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| *Northern B Health and Disability Ethics Committee*  **Annual Report**  **2013** |

Published in October 2014

by the Ministry of Health   
PO Box 5013, Wellington, New Zealand

ISBN: 978-0-478-39332-3 (online) HP5489

This document is available on the New Zealand Health and Disability Ethics Committees’ website: <http://www.ethicscommittees.health.govt.nz>

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# About the Committee

The Northern B Health and Disability Ethics Committee (HDEC) is a Ministerial committee established under section 11 of the [New Zealand Public Health and Disability Act 2000](http://www.legislation.govt.nz/act/public/2000/0091/latest/DLM80051.html). Its members are appointed by the Minister of Health through the public appointments process.

The primary function of the Committee is to provide independent ethical review of health research and innovative practice in order to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy.

The Committee is required by its [Terms of Reference](http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-about-central#tor) to submit an Annual Report to the Minister of Health. The Annual Report must include information on the membership of the Committee, a summary of the applications reviewed during the year, details of any complaints received (and how they were resolved), and areas of review that caused difficulty when making decisions, among other matters.

### Approvals and registrations

The Northern B HDEC is approved by the Health Research Council Ethics Committee for the purposes of section 25(1)(c) of the [Health Research Council Act 1990](http://legislation.govt.nz/act/public/1990/0068/latest/DLM213017.html).

The Northern B HDEC is registered (number IRB00008715) with the United States’ Office for Human Research Protections. This registration enables the committee to review research conducted or supported by the US Department of Health and Human Services.

# Chairperson’s report

2013 has been a very busy year for the Northern B HDEC. We have reviewed many interesting applications.

The Northern B HDEC reviewed 134 applications in 2013. Ninety two applications were reviewed by the full committee and 42 were reviewed through the expedited pathway.

In 2013 the Northern B HDEC held its meetings in Auckland and also at the Waikato Hospital in Hamilton. It is encouraging that many of the researchers attend our meetings in person or by telephone conference. Their involvement greatly assists with the review process.

I wish to acknowledge the participation and contribution of each committee member. I acknowledge the hours of each member’s full and busy lives, and thank them for them time and their contribution. I believe that everyone on the Committee effectively supports health and disability research in New Zealand.

Northern B has lost two members, Mrs Mary-Anne Gill and Dr David Stephens. On behalf of the Committee the Chair thanks both members for their valuable input and wishes them the very best for their future projects.

I would also like to thank the Deputy Chairperson Stephanie Pollard for her invaluable contribution to the committee. The workload has been very high this year and Stephanie’s input is hugely appreciated.

I also acknowledge that Northern B Committee has a very supportive and co-operative working environment which makes this committee very effective and efficient. The Secretariat has provided outstanding support and advice and we are very thankful to them.

****

Ms Raewyn Sporle

Chairperson

Northern B Health and Disability Ethics Committee

# Membership and attendance

No meetings were postponed or cancelled due to inability to make quorum. Two members resigned during 2013.

## Membership

### Lay members

|  |  |
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| **Ms Raewyn Sporle (Chair)** | |
| Membership category: | Lawyer |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Ms Raewyn Sporle was appointed Chairperson in June 2010. Ms Sporle is currently a self-employed Barrister & Solicitor specialising in Family Law, Criminal Law and Employment Law. Ms Sporle is a current Trustee of the Waikato Breast Cancer Trust (2006-present), and Trustee of Trust Waikato (2010-present). Ms Sporle is a previous Chairperson of St Joseph’s Board of Trustees, Fairfield, Hamilton, and holds professional memberships with the New Zealand Law Society, the Waikato / Bay of Plenty Law Society, New Zealand Family Law Society. She is also a trained Mediator (LEADR).

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| **Mrs Maliga Erick** | |
| Membership category: | Consumer / Community Representative |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2014 |

Maliaga Erick is currently working for the Werry Centre Child and Adolescent mental health workforce development as a Pacific Clinical Advisor. She is a mother of seven children and a grandmother of 12 grandchildren. She has in the past been on School Board of Trustees and non-government agencies. Mali has a background in the Care and Protection of children, Family violence, and Mental Health and Pacific health research projects.

