



# **Northern X Regional Ethics Committee**

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## **Annual Report**

**December 2004 to December 2005**

***Northern X Regional Ethics Committee***

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

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

## **Chairperson's Report**

The committee faced a challenging year following the restructuring of the system of ethical review at the end of 2004, which resulted in the creation of two committees in the northern region, one based in Auckland and one in Hamilton.

The majority of researchers submitting applications were Auckland based and preferred to submit their application to their local committee in Auckland rather than have it heard by the Northern Y Regional Ethics Committee in Hamilton. Northern X Regional Ethics Committee, therefore, received more applications at times than could be reviewed at its meeting and determined that 16 new applications was the limit of what could be reviewed effectively at one meeting. When more than 16 applications were received, researchers were given the option of having their application forwarded to Northern Y Regional Ethics Committee or waiting a month until the next meeting. The majority chose to wait for review by the Northern X Regional Ethics Committee in Auckland. The number of inquiries from researchers was very high and created an additional administrative burden.

The volume of serious adverse events received for ongoing studies has been especially onerous and taxing, particularly for medical members of the committee but more generally taking valuable meeting time.

There has been considerable and inconclusive discussion of tissue banking. The committee looks forward to new guidelines in this area.

The committee continues to enjoy very high applicant attendance. My sense is that most researchers are satisfied with the committee's work. Almost all applications are dealt with in a timely fashion, assuming researchers respond promptly to committee requirements.

Pat Chainey continued as Administrator for the committee, and her six years of experience were appreciated by the committee.

Dr Tim Dare  
Chairperson

# Committee Membership

## Appointments

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

### Chairperson

<b>Tim Dare</b>	Lecturer Ethics, BA, LLB, MJur PhD
Representation	Lay member
Member category	Ethicist
Gender	Male
Date of appointment	November 2004
Term of appointment	1 year
Six-year maximum term	December 2005
Professional affiliations	Lecturer Ethics, University of Auckland
Iwi affiliation	None

### Deputy Chairperson

<b>John France</b>	PhD(Biochemistry), DSc, FAACB
Representation	Non-lay member
Member category	Health researcher
Gender	Male
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	April 2009
Professional affiliation	Reproductive Scientist (retired), A/Prof (Honorary) Obstetrics and Gynaecology, University of Auckland
Iwi affiliation	None

### Members

<b>Teena West</b>	Dip Pub Hlth, Mstr Science, BSc
Representation	Non-lay member
Member category	Biostatistician
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Resigned	March 2005
Professional affiliation	Auckland City Hospital
Iwi/hapu affiliation	Ngati Maniapoto

<b>Adina Halpern</b>	MA Law (Hons), LicSpec
Representation	Lay member
Member category	Lawyer
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2007
Professional affiliation	Auckland Law Society
Iwi affiliation	None
<b>Jeffrey Harrison</b>	PhD, DipClin Pharm
Representation	Non-lay member
Member category	Pharmacist/pharmacologist
Gender	Male
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Professional affiliation	University of Auckland
Iwi affiliation	None
<b>Scott Macfarlane</b>	MB ChB FRACP BSC
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 affiliation	RACP, Starship Children's Health
Iwi affiliation	None
<b>Emma Ngawhare</b>	
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
Iwi/hapu affiliation	Ngatihihne Ngati Porou
<b>Robyn Northey</b>	MA(Hons) Social Welfare and Development
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
Iwi affiliation	None

<b>Stephanie Palmer</b>	PhD Psychology, BSc (Hons)
Representation	Non-lay member
Member category	Health researcher
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Iwi/hapu affiliation	Ngati Porou, Ngaiterangi, Marutuahu, Nga Puhi, Cook Islands Māori

<b>Louisa Wall</b>	MPhil(Social Policy)
Representation	Lay member
Member category	Community representative
Gender	Female
Date of appointment	November 2004
Term of appointment	3 years
Six-year maximum term	November 2010
Iwi/hapu affiliation	Ko Ngati Tuwharetoa me Waikato

<b>Patricia Hanlen</b>	
Representation	Lay member
Member category	Community representative
Gender	Female
Date of appointment	November 2004
Term of appointment	2 years
Six-year maximum term	November 2010
Iwi affiliation	None

<b>Lester Reed</b>	BA, MD
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	November 2004
Term of appointment	3 years
Resigned	February 2005
Iwi affiliation	None

## Changes to membership

Lester Reed and Teena West resigned from the committee early in 2005 because they moved overseas. The following appointments were made by the Minister of Health in July 2005.

<b>Wayne Miles</b>	MB Chb, MD, Dip (Psychiat Med), FRANZCP
Representation	Non-lay member
Member category	Health practitioner
Gender	Male
Date of appointment	July 2004
Term of appointment	3 years
Six-year maximum term	June 2011
Professional affiliation	Waitemata District Health Board
Iwi affiliation	None

<b>Joanna Stewart</b>	MSc (Mathematics and Statistics)
Representation	Non-lay member
Member category	Biostatistician
Gender	Female
Date of appointment	July 2004
Term of appointment	3 years
Six-year maximum term	June 2011
Professional affiliation	University of Auckland
Iwi affiliation	None

## Deputy Chairperson

John France was elected deputy chairperson by the Committee at its inaugural meeting on 14 December 2004.

## Members' attendance

There was no meeting in January 2005.

Member	M/F	Lay/ non-lay	Dec 2004	Feb 2005	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	
Tim Dare Chairperson	M	L	Y	Y	Y	Y	Y	Y	A(2)	Y	Y	Y	Y	A(2)	10/12	
John France Health researcher	M	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	A(2)	Y	Y	11/12	
T West Biostatistician	F	N	Y	Y	Y	Resigned March 2005									3/3	
L Reed Health practitioner	M	N	A(2)	Y	Resigned February 2005									1/2		
A Halpern Lawyer	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	A(1)	Y	Y	11/12	
J Harrison Pharmacist/ pharmacologist	M	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12	
S Macfarlane Health practitioner	M	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12	
E Ngawhare* Consumer rep	F	L	Y	Y	Y	Y	A(1)	Y	Y	Y	Y	Y	Y	Y	11/12	
R Northey Consumer rep	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12	
S Palmer * Health researcher	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12	
P Hanlen Community rep	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12	
L Wall* Community rep	F	L	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12/12	
W Miles Health researcher	M	N	Appointed in July 2005								Y	Y	A(2)	Y	Y	4/5
J Stewart Biostatistician	F	N	Appointed in July 2005								Y	Y	Y	Y	Y	5/5
<b>Committee members present</b>			<b>11</b>	<b>12</b>	<b>11</b>	<b>10</b>	<b>9</b>	<b>10</b>	<b>9</b>	<b>12</b>	<b>12</b>	<b>9</b>	<b>12</b>	<b>11</b>		
<b>No. of applications considered</b>			<b>12</b>	<b>11</b>	<b>13</b>	<b>12</b>	<b>12</b>	<b>18</b>	<b>19</b>	<b>15</b>	<b>15</b>	<b>15</b>	<b>15</b>	<b>15</b>	<b>172</b>	

Y = Present

A = Apology

Reasons for absences:

(1) Personal

(2) On leave

## **Training**

### **New member training**

All members of health and disability ethics committees, including those with previous experience, were offered training in January and February 2005. The training was held in Auckland, Wellington and Christchurch. The following members of the Northern X Regional Ethics Committee attended the Auckland programme on 10/11 February (total 11): Tim Dare, John France (Friday only), Adina Halpern, Jeffrey Harrison, Scott Macfarlane, Emma Ngawhare, Robyn Northey, Stephanie Palmer, Louisa Wall, Patricia Hanlen, Teena West.

### **Ongoing training**

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

### **Meeting of legal members and chairpersons**

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

### **Meeting of the Māori members**

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

### **Chairpersons' meeting**

Tim Dare attended the initial meeting of the multi-region and regional ethics committees chairpersons in December 2004 and the two 2005 meetings on 14 April and 13/14 October 2005.

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

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

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

The Northern X Regional Ethics Committee is registered with the United States Department of Health and Human Services. The registration number is: IRB00004664 – Northern X Regional Ethics Committee.

## Response to Cultural Issues

Number of applications deferred because Māori guidelines were not read	0
Number of applications for which consultation with Māori was considered appropriate	171
Number of applications returned through insufficient consultation on cultural issues	0 (Evidence of consultation was required and was carried out concurrently)
Process the committee has for following through on consultation	Written evidence of consultation with appropriate Māori review committee required
Cases of unsatisfactory reasons for not including Māori	0
Mechanisms in place to facilitate consultation with Māori by researchers	DHB, university or institution Māori research committee review committees are available to researchers
Examples of Māori not being included in research	Research purely on Asian, South Pacific or European populations Research on diseases not applicable to Māori Extension studies where no Māori were recruited, that is, transplant studies

# Applications

The committee held 12 scheduled meetings from December 2004 to December 2005.

## Northern X Regional Ethics Committee statistics for December 2004–December 2005

<b>Status at time of report</b>	
Applications approved	162
Applications deferred	3
Applications deferred but later approved	5
Applications declined	2
Applications carried forward (approved subject to conditions)	9
Withdrawn prior to meeting	1
Application terminated by sponsor	1
Approval not required (prospective audit)	47
<b>Total</b>	<b>230</b>
Applications for which approval was not required (audit)	47
Applications considered/approved under delegated authority (CPD)	10
Withdrawn prior to meeting	1
Total number of applications considered by the committee	172
<b>Total number of applications received</b>	<b>230</b>

## Other committee statistics

Number of matters arising considered	5
Number of general business items reviewed	55
Number of amendments reviewed by committee	90
Number of amendments approved under CPD	57

## Audit or matters not requiring ethical approval

Forty-seven projects were confirmed as audits or surveys not requiring ethical approval.

## Innovative practice

One application for innovative practice was reviewed. 'Selective cooling for term infants born following perinatal asphyxia' was reviewed under CPD in December 2004 but has been placed on hold as the researcher is awaiting information from the sponsor around the release of the product for clinical use. Clearance from the United States FDA is also awaited.

## **Complaints**

One complaint was referred to the committee by a third party who believed a research project approved by the committee invited respondents to a SIDS questionnaire to be critical of his product. The Chairperson kept the Ministry of Health informed of progress on the complaint. It was believed the complainant had no genuine grounds for complaint, and he was advised that this was the view of the committee at its March meeting. The complainant wrote to various Government officials and members of the research community but finally settled on a threat to take the matter to the media. As there was no media coverage, either he did not proceed with the threat, or the media decided to take no action.

## **Second opinions**

The committee was involved indirectly in a request for a second opinion over samples going to an off-shore tissue bank. The study was originally approved by the Canterbury Ethics Committee but was transferred to the Multi-region Ethics Committee when a request was received to add another site. The Multi-region Ethics Committee did not give ongoing ethical approval of the collection of tissue for unspecified future research. A second opinion was sought from the Health Research Council Ethics Committee.

