



# **Northern Y Regional Ethics Committee**

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## **Annual Report**

**January 2006 to December 2006**

***Northern Y Ethics Committee***

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# Chairperson's Report

Tēnā koutou katoa.

This report provides an overview of the work of the Northern Y Regional Ethics Committee from January to December 2006. The report was presented to the Northern Y Regional Ethics Committee at its meeting on 28 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.

Over the past year the committee has processed 140 applications. This compares with 112 applications for the preceding 13 months.

The Northern Y Regional Ethics Committee continues to meet mainly at the Bryant Education Centre at the Waikato Hospital, and on occasions at the office of the Ministry of Health, Hamilton. It is encouraging that many of the researchers attend or teleconference into the meetings. As noted in last year's report, their involvement has greatly helped the review process.

The committee appreciates the thorough and professional support given by its administrator, Ms Amrita Kuruvilla. In addition, on one occasion in Ms Kuruvilla's absence Ms Riria Tatau-Grant, from Dunedin, supported the committee.

Members of the Northern Y Regional Ethics Committee have contributed to supporting and developing networks and understanding where opportunities have arisen. Members attended the Society of Oncology Conference, a meeting of local research nurses, and a meeting of the Lakes District Health Board Research and Ethics Committee.

There was one change to the membership of the committee in 2006. In December Dr Elizabeth Spellacy completed six years' membership of ethics committees, and under the Terms of Reference is unable to continue on the committee. Dr Spellacy contributed much to the discussions related to ethical review, and could be relied on to consider an issue from an angle that no one else had considered. Her astuteness and eye for detail were greatly appreciated by her colleagues. Dr Tessa Turnbull replaced Dr Spellacy in January 2007. Dr Turnbull brings a wealth of experience in health research, general practice and geriatric medicine.

Dr John Moodie, who has been Deputy Chairperson for the last two years, stepped down from the role at the end of 2006. Dr Felicity Dumble has now taken the role of Deputy Chairperson.

Advanced training was offered to members of the committee, which many attended in Auckland with members of other committees. The advantage gained from members of two or more committees gathering and learning together was noted, and has been an item that chairpersons are exploring. Another valuable occasion when members from the various committees met at one time was the hui of Māori members held in October 2006. This hui is discussed within this report, particularly regarding Section F of the National Application Form.

In December 2006 a report was received from the Health and Disability Commissioner (HDC) regarding an inquiry by the HDC Office into the practice of a local medical practitioner. Although some studies of the medical practitioner had been approved through the former Waikato Ethics Committee, the inquiry was not related to any study. Rather, the Commissioner was bringing the report to the committee's attention.

The chairpersons of the seven health and disability ethics committees (six regional and one multi-regional) have continued to meet throughout the year. In 2006 they gathered in Dunedin at the time of the biennial Bioethics Conference and were joined by the deputy chairpersons. This conference was also an occasion to meet with members of the Health Research Council and its ethics committee. Further meetings of the chairpersons were held in August, and again for a day in September when Professor Alistair Campbell spoke regarding tissue banking in general and specifically in the United Kingdom.

The new structure for ethical review of health and disability research was established in December 2004. Given that the structure has now existed for two years, the chairpersons were interested in gaining a broad understanding of how the structure is working. It was agreed that it was time for a review of how the committees were working, and how all stakeholders were viewing them. The process for an operational review was initiated with Therese Egan, Manager in the Ministry of Health with responsibility for the administrative support of ethics committees, and the review is to occur in 2007.

In addition, the chairpersons considered and developed a process for which they could peer review each other. The purpose of such peer review is to give each other feedback about their roles as chairpersons in both facilitating their committees and in their functional relationships.

Further issues that chairpersons and their committees considered in 2006 were the following.

- There were concerns over studies with a sponsor company for which a committee considers that potential participants must be fully informed of the limited compensation available. As a result, often researchers are asked to highlight the limitations of compensation within the Participant Information Sheet.
- The process of membership selection for committees has been an area of focus, particularly to enable a smooth transition during membership changes. Aware that the process of membership selection involves Cabinet and ministerial processes, the chairpersons seek to ensure a timely process, and an appropriate acknowledgement of the contributions made by retiring members.
- Training has been necessitated by development of guidelines for targeted issues, such as:
  - tissue banking
  - stem cell research
  - xenotransplantation
  - the expedited review of observational studies.

Lastly it is appropriate to acknowledge the passing of two great people from the Northern Region during 2006. In August the nation joined the people of Tainui and the Kingitanga in mourning and bidding farewell to Te Arikinui, Dame Te Atairangikaahu. And in September Ngāti Whātua mourned the passing of Sir Hugh Kawharu. E ngā mate – haere, haere, haere!

The Northern Y Regional Committee continues to have a stable and collaborative membership, and constitutes a ‘team’ that I am privileged to facilitate and participate in.

Nāku noa nā.

Paul Flanagan  
Chairperson, Northern Y Regional Ethics Committee  
and Chair of the Chairpersons Group

# Committee Membership

## Appointments

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

### Chairperson

<b>Paul Flanagan</b>	B Theol, Grad DipArts, M Couns, PG Cert Couns Supervision, MNZAC
Representation	Lay member
Member category	Community representative
Gender	Male
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	November 2008
Expertise	Social services
Iwi affiliations	N/A

### Members

<b>Dr John Moodie</b>	MB ChB, Dip Obst FRCA, FANZCA
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	December 2007
Expertise	Anaesthetics, clinical research
Iwi affiliations	N/A

<b>Christina Bryant</b>	MA Medical Ethics & Law, LLB(Hons)
Representation	Lay member
Member category	Ethicist
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Expertise	Ethics and law
Iwi affiliations	N/A

<b>Peter Coughlan</b>	Certificate in Social Studies
Representation	Lay member
Member category	Community representative
Gender	Male
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Expertise	Social studies
Iwi affiliations	N/A
<b>Robert Crawford</b>	PhD in Statistics
Representation	Non-lay member
Member category	Biostatistician
Gender	Male
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Expertise	Statistics
Iwi affiliations	N/A
<b>Felicity Dumble</b>	FAFPHM (RACP), MPH (Hons), MBChB
Representation	Non-lay member
Member category	Health researcher
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	December 2008
Expertise	Public health
Iwi affiliations	N/A
<b>Huhana Hickey</b>	LLB/BSocSc, LLM
Representation	Lay member
Member category	Lawyer
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Expertise	Law
Iwi affiliations	Waikato, Ngāti Tahinga

<b>Elizabeth Spellacy</b>	MBBS (UK)
Representation	Non-lay member
Member category	Health practitioner
Gender	Female
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	December 2006
Expertise	General (internal) medicine, human metabolism, geriatric medicine
Iwi affiliations	N/A

Dr Spellacy's last meeting was in November 2006. She had completed six years as a member of the ethics committee.

<b>Claire Stott</b>	B Pharm (Hons)
Representation	Non-lay member
Member category	Pharmacist/pharmacologist
Gender	Female
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Expertise	Pharmacy
Iwi affiliations	Ngā Puhī

<b>Heather Thomson</b>	Māori Health
Representation	Lay member
Member category	Community representative
Gender	Female
Date of appointment	December 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Expertise	Community development, rural health, Māori health, management
Iwi affiliations	Te Whānau a Apanui

<b>Michael Vale</b>	Dip Tchg, Dip Rehab Studies, Grad Cert Career Development, PG Dip (Education)
Representation	Lay member
Member category	Consumer representative
Gender	Male
Date of appointment	December 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Expertise	Disability support
Iwi affiliations	N/A

<b>John Fitzgerald</b>	PhD, MSc (Clinical Psychology), MA Psychology
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
Expertise	Clinical psychology
Iwi affiliations	N/A

The following appointment was made by the Minister of Health in December 2006.

<b>Tessa Turnbull</b>	Dip Obst, FRNZCP, FRACP
Representation	Non-lay member
Member category	Health practitioner
Gender	Female
Date of appointment	December 2006
Term of appointment	3 years
Six-year maximum term	December 2012
Expertise	General (internal) medicine, obstetrics, geriatric medicine
Iwi affiliations	N/A

Dr Turnbull is scheduled to attend her first meeting in January 2007.

### **Deputy Chairperson**

John Moodie continued as deputy chairperson of the committee for the year 2006.