### Non-Lay members

|  |  |  |
| --- | --- | --- |
| **Mrs Kate O’Connor** | | |
| Membership category: | Non-lay, Other | |
| Date of appointment: | | 1 July 2012 |
| Current term expires: | | 1 July 2015 |

Kate O'Connor is the Executive Secretary of the AUT Ethics Committee, having been a member of the committee for 5 years whist working as Senior Research Contracts Specialist in AUT's Research Office. Prior to this she worked as a research Contracts Manager for Uni Services Ltd in the University of Auckland's School of Population Health, and was Secretary for the University of Auckland's Human Participants Ethics Committee, and the Biological Safety Committee. She has Master of Arts in philosophy and a Post Graduate Diploma in Business. She is a member of the NZ Branch Executive of the Australasian Research Management Society. In 2014, Kate began a DHSc investigating how Michel Foucault’s theoretical toolbox may be used to inspire transformation in the practice of research ethics committees.

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| **Ms Kerin Thomson** | | |
| Membership category: | | Health Researcher |
| Date of appointment: | | 1 July 2012 |
| Current term expires: | | 1 July 2015 |

Mr Kerin Thompson is currently Research Manager for Auckland Regional Cancer & Blood Services at Auckland District Health Board. Prior to this she was Team Leader for Oncology Research (2010-2013). Mr Thompson completed a Bachelor of Science at Auckland University (1984) and has been involved in pre-clinical and clinical cancer research since 1985. She is currently a member of the Gastrointestinal Cancer Institute (NZ)’s Scientific Advisory Group (2011-present) and a member of the New Zealand Association of Clinical Researchers since 2008. Mr Thompson is also a member of a number of Australia/New Zealand Collaborative Trial Groups.

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| **Mrs Stephanie Pollard** | | |
| Membership category: | | Health Researcher |
| Date of appointment: | | 1 July 2012 |
| Current term expires: | | 1 July 2015 |

Mrs Stephanie Pollard is currently employed as an independent Clinical Research Consultant. With a 20 year career in clinical trials she specialises in oncology trials and previously held Research Manager roles at the University of Auckland (2007-2011) and University of Leeds, UK (1996-2006). She obtained a Master’s degree in Healthcare Ethics and Law in 2005.

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| **Dr Paul Tanser** | | |
| Membership category: | | Health Practitioner |
| Date of appointment: | | 1 July 2012 |
| Current term expires: | | 1 July 2014 |

Dr Paul Tanser is currently employed as a Cardiology Consultant at North Shore and Waitakere Hospitals (2005-present). Prior to this he was Clinical Head of Cardiology at Palmerston North Hospital (2004-2005). Dr Tanser received his Fellowship and Specialist Certification in the Royal College of Physicians and Surgeons of Canada (1967) and Certification as Specialist in Cardiology Province of Quebec (1969), Royal College of Physicians (Glasgow 2001), Royal Australasian College of Physicians (2010), American College of Physicians, American College of Cardiology, and International College of Angiology. He graduated with a Doctor of Medicine (Magna cum Laude) from Ottawa University (1962). He was Governor of the American College of Cardiology for Ontario (2003) and the American College of Physicians (2001 - 2003). He was Assistant Professor of Medicine, McGill University, Cardiology Consultant, Royal Victoria Hospital, and Head of Cardiology, Queen Elizabeth Hospital, Montreal before becoming Head of Cardiology and Cardiovascular Research and subsequently Chief of Medicine at St Josephs Hospital, and Professor of Medicine McMaster University, Hamilton (1975- 2003). Dr Tanser has published over 100 refereed journal articles and abstracts and presented papers at numerous conferences. He is Cardiovascular Associate Editor of Merck Manual Professional and Home editions and the electronic Handbook edition. He is Major (retired) Canadian Army having been Brigade Surgeon LFCA, M O Royal Hamilton Light Infantry and 3 Bn Royal Canadian Regiment.

**Former Members**

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| **Mrs Mary Anne Gill** | |
| Membership category: | Consumer / Community Representative (lay) |
| Date of appointment: | 1 July 2012 |

**Dr David Stephens**

Membership category: Consumer / Community Representatives (lay)