# Issues for the Committee

## Locality assessment

The form has been adopted by the three District Health Boards in the Auckland region. By sighting and giving designated signatures, management documents all research being carried out in their hospital. It is generally felt that the form could be redesigned to make the requirements clearer.

There were issues regarding the completion of the form by individual researchers and local institutions though these are being worked through.

## Guidelines for the Chairperson's Delegation

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

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

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

## Appendix 1: Applications received December 2004 to December 2005

Appendix I details the applications considered by the committee from December 2004 to December 2005 in open meetings. Two 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	Consultation undertaken
NTX/04/12/001	Computerised delivery of a cognitive behavioural intervention for the treatment of depression in adolescents: development and pilot study. PIS/Cons V#2, 4/05	Ms Karolina Stasiak	29/11/04	14/12/04	Approved subject to conditions		Approved	5/3/05	University of Auckland	A		Sue Cregle (Department Māori Health); Tania Cargo, Rawiri Wharemate (Werry Centre); Mahi Tahī, Māori Mental Health NGO, Otahuhu
NTX/04/12/002	A three year randomised, double-blind, placebo-controlled trial to determine the duration of effect of zoledronate on bone turnover markers and on bone density: PIS/Cons V#2, 12/07/05	Prof Ian Reid	25/11/04	14/12/04	Approved subject to conditions		Approved	27/1/05	Auckland DHB, University of Auckland	A		ADHB MRRC
NTX/04/12/003	Pilot study testing the feasibility and acceptability of a trial of increased choice over types of nicotine replacement therapies (NRT) for smoking cessation: PIS/Cons V#4, 26/1/05	Dr Natalie Walker	29/11/04	14/12/04	Approved subject to conditions		Closed	20/1/05	Waitemata DHB	A		CTRU MRRC, Auckland University, Waitemata
NTX/04/12/004	Children's Oncology Group: AGCT0132: A phase III study of reduced therapy in the treatment of children with low and intermediate risk extracranial germ cell tumours: PIS/Cons V#3, 18/04/05.	Dr Ruelyn Cockcroft	29/11/04	14/12/04	Approved subject to conditions		Approved	11/3/05		A		ADHB MRRC
NTX/04/12/005	Age-related changes in the facial skeleton	Mr Tristan de Chateau	29/11/04	14/12/04	Approved subject to conditions		Approved	4/4/05	Counties Manukau DHB	A		N/A: ethnicity not collected by database
NTX/04/12/006	The relationship between disorders of reality monitoring and anosognosia of hemiplegia following right hemispheric stroke, PIS/Cons V#4, 16/12/05	Ms Aileen Victoria Alegado	29/11/04	14/12/04	Approved		Approved	14/12/04	University of Auckland, Auckland DHB	A		ADHB MRRC
NTX/04/12/007	The relationship between the clinical profile and neural changes in individuals with Huntington's disease: a retrospective analysis: PIS/Cons V#1, 26/11/04	Dr L Tippett	29/11/04	14/12/04	Approved		Approved	14/12/04	University of Auckland	A		N/A: disease not applicable to Māori
NTX/04/12/008	An open-label randomised study of VELCADE/Meplizalan/Prednisone versus melphalan/prednisone in subjects with previously untreated multiple myeloma: Protocol 26866138-MMY-3002	Prof Peter Browett	29/11/04	14/12/04	Approved subject to conditions		Approved	27/4/05	Auckland DHB	B	Janssen-Cilag Pty Ltd	ADHB 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	Consultation undertaken
NTX/04/12/009	An international single-arm protocol to provide expanded access to VELCADE (tm) for patients with multiple myeloma who have received at least two previous lines of therapy and are refractory to or have relapsed after their last therapy for multiple myeloma: Protocol 26866138-IMY-3001, Ph. 3B, 25/08/04; IB Ed #7, 18/3/04 PIS/Cons V#3, 3/10/05	Prof Peter Browett	29/11/04	14/12/04	Approved subject to conditions		Approved	14/4/05	Auckland DHB, Auckland City Hospital, University of Auckland	B	Janssen-Cilag Pty Ltd	ADHB MRRC
NTX/04/12/010	A randomised study to assess the safety and efficacy of adefovir dipivoxil substitution for HBV in liver transplantation patients receiving long-term low dose IM HBV and lamivudine prophylaxis: Protocol IN-AU-103-0129,3/12/03; PIS V#5, 13/5/04	Professor Edward Gane	29/11/04	14/12/04	Approved subject to conditions		Approved	28/1/05	Auckland DHB, Auckland City Hospital	A		Dr. J Koea, Department Surgery, Auckland City Hospital
NTX/04/12/011	Dual vent cardiopulmonary bypass to reduce ischemic brain injury in cardiac surgery: Protocol V#1, 25/11/04; Prot/amend V#2, 14/4/05; PIS/Cons V#3, 25/08/05	Dr. Paget Millsom	29/11/04	14/12/04	Approved subject to conditions		Approved	20/12/04	Auckland DHB	A		ADHB MRRC
NTX/04/12/012	Innovative treatment: selective cooling for term infants born following perinatal asphyxia	Dr Malcolm Battin	25/11/04	14/12/04	Approved subject to conditions		Approved subject to conditions		Auckland DHB, Auckland City Hospital	A		
NTX/05/02/001	Epidural blood patch: the effect of volume: PIS/Cons V#4, 1/3/05	Dr Jack Hill	12/10/04	2/2/05	Approved subject to conditions		Approved	23/3/05	Auckland DHB, Wellington Hospital	A		ADHB MRRC
NTX/05/02/002	Outcome of interventions from a pelvic floor clinic for defecatory disorders: the Auckland experience	Mr Ian Bissett	22/12/04	2/2/05	Approved subject to conditions		Approved	23/9/05	Auckland DHB	Nil		J Koea; ADHB MRRC
NTX/05/02/003	Investigation of the incidence of musculoskeletal discomfort in three squadron pilots in the Royal New Zealand Air Force: PIS/Cons 10/5/05	Ms Lara Blackmore	23/12/04	2/2/05	Deferred	Adverse effects on workplace position	Approved	24/6/05		Nil		N/A
NTX/05/02/004	An open-label trial of telbivudine (LdT) in adults with chronic hepatitis B previously treated in Idenix-sponsored telbivudine studies: Protocol # NV-02B-022, 21/10/04; Prot/amend 1, V 3.0, 18/5/05; PIS/Cons V#3, 24/6/05; IV Ed 8, 9/8/05	Dr Edward Gane	5/1/05	2/2/05	Approved subject to conditions		Approved	13/6/05	Counties Manukau DHB, Waikato DHB	B	Idenix Pharmaceuticals, Protocol NV-02B-022, 21/10/04	Counties-Manukau MRRC; Waikato DHB
NTX/05/02/005	A children's oncology group protocol for collecting and banking paediatric brain tumour research specimens: Protocol COG-ACNS02B3, 2/3/04; PIS/Cons V#3, 12/4/05	Dr Wayne Nicholls	6/1/05	2/2/05	Approved subject to conditions		Approved	5/11/05	Auckland DHB	A		ADHB 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	Consultation undertaken
NTX/05/02/006	Relationship between otitis media with effusion characteristics, sequelae, otomicroscopy and audiometry: PIS/Cons v#2, 14/3/05	Associate Professor Wouter TenCate	13/1/05	2/2/05	Approved subject to conditions		Approved	28/4/05	Counties Manukau DHB, University of Auckland	A		CMDHB MRRC/Kery Hiini
NTX/05/02/007	Development co-ordination disorder and its co-morbidities in 9 and 10 year old school children	Dr Phillipa Clark	17/1/05	2/2/05	Approved subject to conditions		Approved	10/3/05	Auckland DHB, University of Auckland	A		Judy Davies, Christchurch; Madeleine Sands, Community Child Health and Disability Services; M Coogan/Professor C Forrest, P Kingi
NTX/05/02/008	A six-month phase 3 multicentre, masked, randomised, sham-controlled trial (with six-month open-label extension) to assess the safety and efficacy of 700 ug and 350 ug dexamethasone posterior segment drug delivery system (DEX PS DDS applicator system) in the treatment of patients with macular edema following central retinal vein occlusion or branch retinal vein occlusion: Protocol # 206207-009-00; 9/8/04; IB Ed #6, 17/8/04; PIS/Cons V#6, 4/10/05	Dr Mark Donaldson	17/1/05	2/2/05	Approved subject to conditions		Approved	15/6/05	Auckland DHB	B	Allergan	ADHB MRRC
NTX/05/02/009	Adolescents with a chronic condition: parental and self-expectations and their relationship to adjustment: PIS/Cons V#3, 5/05.	Dr Treacia Ann Lyons Woules	18/1/05	2/2/05	Approved subject to conditions		Approved	22/2/05	University of Auckland, Auckland DHB	A		ADHB MRRC
NTX/05/02/010	An intervention for changing symptom perceptions of European and Maori women with angina or a heart attack:	Mrs Cheryl Campbell	17/1/05	2/2/05	Approved		Approved	2/8/05	University of Auckland, Auckland DHB	Nil		Dr Lorna Dyll (Assistant Dean and Senior Lecturer, Maori Health, University of Auckland)
NTX/05/02/011	The immunological effects and efficacy of the nutritional supplement Meracol in the treatment of eczema: Protocol 12/04; PIS/Cons V#5, 1/05; Amend 23/5/05; Pharmacokinetic Protocol and PIS/C V#1, 7/05	Dr Timothy Meakin	18/1/05	2/2/05	Approved subject to conditions		Approved	16/3/05		B	Meracol Corporation Ltd	None
NTX/05/03/012	A randomised double blind placebo controlled trial of site-specific clonidine patches in treatment of neuropathic wound pain following caesarean section: Protocol V#5, 5/05; PIS/Cons V#5, 5/05	Mrs Francesca Storr	14/2/05	2/3/05	Approved subject to conditions		Approved	23/5/05	Auckland DHB	A		ADHB MRRC
NTX/05/03/013	Evaluation of SERUM IGF-II in children and adolescents born prematurely (pilot study): PIS/Cons V#3, 12/3/05	Associate Professor Wayne Cutfield	14/2/05	2/3/05	Approved subject to conditions		Approved	4/6/05	Auckland DHB, University of Auckland, Counties Manukau DHB	A		ADHB 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	Consultation undertaken
NTX/05/03/014	The treatment of non-syndromic plagiocephaly and brachycephaly in infancy: PIS/Cons V#1, 3/05	Professor Ed Mitchell	14/2/05	2/3/05	Approved		Approved	9/3/05	Auckland DHB, Counties Manukau DHB, University of Auckland	A		Dr Bernard Te Paa, GM, Māori Health, Counties Manukau DHB letter of support
NTX/05/03/015	Evaluation of insulin sensitivity and bone density in young adult women in relation to timing of puberty: PIS/Cons V#2, 15/3/05	Associate Professor Wayne Curfield	14/2/05	2/3/05	Approved subject to conditions		Approved	23/3/05	University of Auckland, Auckland DHB	A		University of Auckland Māori consultation with Julie Wade
NTX/05/03/016	An observational study of the impact of long-acting risperidone microspheres in Māori and Pacific people with schizophrenia and related psychotic disorders: ADHB PIS/Cons V#4, 26/9/05; Wai/C-M DHB IS/Cons V.5, 27/1/06	Dr Wayne Miles	14/2/05	2/3/05	Approved subject to conditions		Approved	28/4/05	Auckland DHB, Waitemata DHB, Counties Manukau DHB	A		Waitemata DHB (Jane West), Ana Sokratov (consumer consultant, WDHB)
NTX/05/03/017	Spirit II clinical study: a clinical evaluation of the XIENCE V everolimus eluting coronary stent system in the treatment of patients with de novo native coronary artery lesions: Protocol 03-364, V#1, 18/01/05. PIS/Cons V#2, 16/3/05; IV V#2 100305; IB V#2, 03-364, 10/3/05	Dr Peter Ruygrok	14/2/05	2/3/05	Approved subject to conditions		Approved	17/3/05	Auckland DHB	B	Guidant Corporation	ADHB MRRC
NTX/05/03/018	Constructing a three-dimensional anatomically based mathematical model to investigate the effect of microstructure on the function of the gastro-oesophageal junction: IS/Cons V#2, 22/3/05	Ms Rita Yassi	14/2/05	2/3/05	Approved subject to conditions		Approved	27/4/05	University of Auckland, Auckland DHB	A		Te Kipa (Kepa) Morgan/ Professor Colin Mantell
NTX/05/03/019	A comparison pilot study of oronasal masks in patients receiving non-invasive ventilation: IS/Cons V#3, 15/3/05	Dr Shay McGuinness	14/2/05	2/3/05	Deferred	Compensation not acceptable	Approved	14/4/05	Auckland DHB	B	Fisher & Paykel Healthcare	ADHB MRRC letter of support
NTX/05/03/020	A qualitative study of people with COPD who continue to attend a support group: PIS/Cons V#3, 17/3/05	Ms Maureen Elizabeth Goodman	14/2/05	2/3/05	Approved subject to conditions		Completed	24/3/05	University of Auckland, Counties Manukau DHB	A		MRRC Counties-Manukau DHB (Kerry Hini)
NTX/05/03/021	The effects of aging and endurance training on exercising diastolic function in healthy older males: PIS/Cons V#4, 17/1/06	Mr Graeme Carrick-Ranson	14/2/05	2/3/05	Approved subject to conditions		Approved	8/8/05	University of Auckland	A		Professor Mantell/ Julie Wade
NTX/05/03/022	Young adults' experience of day-stay surgery: a qualitative descriptive pilot study: PIS/Cons V#2, 3/05.	Ms Kaye Louise Neely	14/2/05	2/3/05	Approved subject to conditions		Completed – report required	24/3/05	Auckland University of Technology	Nil		AUT Kawa Whakaruruhau, Division of Health Care Practice, AUT – letter of support
NTX/05/03/023	Māori cardiac and stroke rehabilitation study	Ms Helen Whihongi	16/2/05	2/3/05	Deferred	Concerns re survey design – achieve object?	Completed		Waikato DHB	Nil		Te Kohao Health, Waikato DHB, Stroke Foundation