## Members' attendance in 2006

Member	M/F	Lay/ non-lay	25 Jan	22 Feb	22 Mar	26 Apr	24 May	28 Jun	26 Jul	23 Aug	27 Sep	25 Oct	22 Nov	13 Dec	Total
Paul Flanagan	M	L	Y	Y	A	Y	Y	Y	Y	Y	Y	Y	Y	Y	11/12
John Moodie	M	N	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	11/12
Christina Bryant	F	L	Y	Y	Y	A	Y	Y	A	Y	Y	Y	Y	A	9/12
Peter Coughlan	M	L	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	A	Y	10/12
Robert Crawford	M	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	11/12
Felicity Dumble	F	N	Y	Y	A	Y	Y	A	Y	Y	A	A	Y	Y	8/12
Huhana Hickey*	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12
Elizabeth Spellacy	F	N	Y	Y	A	A	Y	Y	Y	Y	Y	A	Y	A	8/12
Claire Stott	F	N	Y	A	A	Y	Y	Y	Y	A	Y	Y	Y	A	8/12
Heather Thomson*	F	L	T	Y	Y	Y	Y	A	Y	Y	A	A	Y	A	8/12
Michael Vale	M	L	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	Y	11/12
John Fitzgerald	M	N	Y	Y	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	11/12
Members present			12	11	8	10	12	8	11	10	9	8	11	8	
No. of applications			3	12	7	9	12	13	7	12	13	14	18	15	135

\* = Māori member

Y = Present

A = Apology

T = Teleconference

## Training

### New member training

Three members of the Northern Y Regional Ethics Committee were offered training for new members. The training was held in Wellington on 1 April 2006. The following two members attended: Dr Felicity Dumble and Dr John Fitzgerald.

### Ongoing training

Ongoing training for all members was held in June 2006. The one-day training programme was held in Auckland on 27 June. The following 10 members attended: Paul Flanagan, Christina Bryant, Dr Rob Crawford, Michael Vale, Huhana Hickey, Dr Felicity Dumble, Dr John Fitzgerald, Dr Elizabeth Spellacy, Claire Stott, Dr John Moodie.

The following meetings of specialist members were held.

## **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 Northern Y Regional Ethics Committee attended:

Huhana Hickey and Heather Thomson.

## **New Zealand Bioethics Conference**

The following members attended the New Zealand Bioethics Conference in Dunedin on 10–12 February 2006: Paul Flanagan and Dr John Moodie.

## **Training on using cells from established human embryonic stem cell lines for research**

The training on using cells from established human embryonic stem cell lines for research was held on 15 August 2006. The following members attended: Paul Flanagan and Dr John Moodie.

## **Chairpersons' meetings**

Three meetings of the chairpersons of the multi-region and regional ethics committees were held in 2006.

Paul Flanagan and Dr John Moodie attended the meeting held in Dunedin on 9 February 2006.

Paul Flanagan attended the subsequent meetings held on 14–15 February 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.

## **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 Northern Y Regional Ethics Committee is registered with the United States Department of Health & Human Services. This registration enables the committee to review research funded by the United States Government. The registration number is: IRB00004665 – Northern Y Regional Ethics Committee.

## Response to Cultural Issues

Number of applications deferred because Māori guidelines were not read	2
Number of applications for which consultation with Māori was considered appropriate	132
Number of applications returned through insufficient consultation on cultural issues	None. Evidence of consultation was required and carried out subsequently.
Process the committee has for following through on consultation	Referring to iwi, District Health Boards and Māori research review committees.
Cases of unsatisfactory reasons for not including Māori	1
Mechanisms in place to facilitate consultation with Māori by researchers	District Health Boards, Māori research review committees, and tertiary institutions have processes in place.
Examples of Māori not being included in research	Research based purely on certain ethnic populations; research on diseases that Māori are assumed not to have.

It is acknowledged that while compliance has improved, there still appears to be some misinterpretation when it comes to complete the application, along with questions on who to consult and what the research implications for Māori are.

Huhana Hickey and Heather Thomson

# Applications

The Committee held 12 scheduled meetings from January to December 2006.

## Northern Y Regional Ethics Committee statistics for January–December 2006

<b>Status at time of report</b>	
Applications considered under delegated authority (CPD)	5
Applications approved	108
Applications deferred	3
Applications declined	1
Applications carried forward (approved subject to conditions)	19
Approval not required (prospective audit)	3
<b>Total number of applications received</b>	<b>141</b>
Applications withdrawn (by researcher)	1
Application withdrawn prior to meeting	1
<b>Total</b>	<b>141</b>

## Other committee statistics

Number of matters arising considered	10
Number of general business items reviewed	25
Number of amendments reviewed by committee	45
Number of amendments approved under CPD	19

## Audit or matters not requiring ethical approval

Three projects were confirmed audits or surveys not requiring ethical approval in accordance with section 4.1, page 26, of the Operational Standard for Ethics Committees, March 2002.

## Second opinions

No second opinions were requested.

## **Complaints**

In December 2006 a report was received from the Health and Disability Commissioner regarding an inquiry by the HDC Office into the practice of a local medical practitioner. Although some studies of the medical practitioner had been approved through the former Waikato Ethics Committee, the inquiry was not related to any study. Rather, the Commissioner was bringing the report to the committee's attention.

## Issues for the Committee

Some issues that the committee considered in 2006 were the following.

- There were concerns over studies with a sponsor company for which the committee considers that potential participants must be fully informed of the limited compensation available. As a result, often researchers are asked to highlight the limitations of compensation within the Participant Information Sheet.
- The process of membership selection for the committee has been an area of focus, particularly to enable a smooth transition during membership changes. Aware that the process of membership selection involves Cabinet and ministerial processes, the committee – through the chairpersons group – seeks to ensure a timely process and an appropriate acknowledgement of the contributions made by retiring members.
- Training has been necessitated by the development of guidelines for targeted issues, such as:
  - tissue banking
  - stem cell research
  - xenotransplantation
  - the expedited review of observational studies.

## Guidelines for Chairperson's Delegation

At its meeting on 15 December 2004, the committee agreed to delegate the following authority to the Chairperson.

The Chairperson may approve under delegated authority:

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

The Chairperson may approve the matters listed below after review by a minimum of one health professional. A subcommittee of health professional and lay members may be involved and where possible should include a Māori member. The membership of the subcommittee is recommended by the Chairperson and members are contacted by the administrator by phone or email to confirm their availability.

If any subcommittee member has a major concern and recommends the application or amendment be reviewed by the full committee, it will be placed on the agenda for consideration at the next committee meeting and the researcher 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, such as 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.

All applications and amendments approved under delegated authority are listed on the agenda for the next meeting.

The committee also agreed to delegate the same authority to the Deputy Chairperson in the absence of the Chairperson.

## Appendix 1: Applications Received January to December 2006

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

No applications were considered in 'closed' meetings.

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
CEN/06/04/028NTY	A randomised, double-blind, placebo-controlled, parallel group, multicentre study to evaluate the efficacy and safety of GW685698X 200 mcg twice daily, GW685698X 200 mcg and 400 mcg once daily in the morning, and GW685698X 200 mcg and 400 mcg once daily in the evening compared with placebo for eight weeks in adolescent and adult subjects (12 years of age and older) with persistent asthma	Dr John Gillies	24/03/2006	4/11/2006	Deferred	Concerns about inclusion of children  Committee requested more information on gall bladder side effects	Approved	16/06/2006	P3 Research Tauranga	B	GlaxoSmith Kline	Colleen Wineera; HE&R Services
NTY/06/01/001	Breast International Group Trial 1-98; fingernail pilot sub-study; investigating properties of fingernails to determine the efficacy of nail structure for evaluating bone fragility	Dr Ian Campbell	27/01/2006	25/01/2006	Deferred	Deferred as the study design and methodology appears flawed and requires further information from the researcher	Approved	22/02/2006	Waikato Hospital	Nil	Nil	Nil
NTY/06/01/002	The physical activity and disability survey (PADS): a reliability and validity study in people with multiple sclerosis	Ms Nicola Kayes	27/01/2006	25/01/2006	Approved subject to conditions		Approved	14/02/2006	Auckland MS Society	Nil	Summer studentship from AUT	Māori health researchers
NTY/06/01/003	Improving the appropriateness of therapeutic drug monitoring at Waikato Hospital	Mr Andre Mutavdzic	27/01/2006	25/01/2006	Approved		Approved	25/01/2006	Waikato Hospital	Nil		
NTY/06/02/004	To evaluate the 'real world' clinical performance of the Medtronic Endeavor™ ABT-578 eluting coronary stent system	Dr Gerard Devlin	15/02/2006	22/02/2006	Approved subject to conditions		Approved	14/03/2006	Waikato Hospital	Nil	Medtronic	Te Puna Oranga
NTY/06/02/005	A pilot study for enhanced surveillance of infectious syphilis in the Auckland region	Dr Sunita Azariah	15/02/2006	22/02/2006	Approved subject to conditions		Approved	2/05/2006	Auckland Sexual Health Service	A	Diagnostic Medlab	MRR
NTY/06/02/006	Samoans and disabilities study	Mr Nite Imakulata Fuamatu	15/02/2006	22/02/2006	Approved subject to conditions		Approved	20/03/2006	Participants choice	Nil		
NTY/06/02/007	"One for the boys" – evaluative research to improve men's access to primary health care in Tairāwhiti	Ms Diane Williams	15/02/2006	22/02/2006	Approved subject to conditions		Approved	29/03/2006	Tairāwhiti District Health Board	Nil		Ngati Porou Hauora PHO; Turanganui PHO; Te Rungāga O Turanganui A Kiwa

