchurch Hospital Auckland City Hospital	Nil	Funded by Roche pharmaceuticals	
MEC/06/05/049	Family violence evaluation project: Plunket	Dr Jane Koziol-McLain	28/04/2006	16/05/2006	Approved subject to conditions		Approved	12/06/2006	Auckland University of Technology Plunket Mangere East Plunket Ngauruwahia Plunket Castlecliff Plunket Halswell	A	Ministry of Health	Kawa Whakaruru Hau Komiti; Plunket Māori Health Services
MEC/06/05/050	Randomised, double-blind, placebo-controlled Phase-3 induction study to assess the efficacy and safety of 6 mg Sargramostim (Leukine) administered subcutaneously once daily for eight weeks in patients with active Crohn's disease; protocol no. 310187	Dr Frank Weiert	28/04/2006	16/05/2006	Approved subject to conditions		Terminated			B	Schering Pty Ltd	WDHB Kaumatua Kaunihera; Manager of Te Puna Oranga

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
MEC/06/05/051	A multicentre, placebo-controlled, randomised, double-blind, dose-ranging study of SVT-40776 0.05 mg, 0.2 mg, Tolterodine 4 mg and placebo daily doses for four weeks in patients suffering from overactive syndrome	Dr Jane MacDonald	28/04/2006	16/05/2006	Approved subject to conditions		Approved	11/07/2006		A	Urology Research Trust	
MEC/06/05/052	A randomised, double-blind, placebo-controlled, dose ascending, five-way crossover study, to examine efficacy, safety, tolerability, pharmacodynamics and pharmacokinetics of a single administration of three inhaled doses (25, 100 and 400 mg) of GW642444M	Dr Jane MacDonald	28/04/2006	16/05/2006	Approved subject to conditions		Approved	12/07/2006		B	GlaxoSmith Kline	Maori Health Unit of C&C Health
MEC/06/05/053	The initiation, progression, and chemoprevention of hereditary diffuse gastric cancer	Dr Parry Guilford	1/05/2006	16/05/2006	Deferred	Until copy of PIS&CF is received	Approved	11/02/2007	University of Otago, Dunedin Hospital University of Auckland Middlemore Hospital	Nil	HRC	Kimihauora Health Unit
MEC/06/05/054	The effect of Mirena, the levonorgestrel-releasing intra-uterine device, on bone mineral density	Dr Dawn Miller	28/04/2006	16/05/2006	Deferred	Concerns about collecting health information without individuals' prior consent	Approved	21/07/2006		A	HRC funding, plus a donation from Schering Pty Ltd	
MEC/06/05/055	A multicentre, randomised, double-blind, placebo-controlled study to determine the efficacy and safety of the combination of SYR-322 with pioglitazone HCl in subjects with type 2 diabetes	Assoc Prof Patrick Manning	1/05/2006	16/05/2006	Approved subject to conditions		Approved	7/09/2006	P3 Research Tauranga Dunedin Hospital Waikato Hospital North Shore Hospital Wellington Hospital	B	Takeda Global Research & Development Centre Inc	
MEC/06/05/056	Ethics application for further examination of the CAOS data set	Assoc Prof Patrick Manning	1/05/2006	16/05/2006	Approved		Approved	16/05/2006		Nil		
MEC/06/05/057	The Xtract™ Aspiration Catheter Registry Study	Dr Mark Webster	10/05/2006	16/05/2006	Approved subject to conditions		Approved	20/07/2006	Auckland City Hospital Christchurch Hospital	B	Lumen Biomedical, Inc.	MRRCC (Auckland) and Te Komiti Whakarite (Christchurch)
MEC/06/06/058	Audit of anaesthesia fresh gas flow rates	Dr Ross Kennedy	29/05/2006	20/06/2006	Approved		Approved	23/06/2006	Christchurch Hospital	Nil		
MEC/06/06/059	Classification of diseases in mental illness, a survey among general practitioners in New Zealand	Dr Steven Lillis	30/05/2006	20/06/2006	Approved subject to conditions		Approved	8/08/2006	Waikato Hospital	A	Ministry of Health, Waikato DHB	

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MEC/06/06/060	Professional satisfaction and source of stress amongst radiologists in New Zealand	Mr Remy Lim	31/05/2006	20/06/2006	Approved subject to conditions		Approved	6/10/2006	Middlemore Hospital	A	Royal Australasian College of Radiologists (New Zealand branch)	
MEC/06/06/061	A multicentre, double-blind, randomised study to establish the clinical benefit and safety of vitorin (ezetimibe/simvastatin tablet) vs simvastatin monotherapy in high-risk subjects presenting with acute coronary syndrome	Prof Harvey White	1/06/2006	20/06/2006	Approved subject to conditions		Approved	22/09/2006		B	Schering-Plough P/L	
MEC/06/06/062	Drug eluting stent intervention for treating side branches effectively	Dr John Ormiston	2/06/2006	20/06/2006	Approved subject to conditions		Approved	7/08/2006	Auckland City Hospital Christchurch Hospital	B	Devax Inc	
MEC/06/06/063	Whakanui Orana: using the New Zealand Disability Strategy as a framework for strategic policy development for US indigenous peoples with disabilities	Ms Adrienne Wiley	2/06/2006	22/08/2006	Approved subject to conditions		Approved	11/09/2006	Te Pumanawa Hauora	Nil		Te Pumanawa Hauora; Ms Huhana Hickey
MEC/06/06/064	A placebo controlled trial of Zylax or Metamucil for the management of chronic constipation	Dr John Wyeth	2/06/2006	20/06/2006	Approved subject to conditions		Withdrawn	9/01/2007		A	Vital Food Processors Ltd	
MEC/06/06/065	The relative effectiveness of delivering rehabilitation and educational services in a small group community-based programme to older members of the Royal New Zealand Foundation of the Blind	Prof Steve La Grow	6/06/2006	20/06/2006	Declined	Inadequate design (Op Std para 57 iii)	Declined		Massey University Royal New Zealand Foundation of the Blind	Nil		
MEC/06/07/066	Childhood acute lymphoblastic leukaemia: is there a role for genomic imprinting?	Dr Ian Morison	23/06/2006	18/07/2006	Approved subject to conditions		Approved subject to conditions			Nil	HRC	
MEC/06/07/067	New Zealand women living with an increased risk of hereditary ovarian cancer	Alison McEwen	27/06/2006	18/07/2006	Approved subject to conditions		Approved	8/11/2006	Wellington Hospital Gray Matter Research, Wellington	A	Todd Foundation Centenary Fund	
MEC/06/07/068	Prophylactic use of Kiwicrush for prevention of constipation in orthopaedic elective surgery patients	Dr John Wyeth	27/06/2006	18/07/2006	Deferred	Design changed to include placebo	Withdrawn	9/01/2007	Wellington Hospital Wakefield Hospital Hawke's Bay Hospital North Shore Hospital	B	Vital Food Processors Ltd	None