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
NTX/05/03/024	Prevalence of corneal anomalies and early signs of keratoconus in school students: PIS/Cons V#2	Dr Helen Owens	14/2/05	2/3/05	Deferred	Study design does not meet requirements	Completed	3/10/05	University of Auckland	A		Dr Jason Turuwhenua, University of Auckland
NTX/05/04/025	Heart failure services: developing the role of the heart failure nurse to improve service provision	Ms Helen McGrinder	8/3/05	6/4/05	Approved subject to conditions		Approved	23/5/05	Auckland DHB, University of Auckland, Auckland City Hospital	A		Tracey Peters, Maori health advisors GLCC/ Angela Barnes/Mata Forbes, ADH MRRC
NTX/05/04/026	Early inpatient-outpatient hospital-based pulmonary rehabilitation following hospitalisation for acute exacerbations of COPD: a randomised controlled study: IS/Cons V#1.2, 15/4/05	Dr Tam Eaton	2/3/05	6/4/05	Approved subject to conditions		Approved	28/4/05		A		Maori health advisor
NTX/05/04/027	Changes in the burden of medical admissions/discharges in Auckland: Phase 2: PIS/Cons V 26/4/05.	Mr Jagpal Singh Benipal	15/3/05	6/4/05	Approved subject to conditions		Approved	5/3/05	University of Auckland, Auckland DHB, Waitemata DHB	Nil		ADHB and Waitemata DHB MRRC
NTX/05/04/028	Metformin and markers of endothelial dysfunction and inflammation in people with cardiovascular disease and the metabolic syndrome: MEDIC study: Protocol V#2, 8/2/05: PIS/Cons V#2, 13/4/05: Prot/amend V#3, 7/6/05: PIS/Cons V#3, 7/6/05	Dr Jocelyne Benatar	2/3/05	6/4/05	Approved subject to conditions		Terminated	26/4/05	Auckland DHB, Greenlane Clinical Centre	A		ADHB MRRC
NTX/05/04/029	Are drawings associated with the level of disability and adherence to treatment in heart failure and myocardial infarction patients? PIS/Cons V#1.2 14/4/05	Ms Lisa M Reynolds	14/3/05	6/4/05	Approved subject to conditions		Approved	21/4/05	University of Auckland, Auckland DHB	A		Dr Hinemoa Elder, ADHB MRRC
NTX/05/04/030	A placebo controlled study to assess patient-reported outcomes in subjects receiving BOTOX (botulinum toxin type A) for treatment of moderate to severe glabellar rhytids: Protocol 11/3/05: Prot/amend 21/4/05: Prot/amend 11/5/05: PIS/Cons V 11/5/05	Dr Catherine Stone	21/3/05	6/4/05	Approved subject to conditions		Approved	6/5/05		B	Allergan Australia Pty Ltd	University of Auckland Maori/ Pacific Island Health Unit
NTX/05/04/031	Do non-steroidal anti-inflammatory drugs interfere with the antiplatelet effects of aspirin (NADIA)? PIS/Cons V 6, 18/4/05: Questionnaire V#6, 18/4/05	Dr Mark Webster	21/3/05	6/4/05	Approved subject to conditions		Completed	3/5/05		A		ADHB MRRC
NTX/05/04/032	Process evaluation of a framework for services to assess a range of Pacific alcohol and other drugs (AOD) sector: PIS/Cons V#2, 26/4/05	Dr Gail Robinson	21/3/05	6/4/05	Approved subject to conditions		Approved	5/3/05	Waitemata DHB	A		Waitemata DHB MRRC/Te Atea Marino

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
NTX/05/04/033	Development of patient care diaries for head and neck cancer patients undergoing radiotherapy at Auckland City Hospital: PIS/Cons V#2, 02/5/05	Ms Rebecca Basket	22/3/05	6/4/05	Approved subject to conditions		Approved	13/5/05	Auckland DHB, Auckland City Hospital	Nil		ADHB MRRC
NTX/05/04/034	The patient's perception of chronic illness management in primary care: Questionnaire V#2, 8/05: PIS/Cons V#3, 8/05	Ms Kathryn Menary	22/3/05	6/4/05	Approved subject to conditions		Approved	23/5/05	Broadway Health	Nil		Partners of Broadway Health/Cathryn Turner (PHO)
NTX/05/04/035	Do beta-blockers affect the use of beta-agonist inhalers in chronic obstructive pulmonary disease? PIS/Cons V#1, 9/3/05: Prot/amend V#5, 6/5/05: PIS/Cons V#3, 10/5/05	Dr Catherine Chang	23/3/05	6/4/05	Approved		Approved	12/4/05	Waikato Hospital, Waitemata DHB	A		Waikato DHB, Rose Smith
NTX/05/04/036	Outcomes evaluation of the Healthy Housing programme: PIS/Cons V#2, 20/4/05	Dr Janet Clinton	23/3/05	6/4/05	Approved subject to conditions		Approved	2/6/05	Waitemata DHB, Counties Manukau DHB	A		Lorna Dylli, Ngati Maniapoto, senior lecturer in Māori Health, School of Population Health
NTX/05/05/037	Minimising unintended clinical events using electronic health records (EHR) in head and neck cancer care	Ms Pratima Poudel Acharya	31/3/05	4/5/05	Deferred	Design not to Guidelines – confidentiality issue	Approved	23/9/05	Auckland DHB, Massey University	Nil		Auckland DHB MRRC
NTX/05/05/038	Patient-controlled analgesia (PCA) morphine vs a nurse-administered intravenous (IV) morphine protocol in renal colic patients in the Emergency Department: PIS/C V#1, 24/3/05	Dr David Peak	8/4/05	4/5/05	Approved subject to conditions		Approved	11/7/05	Counties Manukau DHB	A		Counties-Manukau MRRC letter of support
NTX/05/05/039	An investigation into the patient's perspective of the nature and impact of swallowing problems resulting from total laryngectomy: PIS/Cons V#2, 24/5/05	Dr Suzanne Purdy	11/4/05	4/5/05	Approved subject to conditions		Approved	15/7/05	University of Auckland, Auckland DHB	A		ADHB MRRC letter of support
NTX/05/05/040	Evaluation of diagnostic assessments carried out at Specialist Services Unit – Central Auckland (SSU)	Ms Francisca Montedonico	12/4/05	4/5/05	Approved subject to conditions		Approved	10/3/05	University of Auckland	Nil		Paora Murupaenga (Clinical Team Leader SSU-Central)
NTX/05/05/041	Family analysis of a unique chromosomal market identified at a sex specific locus: PIS/Cons V#2, 10/5/05	Ms Patricia Stapleton	12/4/05	4/5/05	Approved subject to conditions		Approved	5/12/05		A		Participants non-Māori
NTX/05/05/042	Cognitive functioning and quality of life in neuropsychiatric lupus: IS/Cons V#3, 27/7/05	Ms Ho (Ada) Yan Lo	12/4/05	4/5/05	Approved subject to conditions		Approved	27/7/05	University of Auckland	A		Dr Jason Turuwhenua (Ngata Porou, Tuhoie), Dept of Statistics, University of Auckland
NTX/05/05/043	A good start: resilience in families with infants: PIS/Cons V#2, 5/6/05	Ms Irene de Haan	18/4/05	4/5/05	Approved subject to conditions		Approved	14/6/05	Massey University – Auckland	Nil		Wellsford base of Te Ha O Te Oranga O Ngati Whatua