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
NTY/06/02/008	The effect of exercise training on cardiac and arterial response to exercise in type 2 diabetes	Sophie Lalande	15/02/2006	22/02/2006	Deferred	The committee noted that Section F of the application form was not completed adequately; it was noted that the study was too key a piece of research to approve while overlooking consultation with Maori	Approved	10/05/2006	University of Auckland	A	SPARC	MRRC at ADHB
NTY/06/02/009	An investigation of the potential role of dietetic services in the area of mental health in Counties Manukau	Ms Sian Warriner	15/02/2006	22/02/2006	Deferred	Further documentation required	Approved	22/03/2006	Counties Manukau DHB	Nil		CMDHB
NTY/06/02/010	A multicentre, randomised, double-blind, placebo-controlled, four-way, incomplete block crossover study to examine the efficacy, safety, tolerability, pharmacodynamics and pharmacokinetics of single and repeat administration of three inhaled doses (10, 15 and 20 µg) of GSK159797	Dr John Gillies	15/02/2006	22/02/2006	Approved subject to conditions		Approved	12/05/2006	P3 Research Wellington	B	GlaxoSmith Kline	Janet Mclean
NTY/06/02/011	Validating a global positioning system (GPS) as a new tool for measuring physical activity in adults	Mr Ralph Maddison	15/02/2006	22/02/2006	Approved subject to conditions		Approved	11/04/2006	School of Population Health	A	Harvard University	CTRU MRAC
NTY/06/02/012	A randomised, multicentre Phase IIIb, open label, study of letrozole vs anastrozole in the adjuvant treatment of post menopausal women with hormone receptor and node positive primary breast cancer; protocol no. CFEM345D2411; date: 16 September 2005	Dr Ian Campbell	15/02/2006	22/02/2006	Approved subject to conditions		Approved	11/04/2006	Oncology 161 Waikato Hospital Auckland City Hospital St Annes Breastcare	B	Novartis Pharmaceuticals	Te Puna Oranga
NTY/06/02/013	Does transillumination of veins in children under three improve success rates of intravenous insertion: a randomised controlled trial (A+3417)	Dr David Herd	15/02/2006	22/02/2006	Approved		Approved	27/02/2006	Starship Children's Health	A	ADHB, Joan Mary Reynolds Fellowship	MRRC
NTY/06/02/014	Formative evaluation of parent support to complement well child aka toddlers without tears	Ms Salena Davie	15/02/2006	22/02/2006	Ethical approval not required		Ethical approval not required	22/02/2006	Well child providers	A	Ministry of Social Development	MRRC and various
NTY/06/02/015	Taxus olympha: a global taxus Liberté Registry programme to support worldwide commercialisation (IC and European launch phase)	Dr Gerard Devlin	15/02/2006	22/02/2006	Approved subject to conditions		Approved	14/03/2006	Ascot Hospital Waikato Hospital	Nil	Boston Scientific Corporation	Te Puna Oranga; MRRC

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
NTY/06/03/016	The perceptions and beliefs of health care workers about tuberculosis (TB)	Ms Jill Miller	30/03/2006	22/03/2006	Approved subject to conditions		Approved	19/04/2006	Greenlane Clinical Centre Auckland City Hospital	Nil		Pita Paul; Māori Advisor
NTY/06/03/017	Prevalence of neuroleptic-induced movement disorders in psychotic patients within Northland DHB: ethnic variation	Hossam Mahmoud	30/03/2006	22/03/2006	Deferred	Requires a revised patient information sheet and consent form that is consumer focused	Approved	6/06/2006	Northland DHB	Nil		Marjorie Phillips/ Māori Health Director; Northland DHB
NTY/06/03/018	Reliability and validity of the hospital anxiety and depression scale and the geriatric anxiety inventory in the diagnosis of anxiety disorders in older people with chronic obstructive pulmonary disease (COPD)	Dr Gary Cheung	30/03/2006	22/03/2006	Approved subject to conditions		Approved	19/04/2006	Mental Health Services for Older People	A	Waikato Medical Research Foundation Grant	Te Puna Oranga
NTY/06/03/019	A double-blind, randomised, placebo-controlled, dose finding study of R126638 given as a single or repeat dose in oral solution vs placebo in the treatment of pityriasis versicolor	Dr John Gillies	30/03/2006	22/03/2006	Approved subject to conditions		Approved	24/04/2006	P3 Research Wellington	B	Barrier Therapeutics Inc	Janet McLean/ Māori Health Planning and Funding
NTY/06/03/020	Preoperative steroids and their effect on postoperative recovery in major colonic surgery	Dr Andrew Hill	30/03/2006	22/03/2006	Approved subject to conditions		Approved	17/05/2006	Counties Manukau DHB, Manakau city	A	Auckland Medical Research Fund	MRRC and Māori Health Unit in Middlemore Hospital
NTY/06/03/021	An investigation of the barriers to achieving serum phosphate control among in-centre haemodialysis patients at Waikato regional dialysis unit and possible solutions to improve adherence to therapy	Ms Casey O'Byrne	30/03/2006	22/03/2006	Approved subject to conditions		Approved	6/04/2006	Waikato Hospital	Nil		Kim Southey/ Te Puna Oranga
NTY/06/03/022	Prognostic markers in highly invasive squamous cell carcinomas in the head and neck region of humans	Dr Indunil Gunawardena	30/03/2006	22/03/2006	Approved subject to conditions		Approved	14/06/2006	Waikato Hospital	A	Royal Australian College of Surgeons and Waikato Medical Research Foundation	Te Puna Oranga
NTY/06/04/023	Chronic obstructive pulmonary disease acute exacerbations cohort study	Dr Catherina Chang	9/05/2006	26/04/2006	Approved subject to conditions		Approved	6/06/2006	Waikato Hospital	A	The Respiratory Research Fund – Waikato Hospital	Te Puna Oranga
NTY/06/04/024	Barriers to nutritional supplement use in haemodialysis patients in the Auckland District Health Board (ADHB) and Counties Manukau District Health Board (CMDH)	Ms Sherie Sourial	9/05/2006	26/04/2006	Approved subject to conditions		Approved	18/05/2006	Auckland DHB Counties Manukau DHB	Nil		Mata Forbes; Jennie Ma
NTY/06/04/025	Quality of life (QOL) in disability – contributing towards measure of quality life (QOL) that includes factors people with disabilities consider important	Dr Kath McPherson	9/05/2006	26/04/2006	Approved subject to conditions		Approved	9/08/2006	Auckland University of Technology Local hired facility	Nil		AUT Māori Working Group; Orakei marae