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MEC/06/07/069	Upper gastrointestinal cancer in Maori and non-Maori	Dr Lis Ellison-Looschmann	28/06/2006	18/07/2006	Approved subject to conditions		Approved subject to conditions		Massey University Wellington Apollo Centre for Health and Wellbeing, North Shore City, Auckland School of Medicine, University of Auckland	A	Health Research Council of New Zealand	Kimihaora Trust Tauranga; Ngati Porou Hauora; Māori health reps from six North Island DHBs. Māori members of National Health Promotion Committee of the Cancer Society of New Zealand; Centre for Māori Health Research and Development; Massey University
MEC/06/07/070	A multicentre, double-blind, randomised, placebo and active-controlled, parallel-group, dose-ranging study of MK-0594 in patients with overactive bladder	Dr Stephen Mark	30/06/2006	18/07/2006	Approved subject to conditions		Approved	24/08/2006	Canterbury Urology Research Trust ProMed Urology Roundhay Medical Centre Nelson	B	Merck Sharp and Dohme	Dr Chris Hawke
MEC/06/07/071	Longitudinal study of smokers for tobacco control: New Zealand arm of a multi-country study	Dr Nick Wilson	30/06/2006	18/07/2006	Approved subject to conditions		Approved	19/12/2006	Wellington School of Medicine and Health Sciences Auckland University of Technology	Nil		Christene Rimene
MEC/06/07/072	An extension of the Rembrandt study: an open label SLV308 safety extension to study S308.3.001 in early PD patients; protocol no. S308.3.006, dated 14 April 2006, including amendment 2 dated 4 August 2006	Prof Tim Anderson	30/06/2006	18/07/2006	Approved subject to conditions		Approved	14/09/2006	Van der Veer Institute for Parkinson's and Brain Research Neurology Department, Wellington Hospital	B	Quintiles on behalf of Solway Pharmaceuticals	Māori advisory groups to be consulted; letters to come
MEC/06/07/073	A multicentre, randomised, double-blind, placebo-controlled, parallel group study of the efficacy, safety, and tolerability of E2007 in Levodopa treated Parkinson's disease patients with motor fluctuations; protocol no. E2007-A001-302; amended protocol 01, 11/6/06	Prof Tim Anderson	30/06/2006	18/07/2006	Approved subject to conditions		Approved	25/09/2006	Van der Veer Institute for Parkinson's and Brain Research Neurology Department, Wellington Hospital Neurology Department, Auckland city Hospital The Memory Clinic Ltd, Waitemata Specialist Centre, Auckland	B	Eisai Ltd, UK	Māori advisory groups to be consulted; letters to come
MEC/06/07/076	Heart Guide Aotearoa cardiac rehabilitation programme: understanding access and usage of this programme within the health care service	Ms Stephanie Muncaster	30/06/2006	18/07/2006	Deferred		Approved	23/11/2006	Heart Foundation Te Hoto Manawa Maori Counties Manukau DHB Southland DHB Dunstan Hospital Te Tai Tokerau & Maniaia PHO Waitemata DHB	A	Southland DHB, Canterbury DHB, Dunstan Hospital, Ministry of Health, Heart Foundation	Te Hoto Manawa Maori

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
MEC/06/08/077	A comparison of birth outcomes for first time mothers between those who plan a home birth and those who plan to give birth in a secondary/tertiary hospital setting	Suzanne Miller	20/07/2006	22/08/2006	Approved subject to conditions		Approved	27/10/2006	Victoria University of Wellington	Nil	Research grant from Victoria University Faculty of Humanities and Social Sciences Research Fund	
MEC/06/08/078	Baby friendly community initiative	Ms Geraldine Clemens	31/07/2006	22/08/2006	Deferred	Research method (Op Std para 57 iii)	Deferred		New Zealand Breastfeeding Authority	A		
MEC/06/08/079	Field testing of a quality of life questionnaire for patients receiving home parenteral nutrition (HPN)	Ms Lyn Gillanders	26/07/2006	22/08/2006	Deferred	Concerns about rationale for research	Approved	28/09/2006	Auckland City Hospital	A	NHS Scotland	He Kamaka Oranga through Mata Forbes
MEC/06/08/080	Tangata whaiora and service users' perspectives of mental health classification (diagnosis) systems' focus group research project	Ms Debra Wells	27/07/2006	22/08/2006	Approved		Approved	2/02/2007	Waikato Hospital	Nil		
MEC/06/08/081	Diabetes excess weight loss (DEWL) trial: high protein vs low fat diets	Dr Jeremy Krebs	2/08/2006	22/08/2006	Approved subject to conditions		Approved	25/10/2006	Capital and Coast DHB Hutt Valley DHB Canterbury DHB Auckland DHB	A	Health Research Council	Christene Rimene; Elizabeth Cunningham; Piki te Ora ki te Awaikairangi PHO; Auckland DHB Maori research advisory committee; Kowhai Trust
MEC/06/08/082	HIV Futures New Zealand Survey 2: a national survey of people living with HIV/AIDS	Dr Jeffrey Grierson	2/08/2006	22/08/2006	Approved subject to conditions		Approved	25/09/2006	NZ AIDS foundation	Nil	Funded by Ministry of Health contract with NZAF No. 158811/29045/01; also \$20,000 from NZAF	
MEC/06/08/084	Maternity services consumer satisfaction	Dr Julian King	3/08/2006	22/08/2006	Approved subject to conditions		Approved	16/10/2006	Health Outcomes International, Auckland	Nil	Funded by Ministry of Health; HCI will be paid a fixed fee to conduct the study	Ministry of Health Maori Health Directorate; community groups in Auckland and Waik
MEC/06/08/085	A phase 3 randomised, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of fixed doses of Darusentan in subjects with resistant systolic hypertension receiving combination therapy with four or more antihypertensive drugs, including a diuretic	Prof Mark Richards	4/08/2006	22/08/2006	Approved		Approved	14/09/2006	Christchurch School of Medicine & Health Sciences Hawke's Bay Hospital	B	Myogen, Inc	

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
MEC/06/08/086	A dose-blinded, long-term safety extension study of fixed doses of Darusentan in subjects with resistant systolic hypertension receiving combination therapy with four or more antihypertensive drugs, including a diuretic	Prof Mark Richards	4/08/2006	22/08/2006	Approved subject to conditions	Application incomplete	Approved	25/01/2007	Christchurch School of Medicine & Health Sciences Hawke's Bay Hospital	B	Myogen, Inc	
MEC/06/08/087	A multicentre, randomised, double-blind, placebo-controlled trial of Golimumab, a fully human anti-TNF α monoclonal antibody, administered intravenously, in subjects with active rheumatoid arthritis despite methotrexate therapy; protocol no. C0524T12; protocol date: 5 June 2006	Dr Daniel Ching	4/08/2006	22/08/2006	Approved subject to conditions		Approved	25/09/2006	Dunedin Hospital Timaru Hospital Timaru Rheumatology Studies CGM Research Trust QE Health North Shore Hospital	B	Centocor Inc	
MEC/06/08/088	A phase IV, randomised, multicentre, efficacy and safety study examining the effect of induction dosing with the combination of Peginterferon alfa-2a and Ribavirin in patients with chronic hepatitis C infected with hepatitis C genotype 1	Prof Edward Gane	4/08/2006	22/08/2006	Approved subject to conditions		Approved	30/10/2006	New Zealand Liver Transplant Unit, Auckland City Hospital North Shore Hospital Waikato Hospital Christchurch Hospital	B	Roche	
MEC/06/08/089	Progress: progesterone after previous preterm birth for the prevention of neonatal respiratory distress syndrome	Prof Pippa Kyle	4/08/2006	22/08/2006	Approved subject to conditions		Approved	29/09/2006	Christchurch Women's Hospital Auckland City Hospital Palmerston North Hospital Wellington Women's Hospital Women's and Children's Hospital	A	Funded by NHMRC	
MEC/06/08/090	An open-label extension study to assess the safety and efficacy of Pazopanib in subjects with renal cell carcinoma previously enrolled on protocol VEG105192; protocol VEG107769	Dr Chris Wymne	4/08/2006	22/08/2006	Approved subject to conditions		Approved	16/10/2006	Christchurch Hospital Wellington Hospital	A	Funded by ANZ BCTG	
MEC/06/08/091	A phase II trial evaluating the efficacy and safety of eprubicin and cyclophosphamide (EC) followed by docetaxel with gemcitabine (DG) (+trastuzumab if HER2 positive) as neoadjuvant chemotherapy for women with large operable or locally advanced breast carcinoma	Assoc Prof Bridget Robinson	4/08/2006	22/08/2006	Approved subject to conditions		Approved	4/10/2006	Christchurch Hospital Auckland City Hospital Oncology 161, Auckland Wellington Hospital	A		