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
NTX/05/05/044	Why Pacific patients do not attend ('DNA') outpatient clinics in the Counties Manukau District Health Board ('CMDHB') area: PIS/Cons V#5, 11/5/05	Ms Yvonne Timaloa	18/4/05	4/5/05	Approved subject to conditions		Approved	23/5/05	Counties Manukau DHB	Nil		CMDHB MRRC letter of support
NTX/05/05/045	The persistence and recovery of DNA from skin contact and saliva deposits on post-mortem skin using hydrosoluble tape: Protocol V1, 10/5/05: IS/Cons V#2, 11/5/05	Ms Kirstin McKenzie	16/4/05	4/5/05	Approved subject to conditions		Approved	23/5/05	Auckland DHB	Nil		No ethnicity known
NTX/05/05/046	A case study of the effectiveness of therapy using electropalatography (EPG) for a client with cleft-type speech difficulties	Dr Suzanne Purdy	18/4/05	4/5/05	Approved subject to conditions		Approved	29/7/05	Counties Manukau DHB	A		Counties-Manukau DHB MRRC
NTX/05/05/047	Dual focus contact lens intervention in children with progressing myopia: PIS/Cons V#5, 26/10/06	Ms Nicola Anstice	18/4/05	4/5/05	Approved subject to conditions		Approved	20/5/05	University of Auckland	A		Dr Jason Turuwhenua, Maori in Science, University of Auckland
NTX/05/05/048	Depression and Māori: experiences regarding antidepressant medication: a qualitative study: PIS/Cons V#2, 19/5/05	Associate Professor Bruce Atroll	19/4/05	4/5/05	Approved subject to conditions		Approved	23/5/05	University of Auckland, Auckland DHB	Nil		Colin Mantell, University of Auckland, Tane Taylor, Raukura Hauora o Tainui, Honemoa
NTX/05/06/050	Implementing the blueprint in the New Zealand mental health sector measuring the performance and outcome of social, recreational and prevocational mental health services	Ms Rozlyn Sorensen	27/4/05	1/6/05	Approved subject to conditions		Approved	08/8/05	Waitemata DHB, Auckland DHB, Counties Manukau DHB, Northland DHB	Nil		Waitemata DHB MRRC
NTX/05/06/051	Assessment of learning needs of registered nurses in clinical practice: PIS/Cons V#2, 6/05	Ms Lyn Dyson	27/4/05	1/6/05	Approved subject to conditions		Approved	29/8/05	University of Auckland, Auckland DHB, Northland DHB, Counties Manukau DHB	Nil		Counties-Manukau and ADHB DHB and University of Auckland (Kerry Hini) MRRC letters of support
NTX/05/06/052	Exercise participation in children with heart disease – a survey of caregivers in the paediatric cardiology: PIS/Cons V# 7/05. Questionnaire V# 7/05	Dr Jamie Speeden	11/5/05	1/6/05	Approved subject to conditions		Approved	01/8/05	Auckland DHB	A		ADHB MRRC
NTX/05/06/053	The relationship between health-related quality of life (as measured by the SAQOL-39) and severity of aphasia following stroke: PIS/Cons V 27/05	Dr Suzanne Purdy	1/5/05	1/6/05	Approved subject to conditions		Approved	27/7/05	University of Auckland	A		Counties-Manukau DHB MRRC letter of support
NTX/05/06/054	Randomised controlled trial of tight glycaemic control with insulin in hyperglycaemic preterm neonates. The HINT trial: PIS/Cons V#2, 6/05	Dr Jane Alsweller	12/5/05	1/6/05	Approved subject to conditions		Approved	24/6/05	Auckland DHB, University of Auckland	A		ADHB MRRC and Mata Forbes
NTX/05/06/055	The evaluation of outcome following conservative and/or surgical treatment for children who are idiopathic toe walkers	Associate Professor Susan Stott	12/5/05	1/6/05	Approved subject to conditions		Approved	30/6/05	University of Auckland, Auckland DHB	A		ADHB MRRC letter of support

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NTX/05/06/056	A case-control study of falls occurring in the home environs in the Auckland region in people aged 25 to 60 years resulting in hospitalisation: Protocol 14/4/05: PIS/Cons 27/6/05: Questionnaire 27/6/05	Dr Shanithi Ameratunga	13/5/05	1/6/05	Approved subject to conditions		Approved	4/7/05	University of Auckland, Auckland DHB, Waitemata DHB, Counties Manukau DHB	A		Auckland/Waitemata/ Counties-Manukau DHBs MRRCs
NTX/05/06/057	Randomised, double-blind phase II trial of NY-ESO-1 ISCOMATRIX(R) vaccine and ISCOMATRIX(R) adjuvant alone in patients with resected stage I, II, III or IV malignant melanoma (Clinical Trial No LUD 2003-009): IB V#5, 2/05, Prot 17/2/05.	Dr Catherine Barrow	13/5/05	1/6/05	Approved subject to conditions		Approved	8/8/05	University of Auckland, Waitemata DHB,	A		Waitemata DHB letter of support
NTX/05/06/058	Mechanisms of bone erosion in chronic tophaceous gout: PIS/Cons V#2, 10/6/05: Substudy 8/2/06: PIS/Cons V#3, 8/2/06	Dr Nicola Dalbeth	13/5/05	1/6/05	Approved subject to conditions		Approved	30/6/05	University of Auckland, Auckland DHB, Waitemata DHB	A		Counties-Manukau DHB MRRC
NTX/05/06/059	Screening for high risk older adults in the emergency department and in primary care settings: PIS/Cons V#6, 10/6/05	Dr Michal Boyd	13/5/05	1/6/05	Approved subject to conditions		Approved	15/6/05	Auckland University of Technology, Waitemata DHB	A		Waitemata DHB MRRC/ Tom Ruakere
NTX/05/06/060	Recovery of hand function following stroke: PIS/Cons V#4, 13/2/06	Associate Professor Winston Byblow	16/5/05	1/6/05	Approved subject to conditions		Approved	24/6/05	University of Auckland, Auckland DHB, Counties Manukau DHB	A		Mata Forbes, ADHB MRRC/ Counties-Manukau MRRC
NTX/05/06/061	A proteomic approach in defining pregnancy specific proteins and their role in manifestation of pre-eclampsia: Prot/amend 17/6/05: PIS/Cons V 17/6/05	Associate Professor Robyn North	17/5/05	1/6/05	Approved subject to conditions		Approved	27/6/05	University of Auckland, Auckland DHB	A		ADHB MRRC letter of support
NTX/05/06/062	Phase III randomised trial of concomitant radiation, cisplatin and tirapazamine (SR259075) versus concomitant radiation and cisplatin in patients with advanced head and neck cancer: Protocol EFC5512, 28/10/04: Prot/amend 1 EFC5512, 14/1/05: Prot/amend 2, 1/8/05: CIB Ed E10, 12/11/04: PIS/Cons V#4, 21/9/05: Addend to PIS V#1, 9/1/06	Dr Andrew Macann	17/5/05	1/6/05	Approved subject to conditions		Approved	27/7/05	Auckland DHB	B	Sanofi-Synthelabo	ADHB MRRC letter of support
NTX/05/06/063	A comparison of entropy and bispectral index (BIS) in patients undergoing internal fixation of fractured neck of femur during general anaesthesia: PIS/Cons V#3, 25/6/05	Dr Michal Kluger	18/5/05	1/6/05	Approved subject to conditions		Approved	22/7/05	Waitemata DHB, North Shore Hospital	A		Waitemata DHB MRRC letter of support

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NTX/05/06/064	A randomised, double-blind, controlled evaluation of tenofovir DF versus adefovir dipivoxil for the treatment of presumed pre-core mutant chronic hepatitis B: Protocol GS-US-174-0102, 2/3/05: IB Hepsera. Adefovir Dipivoxil, E#13, 10/5/05: IB Tenofovir Disoproxil, E#1, 2/2/05: IS/C V#3, 19/10/05: Core Safety Info V#5.2, 14/6/05	Associate Professor Ed Gane	18/5/05	6/1/05	Approved subject to conditions		Approved	27/7/05	Counties Manukau DHB, Middlemore Hospital	B	Gilead Sciences Inc., USA	Counties-Manukau MRRC, Mr Jonas Hapuka, Te Puna Oranga, Hamilton; Ms Enid Leighton, GM Ngati Awa Social and Health Services Trust, Whakatane
NTX/05/06/065	A randomised, double-blind, controlled evaluation of tenofovir DF versus adefovir dipivoxil for the treatment of HBeAg positive chronic hepatitis B: Prot GS-US-174-0103, 2/3/3/05: IB Hepsera, Adefovir Dipivoxil, Ed#13, 10/5/05: IB Tenofovir Disoproxil Fumarate Ed#1, 2/2/05: PIS/Cons V#3, 19/10/05: Core Safety Info V#5.2, 14/6/05	Associate Professor Ed Gane	18/5/05	1/6/05	Approved subject to conditions		Approved	27/7/05	Counties Manukau DHB, Middlemore Hospital	B	Gilead Sciences Inc., USA	Counties-Manukau MRRC, Jonas Hapuka, Te Puna Oranga, Hamilton; Ms Enid Leighton, GM Ngati Awa Social and Health Services, Whakatane
NTX/05/06/068	A phase 1b, observer-blind, randomised, placebo-controlled study to evaluate the safety, tolerability, immunogenicity and antiviral effect of HCV core ISCOMATRIX vaccine in patients with chronic hepatitis C infection: Protocol CSLCT-HCV-01-82, P/ot/Amend #5, 16/5/05, P/ot/Amend #6, 6/6/05: IB Ed# 4, 9/04: PIS/Cons V#3, 27/9/05	Associate Professor Edward J Gane	23/5/05	1/6/05	Approved subject to conditions		Approved	3/10/05	Auckland DHB, Auckland City Hospital	B	CSL Ltd	ADHB MRRC letter of support
NTX/05/06/069	Phase IV study of tailored therapy with Peg interferon alfa 2b and Ribavirin for patients with Genotype 3 and high viral load. Genotype 3 extended treatment for HCV (GET-C study): Protocol # P0414 V#3, 27/1/05: PIS	Associate Professor Edward J Gane	24/5/05	1/6/05	Approved subject to conditions		Approved	24/6/05	Auckland DHB, Auckland City Hospital	B	Schering-Plough P/L	ADHB MRRC letter of support
NTX/05/07/071	Support for families of children with disability: PIS/Cons V#2, 4/8/05	Professor Jo Ann Walton	16/5/05	6/7/05	Approved subject to conditions		Approved	8/8/05	Waitemata DHB, Auckland University of Technology	A		Waitemata DHB MRRC/ Child Disability Services
NTX/05/07/072	A pilot study. The evaluation of an internet-based computerised anticoagulant monitoring system: PIS/Cons V#2, 16/8/05	Dr Paul Harper	16/6/05	6/7/05	Approved subject to conditions		Approved	2/9/05	Auckland DHB, Auckland City Hospital	A		ADHB MRRC letter of support
NTX/05/07/073	The experience of patients who present to a New Zealand Emergency Department with minor illness and injury: an interpretive phenomenological inquiry: PIS/Cons V#2, 14/7/05	Mr Lucien Cronin	16/6/05	6/7/05	Approved subject to conditions		Approved	25/7/05	Tauranga Hospital	Nil		Tauranga Hospital Māori Health Services, Te Puna Hauora)