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
NTY/06/04/026	A collaborative inquiry into the puzzle of inappropriate aged care presentation to emergency departments in the Waikato region	Assoc Prof Cheryle Moss	9/05/2006	26/04/2006	Deferred	Ethical approval was deferred due to lack of sufficient information for the committee to make a decision; it was noted that sections of the application were unanswered	Approved	12/05/2006	Waikato Hospital	Nil		Te Puna Oranga
NTY/06/04/027	Outcome evaluation of the centre for continuing education's iwi and Maori community initiatives project of the Frankton/Dinsdale Rauawaawa Trust	Ms Andrea Elliot-Hohepa	9/05/2006	26/04/2006	Ethical approval not required	The committee considers there are no health and disability ethical issues regarding this study; the committee however considers that this study could be reviewed by an educational ethical review committee	Ethical approval not required	26/04/2006	Te Runanga O Kirikiriroa Rauawaawa Trust	Nil		R&D Unit of Te Runanga
NTY/06/04/028	Can computerised topography be helpful in the correction of keratoconus with contact lenses and spectacles?	Mr Grant Watters	9/05/2006	26/04/2006	Approved subject to conditions		Approved	17/07/2006	University of Auckland	A	Corneal Lens Corporation – Christchurch	
NTY/06/04/029	A randomised, double-blind, placebo-controlled, study of the efficacy and safety of subcutaneous or subaponeurotic SABER™ – Bupivacaine in patients undergoing open inguinal hernia repair	Dr John E Moodie	9/05/2006	26/04/2006	Approved subject to conditions		Approved	25/05/2006	Braemar/Anglesea Hospital	B	Direct Corporation	Tangimoana Habib (Tu Wharetoa)
NTY/06/04/030	A randomised, double-blind, placebo-controlled, study of the efficacy and safety of subcutaneous or subacromial SABER™ – Bupivacaine in patients undergoing rotator cuff repair	Dr John E Moodie	9/05/2006	26/04/2006	Approved subject to conditions		Approved	25/05/2006	Braemar/Anglesea Hospital Southern Cross Hospital	B	Direct Corporation	Tangimoana Habib (Tu Wharetoa)
NTY/06/04/031	“Get Checked” annual diabetes review programme in the Waikato: follow-up of diabetes care from 2001–2005	Mrs Grace Joshy	8/05/2006	26/04/2006	Approved	Audit	Approved	26/04/2006	Waikato	Nil		
NTY/06/05/032	Individualised growth assessment in different ethnic groups: an observational ultrasound study of fetal growth	Dr GK Parry	30/05/2006	24/05/2006	Approved subject to conditions		Approved	2/07/2006	Middlemore Hospital	A	Auckland Medical Research Foundation	Māori Ethics Committee
NTY/06/05/033	How do women having their first baby and experiencing a low risk pregnancy choose the place in which they will give birth, and what is their experience of this?	Mrs Jude Howie	30/05/2006	24/05/2006	Approved subject to conditions		Approved	20/06/2006	Participants choice	Nil		Health services for Māori – Lakes DHB; Kaumatua Kaunihera – Waikato

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
NTY/06/05/034	A 52-week randomised, double-blind, parallel group, placebo controlled, multicentre clinical trial, to assess the efficacy and safety of 200 µg of the anticholinergic LAS 34273 compared to placebo, both administered once-daily by inhalation, in the maintenance treatment of patients with moderate to severe, stable chronic obstructive pulmonary disease	Dr Peter Black	30/05/2006	24/05/2006	Approved subject to conditions		Approved	6/07/2006	University of Auckland Manukau Super Clinic P3 Research Tauranga	B	Almirall Prodesfarma SA	At each site
NTY/06/05/035	Field test for development phase of longitudinal study of New Zealand children and families	Dr Susan Morton	30/05/2006	24/05/2006	Approved subject to conditions		Approved	28/06/2006	Auckland DHB	A	Ministry of Social Development and Health Research Council	Ngati Whatua and other groups
NTY/06/05/036	Neonatal hypoglycaemia	Prof Jane Harding	30/05/2006	24/05/2006	Approved subject to conditions		Approved	26/07/2006	Health Waikato	A	Waikato Medical Research Foundation, Maurice and Phyllis Paykel Trust, Liggins Institute	Te Puna Oranga
NTY/06/05/037	Tauranga Hospital in-patient influenza vaccination survey: estimating vaccination prevalence and identifying factors associated with non-vaccination in high risk patients eligible for free vaccination: a pilot study	Dr Neil de Wet	30/05/2006	24/05/2006	Approved subject to conditions		Approved	30/06/2006	Tauranga Hospital Toi Te Ora – Public Health	Nil		Te Puna Hauora/ Kaupapa Māori Services
NTY/06/05/038	Thyroid hormone levels and cortisol levels post congenital heart surgery in infants less than three months of age; delineation of acceptable range and investigation of association with outcome	Dr Kevin Plumpton	30/05/2006	24/05/2006	Approved subject to conditions		Approved	20/06/2006	Starship Children's Health	A	Greenlane Research and Education Fund	ADHB's MRRC
NTY/06/05/039	"In her shoes": the experience of mothers living with mental illness	Ms Lesley Watkins	30/05/2006	24/05/2006	Approved subject to conditions		Approved	28/06/2006	Consumer Action Network Trust (CAN) Whaioranga	Nil		Rawinia haua of Whaioranga
NTY/06/05/040	Joint venture: relevance and helpfulness of education in rehabilitation following primary unilateral total joint replacement – patients' experiences	Mrs Sheree Gare	2/06/2006	24/05/2006	Approved subject to conditions		Approved	25/07/2006	Participants choice	Nil		Te Puna Oranga
NTY/06/05/041	Evaluation of psychometric properties and utility of the SISCRS (system and individual stress contribution and reduction survey) for identifying sources of workplace stress and strategies for reducing workplace stress for mental health clinicians	Ms Angela Curtis-Clark	30/05/2006	24/05/2006	Approved subject to conditions		Approved	20/06/2006	Counties Manukau DHB	Nil		Kaumatua within Mental Health Service

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
NTY/06/05/042	An exploration of the transition of patients from intensive care to the ward environment: a ward nursing perspective	Ms Sandra Bunn	30/05/2006	24/05/2006	Approved subject to conditions		Approved	18/07/2006	Waikato Hospital	Nil		Te Puna Oranga
NTY/06/05/043	Colorectal cancer project: service improvement – patient/family/whanau perspective phase.	Mr Stephen McKernon	30/05/2006	24/05/2006	Approved subject to conditions		Approved	20/06/2006	Participants choice	Nil	Ministry of Health	Jane Sherard – Nga Kai Tataki; WDHB Māori Research Advisory Group
NTY/06/06/045	Warfarin: the deadly lifesaver – examination of a structured patient education initiative to improve warfarin safety	Ms Anne Blumgart	24/05/2006	28/06/2006	Approved subject to conditions		Approved	18/08/2006	Middlemore Hospital Auckland City Hospital	A	CMDHB	Kerry Hinii and Henare Mason of Maori Health
NTY/06/06/046	A randomised placebo-controlled study comparing the effect of the 5-Lipoxygenase modulating extract from Perna canaliculus, an n-3 fatty acid, and placebo on inflammatory markers, leukotriene metabolism, and serum lipids in coronary disease	Dr Patrick Gladding	24/05/2006	28/06/2006	Deferred	Due to lack of sufficient information for the committee to make a decision	Deferred		Northshore Hospital	B	Pharmalink Co	Māori Advisory Group at Northshore Hospital
NTY/06/06/047	Effect of pulmonary valve replacement in tetralogy of Fallot	Dr Brett Cowan	24/05/2006	28/06/2006	Approved subject to conditions		Approved	6/09/2006	Auckland City Hospital Auckland DHB	A	National Heart Foundation	
NTY/06/06/048	The influence of models of primary health care on patterns of self-referral to an emergency department	Ms Lyndsay Skeen	24/05/2006	28/06/2006	Approved subject to conditions		Approved	17/07/2006	Counties Manukau DHB	Nil		MRRC from CMDHB; University of Auckland Tumuaki
NTY/06/06/049	A comparison of play for 5 to 10-year-old children with and without attention deficit hyperactive disorder	Prof Anita Bundy	26/05/2006	28/06/2006	Deferred	Due to lack of sufficient information for the committee to make a decision	Approved	26/07/2006	Counties Manukau DHB Middlemore Hospital	Nil		Heemi Witehira at CMDHB Māori Cultural Advisor
NTY/06/06/050	Does the vein entry indicator device (VEID) improve success rates of intravenous insertion in a childrens emergency department: a randomised controlled trial (A+3487)	Dr David Herd	21/06/2006	28/06/2006	Deferred	Concerns about the study design; the committee awaits further information from the researcher regarding design of the study	Approved subject to conditions		Starship Children's Health	A	ADHB, Joan Mary Reynolds Fellowship	MRRC at ADHB
NTY/06/06/051	An in vitro assessment of amniotic fluid on platelet function in pregnancy using a PFA-100 analyser	Dr Jack Hill	21/06/2006	28/09/2006	Approved subject to conditions		Approved	18/07/2006	Auckland City Hospital	Nil		George Hill; Kaumatua for Nga Uri Te Taou
NTY/06/06/052	Oxycodone use at Auckland District Health Board (ADHB)	Ms Alison Forbes	21/06/2006	28/06/2006	Approved subject to conditions		Approved	11/07/2006	Auckland City Hospital	Nil		MRRC at ADHB
NTY/06/06/053	Natural history of bacterial and fungal DNAemia in cytotoxic neutropenia – LightCycler® SeptiFast Survey	Chris Mansell	21/06/2006	28/06/2006	Approved subject to conditions		Approved	8/08/2006	Waikato Hospital	Nil		Kaumatua Kaunihera at Waikato Hospital