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
MEC/06/08/092	Consumer acceptability of antenatal screening for Down syndrome	Dr Julian King	7/08/2006	22/08/2006	Deferred	Research method (Op Std para 57 iii)	Deferred		Health Outcomes International	Nil	National Screening Unit, MoH	Māori manager within Ministry of Health, community groups in Auckland and Waik
MEC/06/08/093	The PreCISE trial: Costar Paclitaxel-eluting coronary stent catheter system evaluation	Dr Mark Webster	7/08/2006	22/08/2006	Approved subject to conditions	Application incomplete	Approved	16/10/2006	Auckland Hospital Christchurch Hospital Middlemore Hospital	B	Conor Medsystems Inc, USA	
MEC/06/08/094	PATHS (providing access to health solutions) evaluation	Dr Debbie McLeod	7/08/2006	22/08/2006	Deferred	Deferred as not written as research project (Op Std Apr 06, 57 iii))	Ethical approval not required		Ministry of Social Development	Nil	Ministry of Social Development	DHB Māori cultural advisors
MEC/06/08/095	To produce an information resource for electroconvulsive therapy consumers and their family/whānau	Ms Katrina Lenzie-Smith	7/08/2006	22/08/2006	Deferred	Deferred as not written as research project (Op Std Apr 06, 57 iii))	Approved subject to conditions		All 21 DHBs invited	A	Ministry of Health	Jane Sherard
MEC/06/09/096	An international survey of musculoskeletal disorders and related disability	David McBride	8/08/2006	19/09/2006	Approved subject to conditions		Approved	2/02/2007	University of Otago Wellington School of Medicine and Health Sciences University of Southampton	A	University of Otago	
MEC/06/09/099	Prospective outcomes of injury study (POIS): pilot study	Dr Sarah Derrett	31/08/2006	19/09/2006	Deferred	Research method (Op Std para 57 iii)	Approved	17/10/2006	Injury Prevention Research Unit – University of Otago ACC National Office	A		Many groups at each site
MEC/06/09/100	A randomised phase 3 trial of ALIMTA® (Pemetrexed) and Carboplatin versus Etoposide and Carboplatin in extensive-stage small cell lung cancer; protocol H3E-MC-JMHO (a)	Dr Andrew Simpson	1/09/2006	19/09/2006	Approved subject to conditions		Approved	5/12/2006	Wellington Hospital Christchurch Hospital Auckland City Hospital	B	Eli-Lilly	Colleen Wineera (CCDHB) and DHB Māori consultation committees in Auckland and Christchurch
MEC/06/09/101	A multicentre, open-label study to assess the efficacy, tolerability, safety and pharmacokinetics of subcutaneous infusions of Ig NextGen 16% in patients with primary immunodeficiency (PID)	Dr Marianne Empson	1/09/2006	19/09/2006	Approved subject to conditions		Approved	16/02/2007	Auckland City Hospital Christchurch Hospital Wellington Hospital Starship Children's Hospital	B	CSL Ltd	DHB Māori consultation committees
MEC/06/09/102	Perinatal neuroblastoma: expectant observation, a COG pilot study, Children's Oncology Group (COG) ANBL00P2	Dr Wayne Nicholls	1/09/2006	19/09/2006	Approved subject to conditions		Approved	26/10/2006	Starship Children's Hospital Christchurch Hospital	A	COG US	Māori Research Review Committee – ADHB and Te Komiti Whakarite CDHB

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
MEC/06/09/103	A phase II study of conformal radiotherapy in patients with low grade gliomas; Children's Oncology Group (COG) ACNS0221	Dr Wayne Nicholls	4/09/2006	19/09/2006	Approved subject to conditions		Approved	9/10/2006	Starship Children's Hospital Christchurch Hospital	A	COG US	Māori Research Review Committee – ADHB and Te Komiti Whakarite CDHB
MEC/06/09/104	COG AOST0331: A randomised trial of the European and American osteosarcoma study group to optimise treatment strategies for resectable osteosarcoma based on histological response to pre-operative chemotherapy	Dr Ruelyn Cockcroft	4/09/2006	19/09/2006	Approved subject to conditions		Approved	14/12/2006	Starship Children's Health Christchurch Hospital Wellington Hospital	A	COG US	Auckland Hospital Māori research review committee; Te Komiti Whakarite; Colleen Wineera
MEC/06/09/105	The Australasian resuscitation in sepsis evaluation (ARISE) study	Dr Seton Henderson	4/09/2006	19/09/2006	Approved		Approved	19/09/2006	Auckland Hospital Christchurch Hospital Middlemore Hospital	Nil		
MEC/06/09/106	Seasonal morbidity and housing	Ms Lucy Telfar Barnard	4/09/2006	19/09/2006	Approved subject to conditions		Approved subject to conditions		Wellington School of Medicine and Health Sciences	A		
MEC/06/09/107	The cross-cultural adaptation of overseas-trained doctors (OTDs) to the work culture of general practice in New Zealand	Mr Madhukar Pande	4/09/2006	19/09/2006	Approved subject to conditions		Approved	2/10/2006	RNZCGP	Nil		Te Akoranga a Maui (RNZGP)
MEC/06/09/108	A clinical trial comparing treatment with Cangrelor (in combination with usual care) to usual care, in subjects who require percutaneous coronary intervention	Prof Harvey D White	4/09/2006	19/09/2006	Approved subject to conditions		Approved	3/11/2006	Greenlane Hospital Waikato Hospital	B	The Medicines company, USA	Mata Forbes (ADHB); Manager of Te Puna Oranga (Waik)
MEC/06/09/109	Development of systematic behavioural observation to quantify ongoing cognitive activity limitations after brain injury	Dr Duncan Babbage	4/09/2006	19/09/2006	Approved subject to conditions		Approved	26/10/2006	Psychology Clinic, Massey University Cavit ABI Rehabilitation (Wellington, Auckland) Brain Injury Association of New Zealand, Auckland	Nil		Mr Turoa Haronga (Massey); Mr Simon Bennett (Massey)
MEC/06/09/110	The Scandinavian total ankle joint replacement – a review of the New Zealand experience at 2–6 years follow-up	Mr Dawson Muir	4/09/2006	19/09/2006	Approved subject to conditions		Approved	7/12/2006	Tauranga Hospital Christchurch Hospital	A	National Joint Register, Christchurch Hospital	
MEC/06/09/111	Heart Guide Aotearoa cardiac rehabilitation programme: understanding access and usage of this programme within health care service: retrospective review	Ms Stephanie Muncaster	4/09/2006	19/09/2006	Approved subject to conditions		Approved	23/11/2006	Heart Foundation Southland Hospital Te Tai Tokerau and Manaiā PHO Pegasus Health Christchurch Hospital Te Hoto Manawa Maori Waitemata DHB Counties Manukau DHB	Nil		