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NTX/05/07/074	Long-term follow-up of complete unilateral cleft lip and palate to assess bone regeneration in the bone grafted cleft: PIS/Cons V#2, 1/12/05	Dr Sami Al-Ani	10/6/05	6/7/05	Approved subject to conditions		Approved	27/1/06	Counties Manukau DHB, Middlemore Hospital	A		Counties-Manukau MRRC letter of support
NTX/05/07/075	First in Man study of a percutaneously deployed myocardial implant (VPASS myocardial implant) for the treatment of refractory angina: Inv Plan (Prot CL-034) V#1.0, 28/3/05: IB Rev A, 29/3/05: PIS/Cons V#2, 25/7/05	Dr John Ormiston	14/6/05	6/7/05	Approved subject to conditions		Approved	29/7/05	Auckland DHB, Auckland City Hospital, Mercy Hospital	B	Percardia Inc	ADHB MRRC
NTX/05/07/076	European organisation for research and treatment of terminal cancer (EORTC) BEACOPP (four cycles escalated + four cycles baseline) versus ABVD (eight cycles) in stage III and IV Hodgkin's lymphoma: Protocol 20012 V 2.2, 23/9/04	Dr Leanne Berkahn	17/6/05	6/7/05	Approved subject to conditions		Approved	8/8/05	Auckland DHB, Auckland City Hospital, Waikato Hospital	A		ADHB MRRC
NTX/05/07/077	Bier's block revisited: is proximal injection site equally effective when compared to distal injection site? PIS/Cons/Questionnaire V#1, 20/7/05	Dr Murray Delpoit	14/6/05	6/7/05	Approved subject to conditions		Approved	22/7/05	Middlemore Hospital, Counties Manukau DHB	A		Counties-Manukau MRRC
NTX/05/07/078	Temporary pacing in patients using the EBR device system: IB P/N 00022 Rev 03, Inf/Cons V#2, 15/7/05: Prot P/N 00010 Rev 03	Dr Margaret Hood	16/6/05	6/7/05	Approved subject to conditions		Approved	14/9/05		B	PIN 00022 Rev 3	ADHB MRRC
NTX/05/07/079	TRANX Services Inc Health Outcome Study: PIS/Cons V#1 2005	Ms Diane Hewitt	17/6/05	6/7/05	Deferred	Pl leaving New Zealand for six months – no co-inv	Approved	29/8/05		A		ADHB MRRC letter of support
NTX/05/07/080	Ketamine during paediatric emergency department procedural sedation: a pharmacodynamic study/Cons V#4/20/01/06	Dr David Heird	16/6/05	6/7/05	Approved subject to conditions		Approved	25/7/05	Auckland DHB, Starship Children's Hospital	A		ADHB MRRC
NTX/05/07/081	An evaluation of four community service organisations in Tai Tokerau (Northland) New Zealand: PIS/Cons V#2, 2/17/05	Ms Tina Darkins	17/6/05	6/7/05	Approved subject to conditions		Approved	8/9/05	Auckland University of Technology	A		Harrietta Taylor representing Pa O Te Ora/Whaka-Hiku Maori Komiti
NTX/05/07/082	P prospective randomised controlled trial of intracameral perfluoropropylene (CsF8) gas for acute hydrops in keratoconus: PIS/Cons V#2, 7/05	Dr Thomas Stumpf	17/6/05	6/7/05	Approved subject to conditions		Approved	22/7/05	Auckland City Hospital, University of Auckland, Auckland DHB	A		University of Auckland: Department Māori/Pacific Health, ADHB MRRC
NTX/05/07/083	The pharmacogenetic and pathological assessment of CYP2C19 activity in patients with advanced cancer: PIS/Cons V#3, 16/2/06	Professor Michael Findlay	17/6/05	6/7/05	Approved subject to conditions		Approved	29/8/05	University of Auckland, Auckland DHB, Auckland City Hospital	A		ADHB 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	Consultation undertaken
NTX/05/07/084	Observational study of the use of the cobra PLA (peri laryngeal airway) as a conduit for fiberoptic assisted endo tracheal intubation; Protocol V#7, 21/07/05; VPIS/Cons V#2, 21/7/05	Dr Hilmy Ismail	20/6/05	6/7/05	Approved subject to conditions		Approved	25/7/05	Waitemata DHB, North Shore Hospital	A		Waitemata DHB
NTX/05/07/085	Hip protectors: to wear or not to wear; PIS/Cons V#3, 15/7/05	Dr N Kerse	20/6/05	6/7/05	Approved subject to conditions		Approved	15/7/05	University of Auckland	A		University of Auckland MRRC including Julie Wade
NTX/05/07/086	Genetic linkage and environmental risk factor study in Parkinson's disease; Protocol V#1, 31/5/05; PIS/Cons V#2, 8/8/05	Dr Richard Roxburgh	20/6/05	6/7/05	Approved subject to conditions		Approved	12/9/05	Auckland City Hospital, Auckland DHB	A		ADHB MRRC
NTX/05/07/087	Ultrasound guided regional anaesthesia: an audit of practice; PIS/Cons V#3/ 1/06	Dr Neil MacLennan	21/6/05	6/7/05	Approved subject to conditions		Approved	29/8/05	Auckland DHB, Auckland City Hospital	A		J Koea and ADHB MRRC
NTX/05/07/088	A three-year double blind extension to CZOL446H23021 to evaluate the long-term safety and efficacy of zoledronic acid in the treatment of osteoporosis in post-menopausal women taking calcium and vitamin D; Protocol CZOL446H2301E1, 6/4/05; IB Ed#9, 29/3/04 PIS/Cons V#2, 20/6/05; Prof/amend #1, 4/11/05	Professor Ian Reid	19/6/05	6/7/05	Approved subject to conditions		Approved	27/7/05	University of Auckland, Auckland DHB, Auckland City Hospital	B	Novartis Pharmaceuticals	No Māori women enrolled in core study
NTX/05/07/090	Assessment of bioactivity of dairy-derived lipids: screening trials to measure the effects of a dairy lipid bolus on satiety, energy intake and serum markers of appetite regulation and body weight control in a group of lean, healthy men; PIS/Cons V#4, 22/2/06	Dr Sally Poppitt	21/6/05	6/7/05	Approved subject to conditions		Approved	9/9/05	University of Auckland	B	LactoPharma/Fonterra	Associate Professor M Walker, Joint Director Maori Centre of Research Excellence, University of Auckland; Dr Jason Turuwhenua
NTX/05/08/094	A multi-centre, randomised, double-blind, parallel group, placebo controlled trial to evaluate the efficacy and safety of activated recombinant factor VII (rFVIIa/NovoSeven/NiaStase) in severely injured trauma patients with bleeding refractory to standard treatment; Protocol F7/Trauma-1711, V.1, 13/5/05, IB Ed. 14, 20/7/05, PIS/Con V#2, 23/9/05	Dr Yatin Young	21/6/05	6/7/05	Approved subject to conditions		Approved	21/10/05	Auckland DHB, Auckland Hospital	B	Novo Nordisk	ADHB MRRC
NTX/05/08/095	What is the prevalence of airflow obstruction in congestive heart failure? PIS/Cons V#2, 4/8/05	Dr Peter Black	14/7/05	3/8/05	Approved subject to conditions		Approved	30/8/05	University of Auckland, Auckland DHB, Auckland City Hospital	A		ADHB 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	Consultation undertaken
NTX/05/08/096	Analysis of gene expression in breast cancer. PIS/Cons V#5, 16/2/06	Dr Mike Findlay	14/7/05	3/8/05	Approved subject to conditions		Approved	27/9/05	University of Auckland, Auckland DHB, Auckland Hospital	A		ADHB MRRC
NTX/05/08/097	The determination of factors that affect metabolic programming in preterm children	Dr Paul Hofman	14/7/05	3/8/05	Approved subject to conditions		Approved	15/11/05	Waitemata DHB, University of Auckland, Auckland DHB	A		ADHB MRRC
NTX/05/08/098	A phase II study to evaluate the efficacy, safety and pharmacodynamics of lapatinib in combination with Paclitaxel as neoadjuvant therapy in patients with newly diagnosed inflammatory breast cancer. Protocol # EGF 102580, 11/2/05; IB V#5, 28/4/05; Supplement to IB V#5, 21/9/05; PIS/Cons V#3, 10/1/06	Dr Mike Findlay	14/7/05	3/8/05	Approved subject to conditions		Approved	20/10/05	University of Auckland, Auckland DHB, Auckland City Hospital	B	GlaxoSmith Kline	Mata Forbes and ADHB MRRC
NTX/05/08/099	An observational study on quality of care provided in assessment, treatment and rehabilitation and general medical wards	Dr Matthew Parsons	14/7/05	3/8/05	Approved subject to conditions		Approved	12/9/05	University of Auckland, Auckland City Hospital	A		University of Auckland MRRC
NTX/05/08/100	Inflammatory responses following a meal: comparison of the conventional Western diet with a low fat, high fibre diet. PIS/Cons V#2, 9/8/05	Dr Peter Black	4/7/05	3/8/05	Approved subject to conditions		Approved	30/8/05	University of Auckland, Auckland DHB, Auckland City Hospital	A		ADHB MRRC
NTX/05/08/101	Audit of the meningococcal B programme at Mt Eden Medical Centre. PIS/Cons 8/05.	Ms Pandora Muliadi	4/7/05	3/8/05	Approved subject to conditions		Approved	26/8/05	University of Auckland	A		Bridget O'Brien, Immunisation Advisor, Centre (IMAC)
NTX/05/08/102	Anatomical relationship between sensory pathways recruited in spinal cord stimulation and paresthesia for the treatment of chronic refractory angina pectoris and chronic pain. PIS/Cons V#2, 11/8/05	Professor Alan Merry	18/7/05	3/8/05	Approved subject to conditions		Approved	26/8/05	University of Auckland, Auckland DHB	A		ADHB MRRC
NTX/05/08/103	Elders' experiences of aging in the context of their every-day community lives. PIS/Cons V#2, 17/8/05	Ms Valerie Wright-St Clair	14/7/05	3/8/05	Approved subject to conditions		Approved	26/8/05	University of Auckland	A		University of Auckland, Dr Lorna Dyall, Hana Crengle
NTX/05/08/104	Comparison of two methods of bubble continuous positive airway pressure (CPAP) application (Hudson Prong and Midline) in the neonatal intensive care unit (NICU): PIS/Cons V#2, 11/8/05	Ms Chris McHugh	14/7/05	3/8/05	Approved subject to conditions		Approved	23/9/05	Middlemore Hospital, Counties Manukau DHB, Northland DHB	A		Counties-Manukau 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	Consultation undertaken
NTX/05/08/106	A multicentre, randomised, double blind study to evaluate the safety, efficacy and tolerability of L-000 899055 monotherapy in obese patients: Protocol L-000899055 015-00 R, V 3.2, 3/6/05 Prof/amend Appendix 7, 31/5/05: CIB, Ed. 4, 19/5/05; Prof/amend 015-01, 16/8/05; Prof/amend 015-02, 25/8/05: PIS/Cons V#3, 14/9/05; CIB Ed 5, 25/10/05	Dr Jocelyne Benatar	15/7/05	3/8/05	Approved subject to conditions		Approved	6/9/05	Auckland DHB, Counties Manukau DHB	B	Merck Sharpe & Dohme	ADHB MRRC and Counties-Manukau MRRC
NTX/05/08/107	Counselling patients with spinal cord injury: pis/cONS v#2, 30/6/05	Ms Susan Sliedrecht	15/7/05	3/8/05	Approved subject to conditions		Approved	2/9/05	Counties Manukau DHB	Nil		Counties-Manukau DHB MRRC
NTX/05/08/108	Qualitative and quantitative analysis of cellular and sub-cellular structural changes in keratoconus by in vivo and in vitro analysis in the human cornea: PIS/Cons V#2, 3/8/05	Professor Charles NJ McGhee	15/7/05	3/8/05	Approved subject to conditions		Approved	15/12/05	University of Auckland	A		University of Auckland Māori responsiveness committee, C Mantell
NTX/05/09/109	Healthcare site-based partner violence-screening and intervention efficacy study phase I: community participatory action research groups: V#2, 14/9/05	Associate Professor Jane Koziol-McLain	23/8/05	7/9/05	Approved subject to conditions		Approved	22/9/05	Northland DHB, Counties Manukau DHB	A		Raukura Hauora O Tainui, Kawa Whakaruruhau Komiti (AUT), Māori Directorate, Northland Health
NTX/05/09/110	Do physiotherapy interventions reduce the incidence of postoperative complications in patients following pulmonary resection via thoractomy: a randomised controlled trial: PIS/Cons V#2, 19/10/05	Ms Julie Reeve	23/8/05	7/9/05	Approved subject to conditions		Approved	2/11/05	Auckland DHB, Auckland University of Technology	A		ADHB MRRC
NTX/05/09/111	Time-course of parathyroid hormone change following vitamin D supplementation in vitamin D deficient elderly: a pilot study	Ms Catherine Bacon	23/8/05	7/9/05	Approved subject to conditions		Approved	23/9/05	University of Auckland, Auckland DHB	A		ADHB MRRC
NTX/05/09/112	The role of insulin-like growth factor 2 (IGF2) in growth and diabetes study PIS/Cons V#2, 9/05	Dr T Cundy	23/8/05	7/9/05	Approved subject to conditions		Approved	23/9/05	University of Auckland, Auckland DHB	A		
NTX/05/09/113	The incidence of protein Z dependent protease inhibitor (ZPI) mutations in thrombosis patients and possible synergism between factor V Leiden and ZPI mutations causing thrombophilia: PIS/Cons V#2, 15/12/05	Dr Paul Harper	23/8/05	7/9/05	Approved subject to conditions		Approved	24/1/06	Auckland DHB, Counties Manukau DHB, Waitemata DHB	A		ADHB MRRC
NTX/05/09/114	Use of private and public sectors for surgical procedures	Dr Paul Brown	23/8/05	7/9/05	Approved subject to conditions		Approved subject to conditions		University of Auckland	A		Dr Dyll
NTX/05/09/115	Sensorimotor integration in patients with basal ganglia dysfunction: an fMRI and EEG investigation: PIS/Cons V#2, 16/9/05	Dr Vanessa Lim	23/8/05	7/9/05	Approved subject to conditions		Approved	22/9/05	University of Auckland	A		Dr Jason Turuwhenua