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NTY/06/06/054	The effect of augmentation therapy with Aralast fraction IV-1 (Fr.IV-1) alpha1-proteinase inhibitor ( $\alpha$ 1-PI) in the level of $\alpha$ 1-PI and other analytes in the bronchoalveolar epithelial lining fluid (ELF); protocol no. 460502; amendment 1 dated 17 May 2006	Assoc Prof Jeffrey Garrett	21/06/2006	28/06/2006	Approved subject to conditions		Approved	11/09/2006	Middlemore Hospital Waikato Hospital	B	Baxter Healthcare Corporation	Māori advisory groups in each area
NTY/06/06/055	Evaluation of the care of children with epilepsy within the Counties Manukau District Health Board: community focus groups	Dr Francoise Butel	21/06/2006	28/06/2006	Approved subject to conditions		Approved	11/10/2006	Counties Manukau DHB	Nil		Kerry Hini; Tony Kake; Māori Health Unit
NTY/06/06/056	Cognitive performance and closed loop stimulation	Dr Spencer Heald	21/06/2006	6/09/2006	Deferred	Due to the inadequacy of the study design and method of testing cognition	Withdrawn		Waikato Hospital	Nil		Te Puna Oranga; MRRC in Auckland
NTY/06/06/057	Knowledge and beliefs of DHB staff of seasonal influenza and the influenza vaccine, and the enablers/barriers which impacted on the uptake of the free staff seasonal influenza vaccination programme in 2006	Mr Brian Pointon	21/06/2006	28/06/2006	Approved subject to conditions		Approved	17/07/2006	Tauranga Hospital	Nil		Janet McLean; Māori Health
NTY/06/07/059	Epidemiology of thyroid disease in Hamilton general practice	Ms Veronique Gibbons	10/07/2006	26/07/2006	Approved subject to conditions		Approved	9/10/2006	Waikato Clinical School	Nil		
NTY/06/07/060	Optimising selenium intake for cancer prevention – a pilot study in Auckland	Prof Lynnette Ferguson	28/06/2006	26/07/2006	Deferred		Approved	15/09/2006	University of Auckland Auckland Hospital Counties Manukau DHB	A	New Zealand Cancer Society	Mata Forbes of MRRC in ADHB; Kerry Hiini of CMDHB
NTY/06/07/061	Study of acculturation, social supports, cognition and mental health among elderly Indians	Dr Rajendra Pavagada	30/06/2006	26/07/2006	Declined		Declined		Counties Manukau DHB	Nil		
NTY/06/07/062	The use of the pain assessment checklist for seniors with limited ability to communicate (PACSLAC) by caregivers in dementia care facilities	Dr Gary Cheung	10/07/2006	26/07/2006	Approved subject to conditions		Approved	16/10/2006	Mental Health Services for Older People	A	Waikato Clinical School – summer studentship	Kaumata Kaunihera
NTY/06/07/063	Clinical comparison of the handheld EasyOne spirometer with a standard laboratory spirometer	Dr Heather Lane	10/07/2006	26/07/2006	Approved subject to conditions		Approved	1/12/2006	Manukau Super Clinic	A	Dept of Respiratory, Middlemore Hospital	Māori Review Committee of CMDHB
NTY/06/07/064	MRI-based patient-specific musculoskeletal modelling for computation of lower limb muscle lengths during walking in children with cerebral palsy	Ms Katja Oberhofer	10/07/2006	26/07/2006	Approved subject to conditions		Approved	8/09/2006	Auckland DHB University of Auckland	A	Bioengineering Institute of University of Auckland has a NERF grant	Kai Atawhai and Pacific Island family support at Starship Hospital

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NTY/06/07/065	Hepatitis B: a history of the social, ethical and medical issues in New Zealand, 1970–2005	Deborah Jowitt	10/07/2006	26/07/2006	Approved		Approved	26/07/2006	Participants choice	Nil		Mata Forbes at ADHB
NTY/06/08/066	Effect of Roflumilast on exacerbation rate in patients with COPD; a 52 weeks, double-blind study with 500 µg Roflumilast once daily versus placebo	Dr John Gillies	4/08/2006	23/08/2006	Approved subject to conditions		Approved	3/10/2006	P3 Research Tauranga	B	Altana Pharma AG	Janet McLean – Māori Health Planning and Funding; BOP
NTY/06/08/067	Brief mental health interventions in primary care: a comprehensive evaluation of factors effecting outcome	Dr John Fitzgerald	4/08/2006	23/08/2006	Approved subject to conditions		Approved	10/09/2006	Counsellor's office Participants homes	A	Service contract with Waikato PHO	Te Puna Oranga – Kaumatua Kaunihera group
NTY/06/08/068	Outcomes of very low birthweight babies, born weighing less than 1250 g, at eight years of age	Ms Natalie A Keene	4/08/2006	23/08/2006	Approved subject to conditions		Approved	19/09/2006	Waikato Hospital	Nil		Kaumatua Kaunihera group
NTY/06/08/069	Managing multiple sclerosis and motherhood: an interpretive descriptive study	Dr Deborah Payne	4/08/2006	23/08/2006	Approved subject to conditions		Approved	19/09/2006	Auckland University of Technology Participants choice Auckland DHB	Nil		MRRC at ADHB
NTY/06/08/070	The effects of hypertonic fluid administration in patients with severe sepsis or septic shock	Dr Frank van Haren	4/08/2006	23/08/2006	Approved subject to conditions		Approved	16/10/2006	Waikato Hospital	A	Waikato Medical Research Foundation	Te Puna Oranga and Kaumatua Kaunihera group
NTY/06/08/071	EEG response to surgery	Dr Stewart Allan	4/08/2006	23/08/2006	Approved subject to conditions		Approved subject to conditions		Waikato Hospital	A	Waikato Hospital, Department of Anaesthesia	Kaumatua Kaunihera group
NTY/06/08/072	Evaluation of Manaaki Manawa: a Kaupapa Maori cardiac rehabilitation programme	Ms Wendy Henwood	1/08/2006	23/08/2006	Approved subject to conditions		Approved	19/09/2006	Te Mauri O Te U-Kai-Po Ngapuhi Housing	Nil		Te Tai Tokerau; Whariki
NTY/06/08/073	Circadian disruption after anaesthesia and surgery in patients undergoing cardiac surgery	Dr Guy Warman	21/08/2006	23/08/2006	Approved subject to conditions		Approved	27/10/2006	Auckland City Hospital	A	University of Auckland	MRRC at ADHB
NTY/06/08/074	Older adults' experience of a fall/s	Mr Marc Maclean	4/08/2006	23/08/2006	Approved subject to conditions		Approved	4/10/2006	Counties Manukau DHB	Nil		MRRC at CMDHB
NTY/06/08/075	A qualitative study of the skills perceived by community mental health nurses as being necessary for their practice	Ms Moira O'Shea	4/08/2006	23/08/2006	Approved subject to conditions		Approved	19/09/2006	Waikato DHB	Nil		Kaumatua Kaunihera group
NTY/06/08/076	Clinical usefulness of eGFR (estimated glomular filtration reate) as a means of assessing renal status in rheumatoid arthritis	Dr Alan Doube	14/07/2006	23/08/2006	Request for information	Full ethics application is required	Approved	3/11/2006	Waikato Hospital	Nil		
NTY/06/08/077	Differences in profile between those screened and those not screened for diabetic retinopathy	Mr Leo Sheck	4/08/2006	23/08/2006	Approved subject to conditions	Retrospective review of patient data	Approved	19/12/2006	Waikato DHB	Nil		