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
MEC/06/10/112	A phase 3, randomised, double-blinded, placebo-controlled study of ulinastatin in the treatment of subjects with acute decompensated heart failure	Prof Mark Richards	5/09/2006	17/10/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital Auckland Hospital Waikato Hospital Middlemore Hospital Hawke's Bay Hospital	A		
MEC/06/10/113	A formative investigation of the impacts of gambling, including problem gambling, on Maori communities, whanau/hapu/iwi: a national Maori collaborative approach	Naina Watene	5/09/2006	17/10/2006	Approved subject to conditions		Approved	19/03/2007	Te Runanga O Kiriakitoa Trust Inc., Hamilton Toiora Healthy Lifestyles Ltd., New Plymouth Te Kohao Health Ltd., Rotorua Nga Manga Puriri, Whangarei Te Rangihaeata Oranga, Napier Ngati Porou Haurua, Gisborne Te Roopu Tautoki Ki Te Tonga, Dunedin Te Keke Matauranga Pounamu Trust, Invercargill	Nil		
MEC/06/10/114	A longitudinal observational study of clinical outcomes in gout	Dr Nicola Dalbeth	6/09/2006	17/10/2006	Approved subject to conditions		Approved	6/12/2006	Counties Manukau DHB Auckland DHB Hutt Valley DHB	A		CMDHB Maori Research Committee; ADHB Maori Health Unit
MEC/06/10/115	Glossopharyngeal breathing technique alters lung compliance in breath-hold divers	Ms Leigh Seccombe	12/09/2006	17/10/2006	Approved subject to conditions		Approved	8/11/2006	Concord Hospital, Australia	Nil		Colleen Wineera – Maori Health Education and Recreation
MEC/06/10/116	Modelling the long term demand for aged residential care and care and support in the community	Mr Stephen Salzano	13/09/2006	17/10/2006	Approved subject to conditions		Approved	21/12/2006	University of Auckland Hamilton Lower Hutt Canterbury	Nil		
MEC/06/10/117	Transplantation of autologous olfactory mucosal tissue followed by active rehabilitation therapy as treatment for chronic spinal cord injury: safety and efficacy study	Dr James Faed	15/09/2006	17/10/2006	Deferred	Scientific and ethical concerns, external expert advice to be sought	Declined		Dunedin Hospital Waikato Hospital Centre for Innovation, University of Otago	A	Trusts, industry and volunteer groups	Otakou Executive Komiti of Te Runanga o Otakou (Inc)
MEC/06/10/118	Predicting response to corticosteroids in COPD using exhaled nitric oxide	Dr Michael Epton	21/09/2006	17/10/2006	Approved subject to conditions		Approved	23/11/2006	Christchurch School of Medicine and Health Sciences Syft Technologies Ltd, Christchurch Christchurch Hospital	A	HRC	
MEC/06/10/119	Investigation of breast milk for persistent organic pollutants	Dr Andrea t'Manneffe	21/09/2006	17/10/2006	Approved subject to conditions		Approved	7/12/2006	Massey University University of Birmingham University of California	A	Ministry of Health	