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NTX/05/09/116	Predictors of hand function in patients with gout: a three-dimensional CT study. PIS/Cons V#2, 16/9/05	Dr Nicola Dalbeth	23/8/05	7/9/05	Approved subject to conditions		Approved	3/10/05	University of Auckland, Counties Manukau DHB, Auckland DHB	A		Counties-Manukau DHB MRRC, ADHB MRRC
NTX/05/09/117	Efficacy of brief cognitive behavioural therapy for primary insomnia in a primary care setting. A randomised controlled trial: PIS/Cons V#2, 1/12/05	Dr Antonio Fernando	23/8/05	7/9/05	Approved subject to conditions		Approved	19/12/05	University of Auckland	A		Governance Committee Raukura Hauora O Tainui
NTX/05/09/118	ECG electrode placement study: PIS/Cons V#3, 26/9/05	Ms Rachael Palmer	23/8/05	7/9/05	Approved subject to conditions		Approved	30/9/05	Auckland DHB, Auckland City Hospital	A		ADHB MRRC
NTX/05/09/119	Myopia progression and orthokeratology lens wear: PIS/Cons V#3, 15/2/06	Dr Helen Owens	23/8/05	7/9/05	Approved subject to conditions		Approved	22/9/05	University of Auckland	A		Dr Jason Turuwhenua, University of Auckland
NTX/05/09/120	The transition from staff nurse to clinical nurse educator in a New Zealand District Health Board: a descriptive study: PIS/Cons V#2, 14/9/05	Ms Elizabeth Manning	24/8/05	7/9/05	Approved subject to conditions		Approved	22/9/05	Massey University – Auckland, Auckland University of Technology, Counties Manukau DHB	Nil		Counties-Manukau MRRC (Kerry Hini – Chairperson)
NTX/05/09/121	Experiences and perceptions of older adults post discharge from assessment, treatment and rehabilitation wards at Waitemata Health: V#2, 1/10/05	RN Nazreen Hussain	24/8/05	7/9/05	Approved subject to conditions		Approved	26/9/05	Waitemata DHB, University of Auckland	A		WDHB – Jane Sherard
NTX/05/09/122	Fijian Indian patients' understanding on diabetes: how they self manage and their views on a culturally tailored educational intervention: PIS/Cons V#4, 7/11/05	Ms Faieza Ali	24/8/05	7/9/05	Approved subject to conditions		Approved	23/9/05	University of Auckland	A		Fijian Indian participants only
NTX/05/09/123	A qualitative participant outcomes analysis of the activate programme pilot: PIS/Cons V#2.0, 20/9/05	Mr Rory Innes-Mills	24/8/05	7/9/05	Approved subject to conditions		Completed	23/9/05	Massey University – Auckland, Auckland DHB	Nil		ADHB MRRC
NTX/05/10/126	A randomised controlled trial to look at whether fallopian sperm perfusion gives better pregnancy and live birth rates than standard intrauterine insemination for patient having artificial insemination with or without gonadotrophin or clomiphene stimulation: PIS/Cons V#2, 17/10/05	Dr Sonya Jessup	7/9/05	5/10/05	Approved subject to conditions		Approved	14/11/05	Auckland DHB	A		ADHB MRRC
NTX/05/10/127	Screening study in Auckland general practice: PIS V#3, 17/11/05	Associate Professor Bruce Arroll	9/9/05	5/10/05	Approved subject to conditions		Approved	17/11/05	University of Auckland	A		Dr Tane Taylor, Medical Advisor, Raukura Hauora o Tainui
NTX/05/10/128	Empowering primary health care nurses in the community management of diabetes	Ms Barbara Daly	9/9/05	5/10/05	Approved subject to conditions		Approved subject to conditions		Auckland DHB, Counties Manukau DHB, Waitemata DHB	A		Lorna Dyall, ADHB, Counties-Manukau/Waitemata MRRCs

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NTX/05/10/129	The EASAP study: evaluation of asthma in a South Auckland population. Diagnosing asthma accurately and assessing severity in a South Auckland population of asthmatics – do a range of investigations previously validated in research environment have clinical relevance and lead in turn to better management? PIS/Cons V#2, 18/10/05	Associate Professor Jeffrey Garrett	14/9/05	5/10/05	Approved subject to conditions		Approved	2/11/05	Counties Manukau DHB	A		Kerry Hini, Counties-Manukau MRRC
NTX/05/10/130	Feasibility study of a novel strategy to increase physical activity in children (10-14 years). PIS/Consents, 13/10/05	Dr Cilona Ni Mhurchu	15/9/05	5/10/05	Approved subject to conditions		Approved	10/11/05	University of Auckland	A		University of Auckland CTRU Māori Research Advisory Committee
NTX/05/10/131	A pilot study investigating the response that two patients have to art therapy whilst receiving haemodialysis: PIS/Cons V#1, 19/10/05	Ms Magot Pakenham	19/9/05	5/10/05	Approved subject to conditions		Approved	27/10/05	Auckland DHB	N/A		ADHB MRRC letter of support
NTX/05/10/132	The effect of Gentamicin on the expression of factor IX in a case of severe haemophilia B due to a nonsense mutation. PIS/Cons V#2, 4/11/05	Dr Paul Harper	20/9/05	5/10/05	Approved subject to conditions		Approved	14/11/05	Auckland DHB	A		ADHB MRRC
NTX/05/10/133	Post-injury alcohol intervention research (PAIR): acceptability survey and chart review: PIS/Cons V#2, 17/10/05	Dr Shanathi Ameratunga	16/9/05	5/10/05	Approved subject to conditions		Approved	23/11/05	University of Auckland, Auckland DHB	A		University of Auckland MRRC; Sue Gregie, University of Auckland; Rangi Dansey, ADHB MRRC
NTX/05/10/134	Evaluation of the subcutaneous implantable defibrillator (S-ICD) system: Protocol Rev A, Clinical Summary Rev A, IB Rev A PIS/Cons V#2, 7/11/05	Dr Margaret Hood	19/9/05	5/10/05	Approved subject to conditions		Approved	15/11/05	Auckland DHB, Auckland City Hospital	B	Cameron Health	ADHB MRRC
NTX/05/10/135	The effect of a brief acceptance intervention on health-related quality of life in rheumatoid arthritis: a pilot study: PIS/Cons V#2, 14/10/05	Mr Paul Carver	19/9/05	5/10/05	Approved subject to conditions		Approved	20/10/05	University of Auckland, Auckland DHB	A		Paparangi Reed, Julie Wade (University of Auckland), ADHB MRRC
NTX/05/10/137	The clinical utility of transcutaneous carbon dioxide monitoring in acute respiratory conditions: Protocol 10/9/05: PIS/Cons V#2, 25/10/05	Dr Pathmanathan Sivakumaran	19/9/05	5/10/05	Approved subject to conditions		Approved	2/11/05	Counties Manukau DHB, University of Auckland	A		Counties-Manukau DHB MRRC
NTX/05/10/138	Decision making by first time parents regarding childhood vaccination: a pilot study	Ms Elizabeth Dunn	19/9/05	5/10/05	Approved subject to conditions		Approved	10/11/05	Auckland University of Technology	A		Sharon Snell, Clinical Services Manager, Kia Ora Ngatiwai Mobile Primary Health Care, and Rhoena Davis, Kairahi Clinical Services, Hauora Whanui, Ngati Hine Trust, Northland
NTX/05/10/139	Free cortisol estimation in human plasma	Mr Mpatisi Moyo	19/9/05	5/10/05	Deferred	Guidelines not followed	Approved	14/12/05	Auckland DHB	A		ADHB MRRC letter of support