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NTY/06/09/078	A process and outcome evaluation of the development of the acute home-based service at Auckland District Health Board Mental Health Services	Dr Deborah Antcliff	23/08/2006	27/09/2006	Approved subject to conditions		Approved	28/11/2006	Auckland DHB	Nil	ADHB	Wiki Pene; Kaumatua; ADHB
NTY/06/09/079	Combination therapy with tiotropium and salmeterol in moderate to severe chronic obstructive pulmonary disease (COPD): effects on exercise capacity and health related quality of life	Dr Lata Jayaram	23/08/2006	27/09/2006	Approved subject to conditions		Approved subject to conditions		Middlemore Hospital Counties Manukau DHB	A	Auckland Medical Research Foundation	Kerry Hiini – MRRC at CMDHB
NTY/06/09/080	Randomised controlled trial of a New Zealand developed screening questionnaire for depression compared with a gold standard	Assoc Prof Bruce Arroll	25/08/2006	27/09/2006	Approved subject to conditions		Approved	20/10/2006	University of Auckland Auckland DHB	Nil		Raukura Hauora O Tainui; Assoc Prof Papaarangi Reid; Tumuaki; University of Auckland
NTY/06/09/081	The validity of testosterone and cortisol measurements in male saliva in response to a bout of intense exercise	Mr Blair Crewther	25/08/2006	27/09/2006	Approved subject to conditions		Approved	27/10/2006	HortResearch	A	HortResearch	Dr Hare Puke – Kaumatua at WIT; Ngati Wairere (Tainui)
NTY/06/09/082	Development and characterisation of in vitro cell-based assays of innate and acquired immune responses to assess fruits as potential enhancers of the immune system	Dr Suzanne Hurst	1/09/2006	27/09/2006	Approved subject to conditions		Approved	20/11/2006	HortResearch	A	HortResearch	Māori business development team at HortResearch
NTY/06/09/083	An exploratory pharmacokinetic study of plasma concentrations of unchanged platinum-based drugs requiring blood collection from cancer patients having standard chemotherapy	Assoc Prof Mark McKeage	1/09/2006	27/09/2006	Approved subject to conditions		Approved	30/10/2006	Auckland City Hospital	A	The Cancer Society of New Zealand	MRRC at ADHB
NTY/06/09/084	Barriers to care in rural patients with heart failure	Prof Ross Lawrenson	4/09/2006	27/09/2006	Approved	Awaiting amendment to study	Approved	27/09/2006	Waikato DHB	Nil		Te Puna Oranga at WDHB
NTY/06/09/085	Determination of the performance effects and detection of synthetic ACTH (Synacthen)	Dr Norbert Baume	8/09/2006	27/09/2006	Approved subject to conditions		Approved	27/10/2006	University of Auckland	Nil	Swiss Federal Office of Sport, Drug Free Sport, New Zealand	Dr Jason Turuwhenua of University of Auckland
NTY/06/09/086	To determine the efficacy of treatment of type I amiodarone induced thyrotoxicosis (AIT) with combination of carbimazole and cholestyramine versus carbimazole alone	Dr Malgorzata Brzozowska	8/09/2006	27/09/2006	Deferred	Due to lack of clarity on study design	Deferred		Waikato Hospital	A	Self	Kaumatua Kaunihera at WaikatoDHB
NTY/06/09/087	Independent evaluation of the chlamydia trachomatis (CT) screening project in Northland	Mr R McNeill	13/09/2006	27/09/2006	Approved subject to conditions		Approved	26/10/2006	University of Auckland Manaia Health PHO	Nil		Department of Māori Health; local iwi in Whangarei
NTY/06/09/088	Epidemiologic International Day for the evaluation of patients at risk of venous thrombosis in the acute hospital care setting (ENDORSE)	Dr Paul Harper	8/09/2006	27/09/2006	Approved subject to conditions		Approved subject to conditions		Auckland DHB	Nil		

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NTY/06/09/089	Changing rates of herpes simplex virus 1 (HSV-1) vs herpes simplex virus 2 (HSV-2) in causing ano-genital herpes	Ms Erana Gray	23/08/2006	27/09/2006	Approved subject to conditions		Approved	30/10/2006	Waikato DHB	Nil		
NTY/06/09/090	The incidence and management of reduced fetal movements: a clinical audit	Ms Vicki Flenady	13/09/2006	27/09/2006	Approved subject to conditions		Approved	19/12/2006	National Women's Hospital, Australia	Nil		MRRC at ADHB
NTY/06/10/091	Behavioural and neuropsychological changes associated with ventromedial frontal lobe dysfunction in amyotrophic lateral sclerosis	Ms Sandra Meier	19/09/2006	25/10/2006	Approved subject to conditions		Approved	1/12/2006	Participants homes University of Auckland	A	Department of Psychology doctoral fund	Erana Cooper – University of Auckland; Jenny Ma of MRRC at ADHB
NTY/06/10/092	A pilot randomised controlled trial of home-based progressive resistance exercises for treating venous leg ulcers: the PREPARE pilot	Mr Andrew Jull	21/09/2006	25/10/2006	Approved subject to conditions		Approved	20/11/2006	Counties Manukau DHB	A	HRC	CTRU Māori Research Advisory Committee; Te Komiti Kawa Whakaruruhau; local kaumatua
NTY/06/10/093	A phase III, single blind, randomised, cross-over trial of the effects of three novel nicotine replacement therapies (NicoNovum pouch, mouth spray and lozenge) on the relief of tobacco withdrawal symptoms and user satisfaction	Dr Hayden McRobbie	21/09/2006	25/10/2006	Approved subject to conditions		Approved	1/12/2006	University of Auckland	B	NicoNovum	CTRU Māori Research Committee
NTY/06/10/094	Effect of specialised perioperative enteral nutrition on outcome in patients with head and neck cancer undergoing surgery: a randomised pilot study	Dr Mark Izzard	25/09/2006	25/10/2006	Approved subject to conditions		Approved subject to conditions		Auckland City Hospital	A	Greenlane Research and Education Fund	ADHB MRRC
NTY/06/10/095	Intermediate follow-up of the Morscher Cup acetabular component in the Bay of Plenty region	Mr Dawson Muir	27/09/2006	25/09/2006	Approved subject to conditions		Approved	1/12/2006	Tauranga Hospital	Nil		Te Puna Hauora Kaupapa Maori Services
NTY/06/10/096	Exploring Pacific attitudes to food, food consumption, weight loss and weight management	Mr Kenneth Aiolupotea	29/09/2006	25/10/2006	Deferred		Deferred		Counties Manukau DHB	Nil		Pacific health providers
NTY/06/10/097	A prospective, randomised single-blind clinical trial to determine range of motion, patient quality of life, and clinical outcomes in standard posterior stabilised prostheses versus high flexion posterior stabilised prostheses in unilateral total knee arthroplasty	Dr Tony Lambertson	4/10/2006	25/10/2006	Approved subject to conditions		Approved	20/11/2006	Tauranga Hospital Norfolk Southern Cross Cambridge Road Hospital	A	Smith and Nephew – technical support	Te Puna Hauora
NTY/06/10/098	Assessment of psychosocial distress in patients with diabetes in a clinical population	Dr Rick Cutfield	5/10/2006	25/10/2006	Approved subject to conditions		Approved	1/12/2006	North Shore Hospital	Nil		Jane Sherard – Mo Wai Te Ora; Nga Kai Tataki – Māori research advisory group