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
MEC/06/10/120	A study of unilateral retinoblastoma with and without histopathologic high-risk features and the role of adjuvant chemotherapy	Dr Ruellyn Cockcroft	21/09/2006	17/10/2006	Approved subject to conditions		Approved	10/11/2006	Auckland City Hospital Christchurch Hospital	A	Partly by Child Cancer foundation, Trust funds, and the Auckland DHB	
MEC/06/10/121	Evaluating the likelihood of obtaining honest responses to questionnaires on clinical practice at the end of life	Dr Alan Merry	21/09/2006	17/10/2006	Approved		Approved	17/10/2006	Mercy Hospital University of Auckland	Nil	Funded by PI	
MEC/06/10/122	Bortezomib and dexamethasone as treatment and maintenance for multiple myeloma relapse. an Australian myeloma forum multicentre phase II trial	Dr Steve Gibbons	26/09/2006	17/10/2006	Approved subject to conditions		Approved	13/11/2006	Canterbury Health Laboratories Palmerston North Hospital Auckland City Hospital Wellington Hospital Waikato Hospital Northshore Hospital	A		
MEC/06/10/123	Work-related road traffic injuries in New Zealand: investigating the epidemiology, perceived causes and outcomes	Prof Rod Jackson	27/09/2006	17/10/2006			Approved	15/11/2006	University of Auckland	Nil		
MEC/06/10/124	The use of mobile phones to provide value added healthcare support services for people with diabetes	Prof Tony Norris	27/09/2006	17/10/2006	Ethical approval not required		Ethical approval not required		Massey University	Nil	Application has been made to the Lotteries Health Research Fund	
MEC/06/10/125	Organisational pre-requisites to fund, implement, and sustain a Maori health promotion model in a primary care setting	Dr Heather Gifford	28/09/2006	17/10/2006	Approved subject to conditions		Approved	10/04/2007	Whanganui Regional PHO, Whanganui Waioira Healthcare PHO Auckland	Nil		Waioira PHO; Whakauae Research Services; Rata-teitei & Associates; Dr Maureen Holdaway; Te Pumanawa Hauora (Massey)
MEC/06/10/126	International collaborative treatment protocol for infants under one year with acute lymphoblastic or biphenotypic leukaemia	Dr Anne Mitchell	28/09/2006	17/10/2006	Approved subject to conditions		Approved	23/11/2006	Wellington Hospital Christchurch Hospital Starship Children's Health	A	N/A	
MEC/06/10/127	A randomised, double-blind, active-control, parallel group, 90-day safety study of CG5503 immediate release or oxycodone immediate release in subjects with chronic pain from low back pain or osteoarthritis of the hip or knee	Dr Nigel Gilchrist	29/09/2006	31/10/2006	Approved subject to conditions	Study design	Approved	18/12/2006	CGM Research trust, Christchurch Burwood Spinal Unit, Christchurch P3 Research Tauranga North Shore Hospital	B	Janssen-Cilag Pty 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
MEC/06/10/128	Problem gambling assessment and screening instruments project	Prof Max Abbott	29/09/2006	31/10/2006	Approved subject to conditions		Approved	7/12/2006	Auckland University of Technology Problem Gambling Foundation of New Zealand, Auckland Salvation Army Addiction and Supportive Accommodation Services, Auckland Te Rangihaeata Oranga, Hastings Community Alcohol and Drugs Service, Auckland Higher Ground Rehabilitation Trust, Auckland	Nil		Te Rangihaeata Oranga; Gambling Helpline Māori Team – Māori counsellors within the Māori team
MEC/06/10/129	Assessment of the impact of non-negative results (ie, either true positive or requiring repeat HIV testing) in the antenatal screening programme evaluation study	Dr Nigel Dickson	2/10/2006	31/10/2006	Approved subject to conditions	Study design	Approved	21/12/2006	AIDS Epidemiology Group Waikato DHB	Nil		Māori Advisory Group (MAG) with the National Antenatal HIV Screening Implementation Advisory Group (NAHSIAG) – Māori rep
MEC/06/10/130	Health measurement and knowledge translation for improved Maori health outcomes	Dr Robyn Manuel	2/10/2006	31/10/2006	Deferred	The submission lacks detail and the methodology lacks clarity; insufficient connection between aims and method. (Op Std Apr 06 57 iii))	Deferred		Te Whanau o Waipareira, Auckland Korowai Aroha Health Centre, Rotorua	Nil		Wai-Health; Korowai Aroha Hauora; Te Runanga O Ngati Hauiti
MEC/06/10/131	A randomised, double-blind, active- and placebo-controlled, parallel-group, multicentre study to evaluate the efficacy and safety of multiple doses of CG5503 immediate-release formulation in subjects awaiting primary joint replacement surgery for end-stage joint disease	Dr Nigel Gilchrist	2/10/2006	31/10/2006	Approved subject to conditions		Approved	19/12/2006	CGM Research Trust, Christchurch Burwood Spinal Unit, Christchurch P3 Research Tauranga North Shore Hospital	B	Janssen-Cilag Pty Ltd	
MEC/06/10/132	Multicentre international study of capecitabine + bevacizumab as adjuvant treatment of colon cancer (QUASAR 2)	Dr Paul Thompson	2/10/2006	31/10/2006	Approved subject to conditions		Approved	12/02/2007	Oncology Department, Auckland City Hospital and Greenlane Clinical Centre Oncology Service, Christchurch Hospital	A	Roche Pharmaceuticals Pty Ltd	MIRC at Auckland and Christchurch 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/funder	Consultation undertaken
MEC/06/10/133	Ulceration risk assessment of diabetic feet in New Zealand populations	Ms Celia Kuch	2/10/2006	31/10/2006	Approved subject to conditions		Approved	20/02/2007	University of Auckland Funktionsbereich Bewegungsanalytik	Nil	HRC and New Zealand Society for Research on Diabetes	
MEC/06/10/134	Identification of novel gene defects in common variable immune deficiency (CVID): a multicentre study	Dr Rohan Ameratunga	3/10/2006	31/10/2006	Approved subject to conditions		Approved	27/02/2007	Auckland City Hospital Wellington Hospital Christchurch Hospital	A	Australasian Society for Clinical Immunology	
MEC/06/10/135	Living to advanced age – feasibility for a cohort study	Dr Ngaire Kerse	5/10/2006	31/10/2006	Deferred	Insufficient information for committee to make a decision	Approved subject to conditions		Rotorua General Practice Group University of Auckland	A	HRC	Many groups consulted
MEC/06/10/136	Identifying older people to prevent disability: the case-finding trial	Dr Ngaire Kerse	5/10/2006	31/10/2006	Deferred	Information sheet to be rewritten. questionnaires justified	Approved subject to conditions		Capital and Coast DHB Waitemata DHB One other DHB (tbc)	A	HRC	Many groups
MEC/06/11/137	Randomised controlled trial assessing the impact of renal artery angioplasty and stenting plus medical therapy versus medical therapy alone in patients with severe atherosclerotic renal artery stenoses	Assoc Prof Andrew Holden	9/10/2006	21/11/2006	Approved subject to conditions		Approved	2/02/2007	Auckland City Hospital	A	US NIH	
MEC/06/11/138	Improving the practice of nutrition therapy in the critically ill: an international quality improvement project	Ms Lyn Gillanders	13/10/2006	21/11/2006	Approved		Approved	21/11/2006	Auckland DHB Canterbury DHB	Nil		
MEC/06/11/139	School-age outcomes of very preterm infants and antenatal magnesium sulphate therapy: a randomised controlled trial	Prof Brian Darlow	13/10/2006	21/11/2006	Approved subject to conditions		Approved subject to conditions		Christchurch School of Medicine and Health Sciences University of Auckland Waikato Hospital Royal Women's Hospital	A	The Royal Women's Hospital, Melbourne	
MEC/06/11/140	COG D9902: A COG soft tissue sarcoma diagnosis, biology and banking protocol	Dr Scott Macfarlane	24/10/2006	21/11/2006	Approved subject to conditions		Approved	20/12/2006	Starship Children's Health Christchurch Hospital	A	COG	Auckland Hospital MRRC
MEC/06/11/141	COG ARST0331: Vincristine, dactinomycin, and lower doses of cyclophosphamide with or without radiation therapy for patients with newly diagnosed low-risk embryonal/foetoid/ spindle cell rhabdomyosarcoma	Dr Scott Macfarlane	24/10/2006	21/11/2006	Approved subject to conditions		Approved	19/12/2006	Starship Children's Health Christchurch Hospital	A	COG	MRRC Auckland 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
MEC/06/11/142	Children's Oncology Group (COG) AREN0352: renal tumours classification, biology, and banking study	Dr Jane Skeen	24/10/2006	21/11/2006	Approved subject to conditions		Approved	21/12/2006	Starship Children's Health Wellington Hospital	A	COG	MRRC – ADHB; Te Komiti Whakarite – Christchurch Hospital; Colleen Waneera of HE&R Services Ltd, Wellington
MEC/06/11/143	Expectations and satisfaction with orthodontic treatment	Mr David Healey	24/10/2006	21/11/2006	Approved subject to conditions	Study design	Approved	26/03/2007	University of Otago	Nil		University of Otago Ngai Tahu Research Consultation Committee
MEC/06/11/144	Sedation of critically ill patients in Australian and New Zealand intensive care units: a web-based survey	Mr Mark O'Connor	25/10/2006	21/11/2006	Approved subject to conditions		Approved	13/02/2007	University of Melbourne	Nil	Hospira Pharmaceuticals	Te Komiti Whakarite, Christchurch
MEC/06/11/145	The e-Select Registry: a multicentre post-market surveillance	Dr John Ormiston	26/10/2006	21/11/2006	Deferred	Research method (Op Std para 57 iii)	Approved	16/02/2007	Mercy Angiography Unit Christchurch Hospital	Nil	Johnson & Johnson will be funding	
MEC/06/12/146	Does dermoscopy, using the three-point checklist algorithm, improve general practitioners detection rate of melanoma and epithelial cell carcinomas?	Dr Mark Foley	30/10/2006	29/11/2006	Approved subject to conditions		Approved subject to conditions			A	NZGPA; The Skin Clinic Marlborough; 3-Gen	None
MEC/06/11/147	Omeprazole and acute interstitial nephritis: determining a possible relationship to the CYP2C19 phenotype	Janak de Zoysa	30/10/2006	21/11/2006	Approved subject to conditions	Application incomplete	Approved	27/02/2007	Auckland City Hospital Auckland DHB Middlemore Hospital Counties Manukau DHB Christchurch Hospital Canterbury Health Laboratories Dunedin Hospital Otago District Health Board University of Auckland	A	Renal research funds	
MEC/06/11/148	Anthropometric, metabolic and endocrine evaluation of children born following in-vitro fertilisation using frozen embryos	A	31/10/2006	21/11/2006	Approved subject to conditions		Approved	13/03/2007	University of Auckland Fertility Associates Starship Children's Health	A	National Research Centre for Growth and Development Grant	
MEC/06/11/149	An open-label, multicentre, expanded access study of oral AMN 107 in adult patients with Imatinib (Gleevec/Gleevec) – resistant or intolerant chronic myeloid leukemia in blast crisis, accelerated phase or chronic phase	Dr Peter Browett	31/10/2006	21/11/2006	Approved subject to conditions	Application incomplete	Approved	21/12/2006	Auckland City Hospital Christchurch Hospital	B	Novartis Pharmaceuticals	