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NTX/05/10/140	Accommodation needs and preferences for consumers/tangata whai ora of mental health services: PIS/Cons V 1, 26/10/05	Associate Professor Mike O'Brien	20/9/05	5/10/05	Approved subject to conditions		Approved	11/11/05	Massey University – Auckland, Northland DHB	A		Northland DHB GM, Te Tai Tokerau MAPO Trust
NTX/05/11/141	The influence of demographic factors, injury severity and fatigue on post traumatic brain injury employment outcome in a New Zealand population: PIS/Cons V#2, 11/1/06	Mr Timothy Forbes Dyer	30/9/05	2/11/05	Deferred	Design criteria does not meet guidelines	Approved	23/1/06	University of Auckland	A		Winter Puhama, Māori services co-ordinator, Disability Resource Centre
NTX/05/11/142	A 24-month, multicentre, randomised, open-label, non-inferiority study of efficacy and safety comparing concentration-controlled Certican(r) in two doses (1.5 and 3.0 mg/day starting dose) with reduced Neoral versus 1.44 g Myfortic(r) with standard dose Neoral in de novo renal transplant recipients: Protocol # CRAD001A2309, 17/6/05, IB Ed 7, 17/8/05	Dr Helen Pillmore	4/10/05	2/11/05	Approved subject to conditions		Approved	29/11/05	Auckland DHB, Auckland City Hospital	B	Novartis Pharmaceuticals	ADHB MRRC
NTX/05/11/143	Pilot study to investigate a possible association between long QT syndrome type 1, achlorhydria and hypergastrinaemia	Dr Graeme Dickson	4/10/05	2/11/05	Approved subject to conditions		Approved subject to conditions		Auckland DHB	A		ADHB MRRC
NTX/05/11/144	The effectiveness of an integrated approach to lowering calculated risk of a cardiac event in those assessed at 20% or greater	Ms Donna Fea	4/10/05	2/11/05	Declined	Serious concerns re statistical validity	Declined		TLC Healthcare	A		Adhere to principles, company policy at Auckland Healthcare Services
NTX/05/11/145	SAINT-II (stroke – acute ischaemic – NXY treatment): a double blind, randomised, placebo controlled, parallel group, multicentre, phase IIb/III study to assess the efficacy and safety of intravenous NXY-059 in acute ischaemic stroke: Protocol NXY-059, V#6, 26/7/05: IB Ed #8, 14/7/05: PIS/Cons V#2, 22/11/05	Dr Alan Barber	12/11/05	2/11/05	Approved subject to conditions		Approved	2/12/05	Auckland DHB	B	AstraZeneca Pharmaceuticals	ADHB MRRC
NTX/05/11/146	The Scottish pregnancy intervention study: the effect of low molecular weight Heparin and aspirin on recurrent pregnancy loss: PIS/Cons V#2, 15/11/05	Dr Claire McLintock	11/10/05	2/11/05	Approved subject to conditions		Approved	2/12/05	University of Auckland, Auckland DHB	A		ADHB MRRC
NTX/05/11/147	Acuity of force appreciation in adults with osteoarthritis of the knee joint: PIS/Cons V#2, 13/11/05	Ms Helen Brereton	11/10/05	2/11/05	Approved subject to conditions		Approved	22/12/05	Auckland University of Technology, Northland DHB	A		Council of Elders of Taitokerau NDHB, Te Poutokomanawa at Whangarei Hospital
NTX/05/11/148	Patients' perceptions of adjuvant chemotherapy in early breast cancer: what makes it worthwhile: Protocol V#1.33, 8/01	Associate Professor Vernon Harvey	12/10/05	2/11/05	Approved subject to conditions		Approved	2/12/05	Auckland DHB	A		ADHB MRRC

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NTX/05/11/149	Ubiquitin-proteasome system (UPS) function and dysfunction in cancer	Dr Catherine Gilchrist	13/10/05	2/11/05	Approved subject to conditions		Approved	29/11/05	University of Auckland	Nil		Professor Colin Mantell, A/PO Papaarangi Reid, Office of Tumuaki, University of Auckland
NTX/05/11/150	Working with children in short-term music therapy – establishing rapport and goals	Ms Alison Cooper	13/10/05	2/11/05	Approved subject to conditions		Approved	13/12/05	Massey University	Nil		Through Te Whanau o Homai
NTX/05/11/151	Medication errors occurring in patients discharged from hospital following cardiothoracic surgery (CTS): PIS/Cons V#2, 16/2/06	Mr Simon Hurley	14/10/05	2/11/05	Approved subject to conditions		Approved subject to conditions		Auckland DHB, University of Auckland	A		Mata Forbes, ADHB MRRC
NTX/05/11/152	Premenopausal endocrine responsive chemotherapy trial (PERCHE); a Phase III trial evaluating the role of chemotherapy for premenopausal women with endocrine responsive breast cancer who receive endocrine therapy: Protocol # IBCSG 26-02/BIG 4-02 V 1.1, 17/4/03: IB V#5, 29/10/04	Dr Vernon Harvey	14/10/05	2/11/05	Approved subject to conditions		Approved subject to conditions		Auckland DHB, Oncology 16 <sup>th</sup> , Auckland City Hospital	A		ADHB MRRC
NTX/05/11/153	A 24-month, multi-centre, randomised, open-label non-inferiority study of efficacy and safety comparing two exposures of concentration-controlled Certican (everolimus) with reduced Neoral (cyclosporine) versus 3.0 g MMF (mycophenolate mofetil) with standard dose Neoral in de novo heart transplant recipients: Prot.# CRAD001A2310, 29/8/05: PIS/Cons V#4, V 21/12/05	Dr Peter Ruygrok	14/10/05	2/11/05	Approved subject to conditions		Approved	2/12/05	Auckland DHB	B	Novartis Pharmaceuticals	ADHB MRRC
NTX/05/11/154	Twins: timing of birth at term. Timing of birth for women with a twin pregnancy at term – a randomised controlled trial: Protocol V3, PIS/Cons V# 7, 12/05	Dr Jennifer McDougall	14/10/05	2/11/05	Approved subject to conditions		Approved	24/1/06	Auckland DHB, Auckland City Hospital	A		ADHB MRRC
NTX/05/11/155	A randomised, double-blind, placebo controlled multi-centre, study of the efficacy and safety of up to 100 days of Valgancyclovir vs up to 200 days of Valgancyclovir for prevention of cytomegalovirus disease in high-risk kidney allograft recipients. Protocol V# NT18435/A 25/8/05: Sample Repository Research Project Protocol # NT18435RG, 12/09/05 (genetic sampling). IB V#8, 8/05	Dr Ian Dittmer	14/10/05	2/11/05			Withdrawn		Auckland DHB	B	Roche	ADHB MRRC
NTX/05/11/156	Development of an international classification of functioning, disability and health core-set for patients with psoriasis: patients' perspectives: PIS/Cons V#2, 15/11/05	Dr Claire Hocking	17/10/05	2/11/05	Approved subject to conditions		Approved	28/11/05	Auckland University of Technology	Nil		Caroline McKinney, School of Nursing, AUT