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NTY/06/10/099	Gestational diabetes: a long-term follow-up study of diabetic mothers and their children in the Waikato region	Dr Rebecca Wright	4/10/2006	25/10/2006	Approved subject to conditions		Approved	14/12/2006	Waikato DHB	Nil		Morehu Te Whare – Kaumatua
NTY/06/10/100	Project energise substudy – does project energise impact on bone and metabolic markers of health in seven-year-old children who are in project energise programme schools receiving supplemental milk and fruit, compared to children from matched project energise control schools?	Dr David Graham	12/10/2006	25/10/2006	Approved subject to conditions		Approved subject to conditions		Waikato DHB	Nil		Te Puna Oranga-Kaumatua Kaunihera at Waikato DHB
NTY/06/10/101	Dreaming and EEG changes during anaesthesia maintained with propofol or desflurane (GENIE II)	(mEC) Prof James Sleight	4/10/2006	25/10/2006	Approved subject to conditions		Approved	12/12/2006	Waikato Hospital	A	Aspect medical systems	Te Puna Oranga – Kaumatua Kaunihera of Waikato DHB
NTY/06/10/102	A study of cyanotoxin exposure, absorption and potential health risk in white water rafting guides using the Kaituna River during periods of cyanobacterial bloom	Dr Neil de Wet	6/10/2006	25/10/2006	Approved subject to conditions		Approved	20/11/2006	Toi Te Ora – Public Health	Nil		Representative groups of iwi having interest in Kaituna River
NTY/06/10/103	A Phase 1, multicentre, open-label, dose escalation trial of the safety and pharmacokinetics of intravenous PR-104 given weekly in subjects with solid tumours; protocol no. PR-104-1002 dated 25 September 2006	Dr Michael Jameson	6/10/2006	25/10/2006	Approved subject to conditions		Approved	20/11/2006	Auckland City Hospital Waikato Hospital	B	Proacta Inc	Te Puna Oranga – Waikato DHB; MRRC – ADHB
NTY/06/10/104	A randomised control trial of the efficacy of ketamine for analgesia in the field setting	Dr L Giles Chanwai	9/10/2006	25/10/2006	Approved subject to conditions		Approved	7/11/2006	Waikato Hospital	A	Emergency department support, Waikato Hospital	Vi Taha of Kaumatua Kaunihera group
NTY/06/11/105	Identifying facilitators and barriers to physical activity in people with stroke	Ms Nicola Kayes	16/10/2006	22/11/2006	Approved subject to conditions		Approved	22/12/2006	Auckland University of Technology	Nil		Vi Wolfe – Orakei Marae; Matire Harwood and Jane Sherard
NTY/06/11/106	Pilot study for project on the impact of daily consultation from diabetes team on length of hospital stay amongst medical patients admitted to North Shore Hospital under a general medicine team	Dr Shelley Yip	18/10/2006	22/11/2006	Approved subject to conditions		Approved	12/01/2007	North Shore Hospital	A	Waitemata DHB	Jane Sherard; Nga Kai Tataki
NTY/06/11/107	Comparison of mobilisation at day 3 and 8 following split thickness skin grafting to the lower legs	Dr Ben Tallon	19/10/2006	22/11/2006	Deferred		Deferred		Green Lane Hospital	A	Nil	Nil
NTY/06/11/108	Environmental influences on nutrition and physical activity in New Zealand children	Mr Ralph Maddison	19/10/2006	22/11/2006	Deferred	Deferred due to concerns regarding the validity of the survey	Approved	20/12/2006	Counties Manukau DHB	A	Health Research Council and National Heart Foundation of New Zealand	CTRU Māori Research Advisory Committee

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
NTY/06/11/109	Review of duly authorised officer's practice in relation to section 9(2)(D) of the Mental Health (Compulsory Assessment and Treatment) Act 1992	Dr Brian McKenna	19/10/2006	22/11/2006	Approved subject to conditions		Approved	23/01/2007	Auckland DHB Northland DHB Waitemata DHB Counties Manukau DHB	Nil		MRRC from all four DHBs
NTY/06/11/110	Does body composition normalise after liver transplantation?	Dr Lindsay D Plank	19/10/2006	22/11/2006	Approved subject to conditions		Approved	10/01/2007	Auckland City Hospital	Nil		Mata Forbes – ADHB MRRC
NTY/06/11/111	The polypill for primary prevention of cardiovascular disease: a randomised placebo-controlled trial of fixed-dose combination medication in people at raised risk of cardiovascular disease	Dr Anthony Rodgers	25/10/2006	22/11/2006	Approved subject to conditions		Approved subject to conditions		University of Auckland	A	HRC, National Heart Foundation, Dr Reddy's Laboratory in India	CTRU Māori Research Advisory committee and Drs Bramley and Crengle
NTY/06/11/112	Auckland birthweight collaborative study phase 5: 11-year-old follow-up	Professor Ed Mitchell	24/10/2006	22/11/2006	Approved subject to conditions		Approved	5/12/2006	Starship Children's Health	A	Application to lottery, AMRF, HRC, CHRF and Oakley Mental Health Foundation	Mata Forbes – MRRC
NTY/06/11/113	A randomised open-label study of oral CEP-701 administered in sequence with standard chemotherapy to patients with relapsed acute myeloid leukaemia (AML) expressing FLT-3 activating mutations; protocol no. C0701a/204/ON/US	Dr Richard Doocey	24/10/2006	22/11/2006	Approved subject to conditions		Approved	15/12/2006	Auckland City Hospital	B	Cephalon Inc, USA	ADHB MRRC
NTY/06/11/114	A pilot study investigating the effect of humidification during radiotherapy in head and neck cancer	Dr Andrew Macann	24/10/2006	22/11/2006	Approved subject to conditions		Approved	12/01/2007	Auckland City Hospital	B	Fisher & Paykel Healthcare	MRRC at ADHB
NTY/06/11/115	Community-based medical education: benefits and drawbacks from students, PGY 1 HOs (house officers), teaching GPs, practice staff and Maori and non-Maori patients	Dr Tana Fishman	25/10/2006	22/11/2006	Approved subject to conditions		Approved	15/12/2006	University of Auckland	A	Charitable trust of Auckland Faculty and Research and Education Charitable Trust of the Royal New Zealand College of General Practitioners	Papaarangi Reid; Tumuaki at Auckland University
NTY/06/11/116	Relationship of personal dental care to inflammatory markers for cardiovascular disease	Assoc Prof Bruce Arroll	31/10/2006	22/11/2006	Deferred	Ethical approval was deferred due to lack of sufficient information for the committee to make a decision; questionnaires and the details of randomisation are required	Approved	14/12/2006	Department of General Practice and Primary Care Dental practices	Nil		Assoc Prof Papaarangi Reid; University of Auckland

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
NTY/06/11/117	Cook Island community leaders talk about their community's determinants of health	Mr John Natua	2/11/2006	22/11/2006	Deferred	Ethical approval was deferred due to lack of sufficient information and sections of application form not completed; Section D: Privacy and Confidentiality (Operational Standard section 2.3) was not answered	Approved subject to conditions		Cook Island community form Northern region	Nil		Māori colleagues
NTY/06/11/118	Central vein occlusion treatment trial (CVOTT)	Dr Steve Guest	3/11/2006	22/11/2006	Approved subject to conditions		Approved	21/12/2006	Waikato Hospital Bridgewater Day Surgery	A	Normal budget of Waikato Hospital and private insurance companies	Te Puna Oranga – Kaumatua Kaunihera
NTY/06/11/119	A double-blind, placebo controlled, pharmacodynamic and pharmacokinetic dose response study of SABER™ – Bupivacaine instilled into the wound in patients undergoing open inguinal hernia repair	Dr John E Moodie	3/11/2006	22/11/2006	Approved subject to conditions		Approved	14/12/2006	Braemar Hospital	B	Direct Corporation	Tangimoana Habib – iwi affiliation Tu Wharetoa
NTY/06/11/120	Comparison of ventolin and salamol inhalers in acute bronchoconstriction	Dr Catherina Chang	3/11/2006	22/11/2006	Approved subject to conditions		Approved	22/12/2006	Waikato Hospital	A	The Respiratory Research Fund, Waikato Hospital	Waikato DHB – Kaumatua Kaunihera
NTY/06/11/121	Pacific smoking cessation: exploring issues to increase the quit rate of Pacific smokers in New Zealand	Ms Josephine Samuelu	7/11/2006	22/11/2006	Approved subject to conditions		Approved	15/12/2006	Counties Manukau DHB	Nil		MRRC at CMDHB
NTY/06/11/122	An introduction to cardiac anesthesia for registrars – a video presentation	Dr Craig Surtees	7/11/2006	22/11/2006	Approved subject to conditions		Approved	18/12/2006	Waikato Hospital	Nil		Te Puna Oranga
NTY/06/12/126	A Phase III, Double-Blind, Randomised Study to Evaluate the Safety and Efficacy of BAL8557 Versus a Caspofungin Followed by Voriconazole Regimen in the Treatment of Candidemia and Other Invasive Candida Infections. Protocol number/Version: 18 September/Final. Protocol Date: 18 September 2006	Dr Graham Mills	15/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Waikato Hospital	B	Basilea Pharmaceutica Ltd	Te Puna Oranga
NTY/06/12/127	Determining standard criteria for endotracheal suction in the paediatric intensive care patient: a descriptive survey	Ms Kylie Davies	22/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Starship Children's Health, Waikato Hospital	Nil		
NTY/06/12/128	A product evaluation of a paediatric nasal interface used to deliver humidified oxygen therapy	Dr David Buckley	23/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Auckland DHB	B	Fisher & Paykel Healthcare	