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
MEC/06/11/150	A single-blind randomised controlled trial to determine whether smokers who have more choice over which nicotine replacement therapy (NRT) delivery methods they use have a higher level of smoking cessation at six months, than smokers with current practice (with NRT available only by patch and/or gum)	Dr Natalie Walker	1/11/2006	21/11/2006	Approved		Approved	21/11/2006	Clinical Trials Research Unit, Auckland Quit Group, Wellington	A	Health Research Council; National Heart Foundation	
MEC/06/12/151	A randomised, double-blind, placebo-controlled trial of intranasal insulin (1.6 mg and 16 mg) in children and young adults at risk of type 1 diabetes: intranasal insulin trial II (INIT II)	Prof Russell Scott	6/11/2006	29/11/2006	Approved subject to conditions		Approved subject to conditions		Christchurch Hospital University of Auckland	A	Diabetes Vaccine Development Centre; Novo Nordisk	
MEC/06/12/152	A randomised, multicentre, phase III study of Erlotinib versus observation in patients with no evidence of disease progression after first line, platinum-based chemotherapy for high-risk Stage I and Stage II-IV epithelial ovarian, primary peritoneal, or fallopian tube cancer	Dr Bernie Fitzharris	2/11/2006	29/11/2006	Approved subject to conditions		Approved	25/01/2007	Christchurch Hospital Palmerston North Hospital	A	EORTC	Manager, Māori Health Services, Midcentral Health, Te Komiti Whakairi, Christchurch
MEC/06/12/153	The work environment and nurse-reported outcomes in renal dialysis units in New Zealand	Ms Claire Minton	2/11/2006	29/11/2006	Deferred	Study design, methods and proposed analysis	Approved	27/02/2007		Nil	Massey University	
MEC/06/12/154	A phase 3 randomised, double-blind, placebo- and active-controlled, multicentre, parallel group study to evaluate the safety and efficacy of darusentan in subjects with resistant hypertension receiving combination therapy with three or more antihypertensive drugs, including a diuretic, as compared to guanfacine or placebo	Prof Russell Scott	3/11/2006	29/11/2006	Approved subject to conditions		Approved	4/04/2007	Lipid and Diabetes Research Group, Christchurch Hospital Bay of Plenty Medical Research Trust, Tauranga Hospital Cardiology Clinical Trials Unit, Waikato Hospital CCRep, Middlemore Hospital CVRU Cardiovascular Research Unit, Greenlane Clinical Centre	B	Myogen, Inc	Māori reps at each DHB will be forwarded
MEC/06/12/155	An investigation of the barriers to help seeking behaviour for problem gamblers and their families and whānau	Prof Max Abbott	3/11/2006	29/11/2006	Approved subject to conditions		Approved	12/12/2006		Nil	Ministry of Health	

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
MEC/06/12/156	A phase III, randomised, double-blind study of galiximab in combination with rituximab compared with rituximab in combination with placebo for the treatment of subjects with relapsed or refractory, follicular non-Hodgkin's lymphoma: Biogen Idec protocol no. 114-NH-301; protocol version 1 dated 7 June 2006	Dr Michael Jameson	3/11/2006	29/11/2006	Approved subject to conditions		Approved	14/03/2007	Waikato Hospital Wellington Hospital Dunedin Hospital Palmerston North Hospital	B	Biogen Idec Inc	Waikato: Te Puna Oranga and Kaumatua Kaunihera rep group at Waikato DHB; PN: Maori Health Unit at Te Whare Rauora; Wellington: Colleen Wineera; Dunedin: Ngai Tahu Research Consultation Committee
MEC/06/12/157	Quantitative assessment of one piece closed ostomy pouches constructed with barrier HGL-006 against the currently marketed soft-flex barrier using ostomate volunteers	Dr Nigel Gilchrist	3/11/2006	29/11/2006	Approved subject to conditions		Approved	18/12/2006	CGM Research Trust Middlemore Hospital	B	Hollister Inc	Christchurch: Mr Pete Mason; Middlemore: Whanau Support – Maori Health Services
MEC/06/12/158	The use of tasers by the police with proposed patients under the Mental Health (Compulsory Assessment and Treatment) Act 1992	Dr Brian McKenna	3/11/2006	29/11/2006	Deferred	Concerns that methodology does not match the study hypothesis; resubmission required	Deferred		University of Auckland Waitemata DHB Counties Manukau DHB Capital and Coast DHB Hutt Valley DHB	Nil		Maori authorities in each DHB have been/are being consulted
MEC/06/12/159	A multicentre, double-blind study to determine the efficacy and safety of SYR-322 plus pioglitazone HCl (Actos), SYR-322 alone or pioglitazone HCl alone in subjects with type 2 diabetes	Dr John Gillies	3/11/2006	29/11/2006	Approved subject to conditions		Approved	3/04/2007	P3 Tauranga, P3 Wellington, Greenlane Hospital, Waikato Hospital, Wellington Hospital, CURT	B	Takeda Global Research and Development Centre Inc	
MEC/06/12/160	An open-label, expanded access study of lapatinib and capecitabine therapy in subjects with ErbB2 over-expressing locally advanced or metastatic breast cancer	Dr Andrew Simpson	3/11/2006	29/11/2006	Approved subject to conditions		Approved	1/02/2007	Wellington Hospital Christchurch Hospital Auckland City Hospital	B	GlaxoSmith Kline	
MEC/06/12/161	A phase III, multicentre, randomised, double blind clinical trial to study the safety and efficacy of the addition of sitagliptin (MKO-431) to patients with type 2 diabetes mellitus who have inadequate glycaemic control on insulin therapy (alone or in combination with metformin)	Prof Russell Scott	6/11/2006	12/12/2006	Approved subject to conditions		Approved	1/02/2007	North Shore Hospital Hawke's Bay Hospital Christchurch Hospital	B	Merck Sharp and Dohme	

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
MEC/06/12/162	A randomised phase 2 trial of double-blind, placebo controlled AMG 706 in combination with paclitaxel, or open-label bevacizumab in combination with paclitaxel, as first line therapy in women with HER2 negative recurrent or metastatic breast cancer	Dr Vernon Harvey	6/11/2006	29/11/2006	Approved subject to conditions		Approved	13/02/2007	Auckland City Hospital Christchurch Hospital Waikato Hospital	B	Amgen Inc	
MEC/06/12/163	The cost of disability	Dr Paul Brown	6/11/2006	29/11/2006	Approved subject to conditions	Study design and incomplete application	Approved	12/02/2007	University of Auckland Disability Resource Centre, Auckland	A		
MEC/06/12/164	A randomised, double-blind, multicentre study of denosumab compared with Zoledronic acid (Zometa) in the treatment of bone metastases in men with hormone-refractory prostate cancer	Dr Chris Wymne	7/11/2006	29/11/2006	Approved subject to conditions		Approved	13/02/2007	Christchurch Hospital Tauranga Hospital	B	Amgen Inc.	
MEC/06/12/165	Protocol no. CSAD448B2 101: a multicentre, randomised, placebo-controlled, double masked, four-arm parallel group study to assess the tolerability, safety and efficacy of SAD488 0.02% and 0.01% ophthalmic solution given once to subjects with ocular hypertension	Dr Anthony Wells	7/11/2006	12/12/2006	Deferred	Application incomplete	Approved subject to conditions	13/03/2007	Capital Vision Research Trust Eye Institute	A	Novartis Pharmaceuticals Corp	
MEC/06/12/167	A double-blind, active-controlled, long-term safety extension study of optimised doses of darusentan in subjects with resistant hypertension despite receiving combination therapy with three or more antihypertensive drugs, including a diuretic, as compared to guanfacine (protocol DAR-312-E)	Prof Russell Scott	16/11/2006	29/11/2006	Approved subject to conditions		Approved	11/04/2007	Lipid & Diabetes Research, Christchurch Hospital Bay of Plenty Medical Research Trust Cardiology Clinical Trials Unit Greenlane Clinical Centre	B	Myogen, Inc	
MEC/06/12/168	A randomised, blinded, consecutive enrolment evaluation of the elixir novolimus-eluting stent compared to an approved drug eluting stent in the treatment of patients with de novo native coronary artery lesions; elixir medical clinical evaluation of the novolimus-eluting coronary stent; the EXCELLA study	Dr Mark Webster	24/11/2006	12/12/2006	Approved subject to conditions		Approved subject to conditions		Auckland City Hospital Mercy Angiography Unit Middlemore Hospital Wellington Hospital Christchurch Hospital	B	Elixir Medical USA	
MEC/06/12/170	A randomised, double-blind, placebo-controlled safety and tolerability study of repeated doses of anti-IgE immunotherapy in allergic patients: study no. 2006-24	Dr Dean Quinn	24/11/2006	12/12/2006	Approved subject to conditions		Approved	5/02/2007	P3 Research Wellington P3 Research Tauranga	B	Resistentia Pharmaceuticals AB, Sweden	