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
NTX/05/12/157	Familial congenital bowing of the tibia with pseudarthrosis and pectus excavatum – a 30- year follow-up	Mr. Laurence P McEntee	15/11/05	7/12/05	Approved subject to conditions		Approved subject to conditions		Auckland DHB	A		ADHB MRRC letter of support
NTX/05/12/158	A case-control study of the prevalence of mycoplasma genitalium (MG) in men with non-gonococcal urethritis (NGU) at Auckland Sexual Health Service (ASHS); PIS/Cons V#2, 13/12/05	Dr Sunita Azariah	7/11/05	7/12/05	Approved subject to conditions		Approved	19/12/05	Auckland DHB	A		ADHB MRRC letter of support
NTX/05/12/159	Pacific Islands families: nutrition and body size of six year old Pacific children (PIF-NBS); PIS/Cons V#2, 15/12/05; Amend 18/1/07	Dr Janis Paterson	16/11/05	7/12/05	Approved subject to conditions		Approved	19/12/05	Auckland University of Technology	Nil		HRC Māori Committee
NTX/05/12/160	The influence of the human immune system on the evolution of mutations in the hepatitis B virus genome PIS/Cons V#2, 24/12/05	Dr William Abbott	9/11/05	7/12/05	Approved subject to conditions		Approved	17/2/06	Auckland DHB	A		No groups consulted as exclusively Tongan community
NTX/05/12/161	Evaluation of the prevalence, aetiology and to identify possible management options for musculoskeletal disorders (MSDs) among Sterile Supply Unit hospital workers at Middlemore Hospital	Mr Jon Nelson	12/11/05	7/12/05	Declined	Study design inadequate guidelines not followed for information sheet and consent form	Declined		Counties Manukau DHB, Middlemore Hospital	Nil		Required
NTX/05/12/162	Quality of life (as measured by the WHOQOL-BREF) and participation in life roles (as approximated by the London Handicap Scale) in a population over a time of outpatient rehabilitation. PIS/Cons V#2, 15/12/05	Ms Suzanne Ackerley	18/11/05	7/12/05	Approved subject to conditions		Approved	22/12/05	Auckland DHB	Nil		ADHB MRRC
NTX/05/12/163	A randomised controlled trial to assess the antiplatelet effect of a 600 mg (single-dose) and 1200 mg (split-dose) loading dose of clopidogrel and the impact of verapamil, a potent CYP3A4 inhibitor on the incidence of clopidogrel resistance defined by the VerifyNow (Accumetrics Ltd P2Y12 platelet function analyser in patients with coronary disease. PIS/Cons V#2, 16/12/05	Dr Patrick Gladding	17/11/05	7/12/05	Approved subject to conditions		Approved	22/12/05	Auckland DHB	A		ADHB MRRC
NTX/05/12/164	HIV behavioural surveillance study: Gay Auckland Periodic Sex Survey 2006.	Mr Peter Saxton	21/11/05	7/12/05	Approved subject to conditions		Approved	22/12/05	NZ AIDS Foundation	Nil		Hauora Takataapui Programme of NZ AIDS Foundation
NTX/05/12/165	A survey of the attitudes and beliefs of patients regarding cancer associated weight loss and weight assessment: PIS/Cons V#2, 9/2/06	Dr Simon Coulter	21/11/05	7/12/05	Approved subject to conditions		Approved	17/2/06	Auckland DHB, Mercy Hospital	A		ADHB 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	Consultation undertaken
NTX/05/12/166	Controlled double-blind randomised study of BAY 59-7939 in the extended prevention of VTE in patients undergoing elective total hip replacement – RECORD 2 study-regulation of coagulation in orthopaedic surgery to prevent DVT and PE: Protocol BAY 59-7939 V#2, 27/10/05; IB BAY 59-7939, 17/10/05	Dr Sanjeev Churnilal	21/11/05	7/12/05	Deferred	Compensation – inadequate – information sheet/consent form guidelines not met	Deferred		Waitemata DHB, Auckland DHB	B	Bayer New Zealand Ltd	ADHB and Waitemata DHB MRRCs
NTX/05/12/167	Bioabsorbable vascular solutions everolimus eluting coronary stent system first in man clinical investigations: a clinical evaluation of the BVS everolimus eluting coronary stent system in the treatment of patients with single de novo native coronary artery lesions: Clinical Investigation Plan 05-370, V#2, 16/11/05, IB 17/11/05; PIS/Cons V#2, 15/12/05	Dr John Ormiston	21/11/05	7/12/05	Approved subject to conditions		Approved	12/1/06	Auckland DHB, Mercy Hospital	B	Guidant Corporation	ADHB MRRC
NTX/05/12/168	An evaluation of an electronic dosing aid to evaluate the effect on compliance when administering Travoprost eye drops 0.004%	Associate Professor Helen Danesh-Meyer	21/11/05	7/12/05	Approved subject to conditions		Approved subject to conditions			A		No consultation
NTX/05/12/169	A multicentre, randomised open label study to compare the development of liver fibrosis at 12 months after transplantation for hepatitis C cirrhosis in patients receiving either Neoral or tacrolimus: Protocol COLO400A2426, 22/6/05, Amend 1 to Prot, 3/11/05; PIS/Cons V#2, 21/11/05	Associate Professor Edward J Gane	21/11/05	7/12/05	Approved subject to conditions		Approved	23/2/06	Auckland DHB	B	Novartis Pharmaceuticals	ADHB MRRC letter of support
NTX/05/12/170	Effect of ultraviolet radiation on blood pressure, cardiac function and insulin sensitivity: PIS/Cons V#2, 21/2/06	Associate Professor Robert Scragg	21/11/05	7/12/05	Approved subject to conditions		Approved	27/2/06	University of Auckland	A		Lorna Dyal, Board of Langimallie
NTX/05/12/171	Quantitative analysis of Vigabatrin induced visual loss with optical coherence tomography of the retinal nerve fibre layer and correlation with visual field defects	Dr Helen Danesh-Meyer	21/11/05	7/12/05	Approved subject to conditions		Approved subject to conditions		University of Auckland, Auckland DHB	A		ADHB MRRC letter of support

## Applications approved by the Chairperson under delegated authority

Project key	Full title	Primary investigator	Date received	Meeting reviewed	Outcome	Why deferred/declined	Status at time of report	Date of approval	Locality organisations	Form	Sponsor	Consultation undertaken
NTX/05/01/CPD	Circumstances and pattern of hand injuries secondary to power saws admitted to Middlemore Hospital January 2001 to May 2004	Dr Mohannad Hamed	19/5/05	6/1/05	Approved subject to conditions	CPD	Approved	24/5/05	Counties Manukau DHB	Nil		Counties-Manukau MRRC
NTX/05/02/CPD	An investigation into the efficacy of ozone stents in clinical dentistry. PIS/Cons 20/5/05	Dr Richard Wayne Owen	20/5/05	24/5/05	Approved	CPD	Approved	24/5/05		Nil		No Māori participants
NTX/05/03/CPD	What is it like for New Zealand men to live with severe haemophilia? A pilot study. PIS/Cons V#2, 10/8/05	Ms Karen Edgcombe	19/5/05	6/7/05	Approved subject to conditions	CPD	Approved	29/8/05	Auckland DHB, Massey University	Nil		ADHB MRRC letter of support
NTX/05/04/CPD	Perilunate and fracture dislocations: a review from Middlemore Hospital: PIS/Cons V#2, 19/7/05	Dr Alpesh Patel	21/6/05	7/6/05	Approved subject to conditions	CPD	Approved	29/9/05	Counties Manukau DHB, Middlemore Hospital	A		Counties-Manukau MRRC
NTX/05/05/CPD	Influenza vaccine uptake in patients admitted to General Medicine, Auckland City Hospital: PIS/Cons V#2, 18/7/05	Dr Simon Briggs	27/6/05	7/6/05	Approved subject to conditions	CPD	Approved	29/7/05	Auckland DHB	A	Novo Nordisk A/S Denmark	ADHB MRRC
NTX/05/06/CPD	Investigation of the causes of overanticoagulation in hospitalised patients with an international normalised ratio (INR) greater than 3.5 prescribed warfarin therapy: PIS/Cons V# 1.1, 9/5/05	Mr Daniel Wellington	24/6/05	7/6/05	Approved subject to conditions	CPD	Approved	9/8/05	Waitemata DHB, North Shore Hospital	A		Waitemata DHB MRRC
NTX/05/07/CPD	A hospital pharmacy discharge summary to community pharmacy: PIS/Cons V#1, 20/6/05	Ms Bernadette Rehman	24/6/05	7/6/05	Approved subject to conditions	CPD	Approved	1/8/05	Waitemata DHB, Waitakere Hospital	A		Jane Sherard, Māori Research Advisor, Waitemata DHB
NTX/05/08/CPD	Evaluating the benefits of employment on emotional health and wellbeing of people receiving mental health support services: PIS/Cons V#3, 16/9/05	Ms Janet Catherine Haworth	12/5/05	14/12/05	Approved subject to conditions	CPD	Approved	22/9/05	Massey University – Auckland	Nil		EDGE Supported Employment Service
NTX/05/09/CPD	Community Nutrition Project: PIS/Cons V#3, 26/9/05	Ms Franica Yovich	9/5/05	23/9/05	Approved subject to conditions	CPD	Approved	3/10/05	Counties Manukau DHB	A		Counties-Manukau MRRC letter of support
NTX/05/10/CPD	Does having the arm down improve pulmonary artery opacification during CT pulmonary angiography: PIS/Cons V#3, 21/12/05	Associate Professor Mike O'Brien	12/5/05	14/12/05	Approved subject to conditions	CPD	Approved	22/12/05	Waitemata DHB	A		Waitemata DHB

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

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

The Northern X REC 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 Northern X REC.

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

The Northern X REC shall have responsibility 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 X REC is jointly responsible with the Northern Y 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 X REC.

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

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

The Northern X 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 X Regional Ethics Committee**

The primary role of the Northern X 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 X 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 X REC is to ensure that the Northern X REC has the appropriate expertise, skills, knowledge and perspectives to conduct ethical review of the best quality.

### **Member numbers**

The number of members of the Northern X REC should be 12.

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

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

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

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

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

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

## **Whole committee requirements**

At any time, consistent with the requirements of the New Zealand Public Health and Disability Act requirements for District Health Boards, the Northern X 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 X REC are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

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

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

Despite being drawn from groups identified with particular interests or responsibilities in connection with health and community issues, Northern X 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 X REC as equal individuals of sound judgement, relevant experience and adequate training in ethical review.

## **Terms and conditions of appointment**

Members of the Northern X 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 X 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 X 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 X REC. Those persons shall not be eligible for appointment to the Northern X 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 X 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 X REC and National Ethics Advisory Committee or the Health Research Council Ethics Committee simultaneously.

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

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

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

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

### **General**

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

### **Conflicts of interest**

Northern X 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 X REC and its members and will ensure it retains public confidence.

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

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

A member of the Northern X REC who has a proposal before the Northern X REC or who has an involvement in the proposal such as a supervisory role shall not take part in the Northern X 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 X 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 X REC meetings should be available to the public. Copies of proposals should be available to individuals outside the Northern X 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 X 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 X 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 X REC. The Northern X REC will need to consider the Privacy Act 1993 and the Health Information Privacy Code 1994 in developing these processes.

Within the Northern X 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 X REC shall be held monthly or less frequently, as determined by the workload.

At any meeting, a quorum shall consist of at least six 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 X REC to be open to the public. Meetings of the Northern X REC should therefore be:

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

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

## **Decision-making process**

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

In relation to research involving Māori, it is important that Māori expertise be available to ensure that all issues are appropriately considered. Where it is not possible for Māori members to attend a Northern X 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 X REC must state to its applicant whether its action is to Approve, Approve subject to conditions, Defer, or Decline that application. It must state its grounds for any action to Defer or Decline. For any action to approve subject to conditions, it must specify the conditions, the grounds for these, and its process for assessing whether these conditions are subsequently met. In all cases, it must state which matters its action is based upon, and which are instead matters of comment, information, or advice to its applicant.

## **Expert advice and consultation**

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

Where the Chairperson or quorum of Northern X REC members believes there is insufficient expertise on the Northern X 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 X REC's decision on a proposal.

## **Second opinions and appeals**

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

The decisions of the Northern X 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 X 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 X REC, including any change in the Northern X REC's membership or other substantive changes the Northern X REC or its chairperson feels should be noted.

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

- i. the research title
- ii. principal investigator
- iii. institutions where the research is to be/has been undertaken
- iv. date of first review
- v. date of final outcome
- vi. outcome (which will be one of: approved, approved 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 Northern X REC members, and a statement on processes for orientation and training of new Northern X REC members should be included.
- ii. A list of complaints received by the Northern X REC (if any), the actions taken to resolve the complaint and a comment on the outcome of the complaint(s).
- iii. Any areas of review that caused difficulty for the Northern X REC in making a decision on any particular protocol(s), and any questions on policy or other matters the Northern X 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 X 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 X REC are entitled to be paid fees for attendance at meetings. The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies.

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

## **Servicing of the Northern X Regional Ethics Committee**

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