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
NTY/06/12/129	The development of a questionnaire to assess the utilisation and perception of formal and informal services available in a rural community to assist people with chronic diseases to maintain their health	Ms Julie Daltrey	20/11/2006				Withdrawn prior to meeting		Tokoroa	Nil		Papaarangi Reid, University of Auckland and Raukawa Trust
NTY/06/12/130	He Kete Korero: Māori health researcher and provider views on Kaupapa Māori and validation frameworks	Dr Leonie Pihama	23/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Maori and Indigenous Analysis Ltd, Auckland	Nil		Karangaora; Nga wahine Tiaki O Te Ao; Te Atawhai on Te Ao; Hapai Te Hauora Tapui Ltd; Mera Penehira; Dr Papaarangi Reid
NTY/06/12/131	Falls – risk profile of elderly new chiropractic patients	Dr Kelly Holt	23/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		New Zealand College of Chiropractic	A	Australian Spinal Research Foundation	New Zealand College of Chiropractic Māori Cultural Advisor
NTY/06/12/132	An examination of the effect of a client centred goal facilitation tool on service provision, quality of life and independence among older people	Mr John Parsons	23/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Counties Manukau DHB	A	HRC PhD Fellowship	Kerry Hiini – CMDHB MRRC; Tom Ruakere – Māori Advisor Waitemata DHB
NTY/06/12/133	A retrospective analysis of the incidence of venous thromboembolism, within three months of primary hip and knee joint replacement surgery at Tauranga Hospital (Tauranga Public and Norfolk Southern Cross private hospitals): the impact of pharmacological and mechanical prophylactic measures and the method of anaesthesia on the incidence of thromboembolism	Ms Jacqui Everitt	23/11/2006	13/12/2006	Approved subject to conditions		Approved	23/01/2007	Tauranga Hospital Norfolk Southern Cross Cambridge Road Hospital	A	Tauranga Orthopaedic Society Inc	Te Puna Oranga
NTY/06/12/134	Describing community participation for New Zealand children after traumatic brain injury	Ms Margaret Jones	23/11/2006	13/12/2006	Approved subject to conditions		Approved	15/01/2007	Waitemata DHB	Nil		Louisa Elia – Whaea WDHB cultural support; Jane Sherard – Nga kai tatakai
NTY/06/12/135	Team working in primary health care – an evaluation of student placements in primary care in Waitemata district	Ms Mary-Anne Boyd	24/11/2006	13/12/2006	Ethical approval not required		Ethical approval not required	13/12/2006	Coast to Coast PHO West Auckland	Nil		Jane Sherard – Waitemata DHB; Tihi Ora Mapo
NTY/06/12/136	The experience of gout in South Auckland: a grounded theory approach using interview and focus groups in patients and healthcare providers	Ms Karen Lindsay	24/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Counties Manukau DHB	Nil		Māori health care workers
NTY/06/12/137	Tissue adhesive for skin grafts in oculoplastic surgery	Dr Stephen Ng	24/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Hamilton Eye Clinic Waikato Hospital	A	Dr Ng	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
NTY/06/12/138	Children's Oncology Group (COG) AEWS0331 European Ewing tumour working initiative of national groups Ewing tumour studies 1999 (Euro-EW/ING.99)	Dr Jane Skeen	27/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Starship Hospital	A	Child Oncology Group	MRRC – ADHB
NTY/06/12/139	A prospective school-based study of the prevalence of rheumatic heart disease in children from a high risk New Zealand population	Dr Rachel Webb	27/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Counties Manukau DHB	Nil		MRRC – CMDHB and Te Hotu Manawa Maori
NTY/06/12/140	Ethnic women's experience of traumatic birth and PTSD following childbirth	Ms Nimisha Waller	27/11/2006	13/12/2006	Approved subject to conditions		Approved subject to conditions		Auckland University of Technology	Nil		Relevant groups

### Applications reviewed under chairperson's delegated authority

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor/funder	Consultation undertaken
NTY/06/06/044	The use of BNP in Waikato: a 12-month retrospective review of data	Ms Veronique Gibbons	12/06/2006		Approved subject to conditions		Approved	15/06/2006	Waikato Hospital	Nil		
NTY/06/06/058	Evaluation of statin use in dialysis patients at Middlemore Hospital	Ms Monica Zolezzi	30/05/2006		Approved subject to conditions		Approved	10/08/2006	Middlemore Hospital	Nil		
NTY/06/11/123	Does cardiovascular rehabilitation improve the quality of life for Maori?	Ms Helen Wihongi	27/10/2006		Approved subject to conditions		Approved subject to conditions		Waikato DHB	Nil		
NTY/06/11/124	The utility of thyroid function tests in Waikato 1991–2005	Ms Veronique Gibbons	16/11/2006		Approved		Approved	22/11/2006	Waikato DHB	Nil		
NTY/06/11/125	Investigation of the histological margins of clearance for skin cancer treated in the Bay of Plenty	Dr Paul JM Salmon	10/11/2006		Approved		Approved	22/11/2006	Skin Centre, Mt Maunganui	Nil		

## **Appendix 2: Northern Y Regional Ethics Committee Terms of Reference**

### **Public authority of the Northern Y Regional Ethics Committee**

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

### **Authority of the Northern Y Regional Ethics Committee**

The Northern Y REC shall have joint responsibility with the Northern X Regional Ethics Committee for ethics committee review of health and disability research and innovative practice occurring in the following District Health Board regions:

- Northland
- Waitemata
- Auckland
- Counties Manukau
- Waikato
- Tairāwhiti
- Lakes
- Bay of Plenty.

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

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

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

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

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

## **Approval of the Northern Y Regional Ethics Committee**

The Northern Y REC has to be approved for the purposes outlined in the following enactments:

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

## **Role of the Northern Y Regional Ethics Committee**

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

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

## **Composition and membership**

### **Guiding principle**

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

### **Member numbers**

There should be 12 members on the Northern Y REC.

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

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

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

## **Member categories**

The Northern Y REC's lay membership shall include:

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

The Northern Y REC's non-lay members shall include:

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

## **Whole committee requirements**

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

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

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

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

## **Terms and conditions of appointment**

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

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

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

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

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

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

## **Chairperson and Deputy Chairperson**

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

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

The Chairperson and Deputy Chairperson may act with the delegated authority of the Northern Y REC between meetings.

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

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

### **General**

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

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

Members have a duty to act responsibly with regard to the effective and efficient administration of the Northern Y REC and the use of Northern Y REC funds.

### **Conflicts of interest**

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

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

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

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

## **Confidentiality and information sharing**

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

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

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

## **Committee meetings**

Meetings of the Northern Y REC shall be held monthly or less frequently, as determined by the workload.

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

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

- i. open meetings for the discussion of broad issues, particularly if the Northern Y REC is reviewing health research
- ii. closed meetings when necessary to ensure the privacy and confidentiality of participants

- iii. closed meetings when applicants provide good and sufficient reasons for this to occur, and the minutes of the meeting should reflect these reasons.

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

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

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

## **Decision-making process**

Wherever possible, the Northern Y REC should determine matters by consensus decision. Where a consensus cannot be reached, a vote shall apply, with a two-thirds majority of agreement among those voting required for any decision 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 Northern Y REC meeting or for those members' views to be sought and represented at the meeting, the matter should be deferred.

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

## **Ethics committee actions**

For each application it reviews, the Northern Y REC must state to its applicant whether its action is to approve, approve subject to conditions, defer or decline that application. The Northern Y REC must state its grounds for any action to defer or decline. For any action to approve subject to conditions, the Northern Y REC must specify the conditions, the grounds for these and its process for assessing whether these conditions are subsequently met. In all cases, the Northern Y REC must state which matters its action is based upon and which are instead matters of comment, information or advice to its applicant.

## **Expert advice and consultation**

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

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

Advice may be sought from recognised experts with:

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

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

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

## **Second opinions and appeals**

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

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

## **Training for members**

Training should be provided for new members and chairpersons within six months of appointment to the Northern Y REC.

## **Reporting requirements**

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

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

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

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

The annual report shall also include the following details:

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

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

## **Fees and allowances**

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

The Chairperson shall receive a meeting attendance fee of \$330 per day of attendance (plus half a day's preparation fee). The meeting attendance fee for members is set at \$250 per day of attendance (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 Northern Y REC by the Chairperson and Deputy Chairperson. The Ministry of Health shall pay actual and reasonable travel and accommodation expenses of the Northern Y REC members.

## **Servicing the Northern Y Regional Ethics Committee**

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