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
MEC/06/12/171	A comparison of ipratropium bromide/salbutamol delivered by the respimat inhaler to combivent in halation aerosol and ipratropium bromide delivered by the respimat in a 12-week, double-blind, safety and efficacy study in adults with chronic obstructive pulmonary disease: study no. 1012.56	Dr Dean Quinn	24/11/2006	12/12/2006	Approved subject to conditions		Approved	8/03/2007	P3 Research Wellington Auckland City Hospital Middlemore Hospital Waikato Hospital Dunedin School of Medicine P3 Research Tauranga	B	Boehringer Ingelheim	
MEC/06/12/172	Seasonal influenza prevalence in arriving international airline passengers	Dr Patricia Priest	24/11/2006	12/12/2006	Approved subject to conditions		Approved subject to conditions		University of Otago Canterbury Health Laboratories Christchurch School of Medicine and Health Sciences Wellington School of Medicine and Health Sciences	Nil		
MEC/06/12/173	A randomised, double-blind, placebo-controlled, multicentre, dose-escalation and dose-confirmation study to evaluate the safety and efficacy of revaroxaban in combination with aspirin alone or with aspirin and a thienopyridine in subjects with acute coronary syndrome	Prof Harvey White	24/11/2006	12/12/2006	Approved subject to conditions		Approved	19/02/2007	Auckland City Hospital Waikato Hospital Christchurch Hospital Dunedin Hospital Tauranga Hospital North Shore Hospital Taranaki Base Hospital Wellington Hospital Middlemore Hospital Hawke's Bay Hospital	B	Bayer Health Care, Johnson & Johnson and Janssen-Cilag	
MEC/06/12/175	The prevalence, nature and impact of workplace bullying on nurses in New Zealand	Hayley Milne	27/11/2006	12/12/2006	Deferred	Study design does not meet aims	Approved	21/02/2007	University of Auckland	Nil		
MEC/06/12/176	A prospective study of a novel urine diagnostic test for the detection of urinary tract transitional cell carcinoma	Dr Peter Davidson	27/11/2006	12/12/2006	Approved subject to conditions		Approved	13/03/2007	CURT Medical Trials Trust Board Inc Promed House, Tauranga Christchurch Hospital	Nil		Mr Pete Mason; W/hakatane
MEC/06/12/177	Investigation of dental enamel hypomineralisation and hypoplasia, relationships with general health, family history and methods to improve the quality of the enamel	Rami Amin Farah	27/11/2006	12/12/2006	Approved subject to conditions		Approved	2/03/2007	School of Dentistry, University of Otago	Nil	Department of Oral Sciences, School of Dentistry, University of Otago	
MEC/06/12/178	A phase III randomised, double-blind, dexamethasone-sparing study comparing human corticotrophin-releasing factor (hCRF) to placebo for control of symptoms associated with peritumoral brain edema in patients with malignant brain tumour requiring chronic administration of high dose dexamethasone	Dr C Wynne	27/11/2006	12/12/2006	Approved subject to conditions		Approved	3/04/2007	Christchurch Hospital, Wellington Hospital, Dunedin Hospital	B	Neurobiological Technologies Inc	Te Komiti Whakariri, Christchurch

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
MEC/06/12/179	A phase III randomised, double-blind study comparing human corticotrophin-releasing factor (hCRF) to dexamethasone for control of symptoms associated with peritumoral brain edema in patients with primary malignant glioma	Dr Chris Wynne	27/11/2006	12/12/2006	Approved subject to conditions		Approved	3/04/2007	Christchurch Hospital Wellington Hospital Dunedin Hospital	B	Neurobiological Technologies Inc	Māori groups at Auckland, Christchurch, Dunedin, Wellington hospitals
MEC/06/12/180	Does prematurity affect glucose metabolism in adulthood and in the next generation?	Dr Paul Hofman	27/11/2006	12/12/2006	Approved subject to conditions		Approved	20/02/2007	Liggins Institute	A	National Research Centre for Growth and Development	
MEC/06/12/181	A prospective, randomised, double-blind, double-dummy, parallel-group, multicenter, event-driven, non-inferiority study comparing the efficacy and safety of once-daily oral rivaroxaban (BAY 59-7939) with adjusted-dose oral Warfarin for the prevention of stroke and non-central nervous system systemic embolism in subjects with non-valvular atrial fibrillation	Prof Harvey White	27/11/2006	12/12/2006	Deferred	Information sheet and consent form inappropriate	Approved	13/04/2007	Auckland City Hospital and Greenlane Clinical Centre Wellington Hospital Waikato Hospital North Shore Hospital Dunedin Hospital Christchurch Hospital	B	Johnson and Johnson and Bayer	Mata Forbes, RGON, Auckland DHB; Elizabeth Cunningham, Christchurch Hospital; Manager of Te Puna Oranga Waikato; Te Aniwa Tutara – Nga Kai Tatakai Māori Research Advisory Group – Waitemata DHB; Whānau Wellington Hospital; Manawhenua Health Working Party – Dunedin Hospital
MEC/06/12/182	Capacity to consent to treatment in forensic mental health care: ethical, clinical and legal issues	Dr Jeremy Skipworth	27/11/2006	12/12/2006	Approved subject to conditions		Approved	13/02/2007	Ministry of Health University of Otago	Nil	Wellington Medical Research Foundation and/or New Zealand Law Foundation	
MEC/06/12/184	Children's Oncology Group (COG) AEW502P: a pilot study of low-dose antiangiogenic chemotherapy in combination with standard multiagent chemotherapy for patients with newly diagnosed metastatic Ewing sarcoma family of tumours	Dr Jane Skeen	24/11/2006	12/12/2006	Approved subject to conditions		Approved	16/03/2007	Starship Children's Health Christchurch Hospital	A	Child Cancer Foundation	

Applications considered in 'closed' meetings

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
MEC/06/02/009	Development of an economic model of vaccination against human papilloma virus to reduce the risk of cervical cancer and genital warts	Dr Richard Milne	26/01/2006	13/02/2006	Approved		Approved	13/02/2006		Nil		
MEC/06/02/017	An eight-week randomised, double-blind, placebo-controlled, parallel group proof of concept dose ranging study to assess the efficacy, safety and tolerability as well as the pharmacokinetic profile of oral solabegron (GW427353) 250 mg, 125 mg, and 50 mg administered twice daily vs placebo, in women with overactive bladder	Dr Sharon English	27/01/2006	Withdrawn prior to consideration			Withdrawn			Nil		
MEC/06/03/034	Multi-agency liquor enforcement study	Dr Murray Sim	10/03/2006	21/03/2006	Approved subject to conditions		Approved	25/08/2006	NZ Police St John Ambulance Christchurch Hospital 24-hour surgery, Christchurch Eastcare Accident and Medical Centre, Howick Middlemore Hospital Lakes District Hospital, Queenstown	A		
MEC/06/07/074	A randomised, double-blind, placebo-controlled, multicentre phase III study to evaluate the efficacy and safety of Pazopanib (GW786034) compared to placebo in patients with locally advanced and/or metastatic renal cell carcinoma; protocol no. VEG105192	Dr Murray Sim	30/06/2006	18/07/2006	Approved subject to conditions		Approved	4/09/2006	Christchurch Hospital, Wellington Hospital	B	GlaxoSmith Kline	
MEC/06/07/075	Worldwide, multicentre, double-blind, parallel study to evaluate the tolerability of MK-0524A versus niacin extended-release	Prof Russell Scott	30/06/2006	18/07/2003	Approved subject to conditions		Approved	8/08/2006	Lipid and Diabetes Research, Christchurch Hospital Waikato Hospital	B	Merck Sharpe & Dohme	Mr Peter Mason; Jonas Hapuku
MEC/06/08/083	EXTEND (Eltrombopag eXTENDED Dosing Study): an extension study of eltrombopag olamine (SB-497115-GR) in adults, with idiopathic thrombocytopenic purpura (ITP), previously enrolled in an eltrombopag study; protocol no. TRA105325	Dr David Simpson	2/08/2006	22/08/2006	Approved subject to conditions	Application incomplete	Approved	16/10/2006	Auckland City Hospital Middlemore Hospital Christchurch Hospital North Shore Hospital	B	GlaxoSmith Kline	
MEC/06/09/097	A randomised, double-blind, placebo-controlled phase III study, to evaluate the efficacy, safety and tolerability of eltrombopag olamine (SB-497115-GR), a thrombopoietin receptor agonist, administered for six months as oral tablets once daily in adult subjects with previously treated chronic idiopathic thrombocytopenic purpura (ITP); protocol no. TRA102537	Dr David Simpson	29/08/2006	19/09/2006	Approved subject to conditions		Approved	6/12/2006	North Shore Hospital Middlemore Hospital Auckland City Hospital Christchurch Hospital	B	GlaxoSmith Kline	

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
MEC/06/09/098	A multicentre, randomised, placebo-controlled, double-blind, four-arm parallel-group, two-week study to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of GW624444H (100 and 400 mcg administered once-daily in the morning via DISKUS dry-powder inhaler) compared with salmeterol (50 mcg administered twice-daily via DISKUS drypowder inhaler) and placebo in subjects with moderate chronic obstructive pulmonary disease (COPD); protocol no. B2C-108562	Dr Margaret Wisler	30/08/2006	19/09/2006	Approved subject to conditions		Approved	26/10/2006	Green Lane Hospital Dunedin Hospital Tauranga Hospital	B	GlaxoSmith Kline	

Applications considered 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/funder	Consultation undertaken
MEC/06/01/CPD	Survey of the New Zealand RANZCOG Fellows on the use of the Levonorgestrol intra uterine device (Mirena) in adolescents	Dr Helen Paterson	22/09/2006				Approved	29/09/2006	Nationwide survey	Nil		
MEC/06/02/CPD	Mental health nursing survey	Rachel Aitchison	10/10/2006				Approved	13/10/2006	Waikato Hospital	Nil		
MEC/06/03/CPD	The general practitioner and palliative medicine specialist working in the community: reaching the patient at the bedside	Dr Carol McAllum	6/11/2006				Approved	8/11/2006	University of Auckland	Nil	Study grant to James Wethasinghe from AUT	
MEC/06/04/CPD	Evaluation of South Link health/ACC primary care of shoulder injuries programme	Ms Mary O'Brien	6/12/2006				Approved	7/12/2006	South Link Health, Dunedin	Nil		
MEC/06/12/166	The health of log truck drivers and comparisons with the New Zealand population	Dr Hamish Mackie	9/11/2006			Retrospective review application declined; full application required	Declined			Nil		
MEC/06/12/169	Acute rheumatic fever and household crowding in New Zealand	Dr Mark Webster	24/11/2006			Retrospective review application declined; full application required	Declined			Nil		
MEC/06/12/174	Audit of deaths in New Zealand public hospital intensive care units	Prof Harvey White	24/11/2006			Additional information requested	Approved subject to conditions			Nil		

Appendix 2: Multi-region Ethics Committee Terms of Reference

Public authority of the Multi-region Ethics Committee (MEC)

The MEC is 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 MEC.

Authority of the Multi-region Ethics Committee

The MEC shall have responsibility for ethics committee review of national and multi-region health and disability research and innovative practice occurring in New Zealand.

Multi-region or national research is defined as research conducted by the investigator(s) in more than one Regional Ethics Committee region or nationally, with identical methods and following the same protocol.

The MEC is responsible for any national and multi-region research that is currently being undertaken in New Zealand, 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* on any point of conflict, but otherwise, the Operational Standard applies to the MEC.

Relations with other public sector organisations

The MEC shall liaise with other relevant ethics committees on matters of common interest, such as jurisdiction over borderline cases. The MEC 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 Multi-region Ethics Committee

The MEC 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 Multi-region Ethics Committee

The primary role of the MEC is to provide independent ethical review of national and multi-region health research and innovative practice that will be conducted in New Zealand 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 MEC 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 MEC is to ensure that the MEC has the appropriate expertise, skills, knowledge and perspectives to conduct ethical review of the best quality.

Member numbers

The number of members of the MEC should be 12.

Lay/non-lay membership

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

- currently, nor has recently been, a registered health practitioner (for example, a doctor, nurse, midwife, dentist, pharmacist)
- involved in conducting health or disability research or who is employed by a health agency and who is in a sector of that agency which 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 MEC's lay membership shall include:

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

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

The MEC's membership should include expertise in the main kinds of health and disability research (eg, 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 that the MEC 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, MEC 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 MEC as equal individuals of sound judgement, relevant experience and adequate training in ethical review.

Terms and conditions of appointment

Members of the MEC 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 MEC 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 MEC.

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

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

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

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

General

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

Conflicts of interest

MEC 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 MEC and its members and will ensure it retains public confidence.

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

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

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

Confidentiality and information sharing

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

Within the MEC, 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 MEC 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 MEC to be open to the public. Meetings of the MEC should therefore be:

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

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

Decision-making process

Wherever possible, the MEC 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 MEC 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 MEC 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, the MEC 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 quorum of MEC members believes there is insufficient expertise on the MEC 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 MEC's decision on a proposal.

Second opinions and appeals

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

The decisions of the MEC 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 MEC.

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 MEC, including any change in the MEC's membership or other substantive changes the MEC 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 subject to conditions, deferred, declined)
- vii. for each protocol deferred or declined, the reason(s) for the decision

The annual report shall also include:

- i. A list of training undertaken by MEC members, and a statement on processes for orientation and training of new MEC members should be included.
- ii. A list of complaints received by the MEC (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 MEC in making a decision on any particular protocol(s), and any questions on policy or other matters the MEC referred to the National Ethics Advisory Committee or the Health Research Council Ethics Committee for comment or guidance.

In compiling annual reports, the MEC 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 MEC are entitled to be paid fees for attendance at meetings. The levels 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 MEC by the Chairperson and Deputy Chairperson. The Ministry of Health shall pay actual and reasonable travel and accommodation expenses of the MEC members.

Servicing of the MEC

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