Date of appointment 1 July 2012

## Attendance

The Northern B HDEC held 11 meetings in 2013.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | | | **Meetings** | | | | | | | | | | | | **Total** |
| Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |  |
| Lay members | L | Mrs Raewyn Sporle |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 11/11 |
| Cm | Mrs Maliaga Erick |  | ***A*** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | 8/11 |
| Cn | Mrs Mary Anne Gill |  | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | 9/11 |
| Cn & L | Dr David Stephens |  | **✓** | ***A*** | **✓** | ***A*** | ***A*** | ***A*** | **✓** | ***A*** |  |  |  | 3/8 |
| Cm | Mr Kerry Hiini  Co-opted from Northern A Committee |  |  |  |  |  | **✓** |  |  |  |  |  |  | 1/1 |
|  | Mrs Helen Walker  Co-opted from Central Committee |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |
| Non-lay members | HR | Mrs Stephanie Pollard |  | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 10/11 |
| Cn | Dr Brian Fergus  Co-opted from Northern A Committee |  |  |  |  | **✓** |  |  |  |  |  |  |  | 1/1 |
| HR | Ms Kerin Thompson |  | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 10/11 |
| HP | Dr Paul Tanser |  | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 10/11 |
| HR | Mrs Kate O’Connor |  | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | ***A*** | 9/11 |
| HR | Dr Etuate Saafi  Co-opted from Northern A Committee |  |  |  |  |  | **✓** |  |  |  |  |  |  | 1/1 |
|  | Mr Mathew Zacharius  Co-opted from Southern Committee |  |  |  |  |  |  | **✓** |  |  |  |  |  | 1/1 |

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| Key: | L | Lawyer | P | Pharmacist/pharmacologist | **✓** | present |
|  | E | Ethicist | B | Biostatistician | ***A*** | apologies |
|  | Cm | Community representative | HP | Health practitioner | **X** | absent |
|  | Cn | Consumer representative | HR | Health researcher |  | not applicable |

## Training and conferences

The Northern B Committee did not have training during 2013.

Committee members were invited to attend the Annual Cartwright Conference held in Auckland. Ms Kate O’Conner attended.

## Chairpersons’ meetings

Ms Raewyn Sporle attended two Chairs’ day meetings in 2013. Both meetings were held in Wellington in the Medsafe Boardroom.

The first meeting was held on 5 April. The Chairs were updated by the Secretariat about:

* appointments of new members
* annual reports to the Minister
* preliminary trends and measuring quality
* upcoming changes to the online system.

The Chairs and Secretariat identified seven key issues that were discussed.

* Bio-banking.
* Peer review.
* Restrictions on publication.
* Remuneration.
* Data safety monitoring.
* Examples of good practice.
* The possibility of a protocol template.

The Chairs spent the afternoon participating in a training session on ‘Managing Meetings’.

The second meeting was held on 23 August. The Chairs were updated by the Secretariat about:

* annual reports to the Minister
* further improvements planned for the online system.

The Chairs and Secretariat identified four key issues that were discussed.

* Peer review.
* Conflicts of interests.
* Restrictions on publication.
* Data safety monitoring.

Mr John Hancock, a legal adviser for the Office of the Commissioner for Children, gave a videoconference presentation to the Chairs about children’s consent in health research. The Chairs had a presentation and discussion with Associate Professor Martin Tolich on his recent academic work and practical observations of HDECs.

# Applications reviewed

The Northern B HDEC received 134 applications in 2013. From the 134 applications reviewed 92 applications were reviewed by the full committee and 42 were reviewed through the expedited pathway.

At each of its meetings in 2013 the Committee reviewed an average of eight applications.

|  |  |  |
| --- | --- | --- |
| Full | Approved | 85 |
| Declined | 4 |
| Provisional Approval (as at 31 December 2013) | 3 |
| *Total (with a decision at 31 December 2013)* | 92 |
| Expedited | Approved | 38 |
| Declined | 0 |
| Provisional Approval (as at 31 December 2013) | 4 |
| *Total (with a decision at 31 December 2013)* | 42 |
| **Total applications reviewed** | | ***134*** |

A summary of these applications can be found in Appendix A.

## Applications processed by Secretariat

The Northern B HDEC received 32 applications that were screened by the HDEC secretariat and were deemed out of scope for HDEC review.

The Northern B HDEC received 84 Minimal Dataset Forms (MDF). These forms are used to broker applications from the previous HREC Lotus Notes database to the new HDEC database.

## Average review time

## Average review times take into account the time taken for the Secretariat to process applications and the time taken for the Committee to review applications. The clock is stopped when a decision letter is emailed to applicants. The average time excludes time taken for researchers to respond to requests for further information.

The average review time for full applications was 23 days compared to a target timeframe of 35 calendar days.

The average review time for expedited applications was 34 days compared to a target timeframe of 15 calendar days.

# Post approval items reviewed

The Northern B HDEC reviewed a total of 586 post approval items. A graph of the different types reviewed is below.

**Post approval items reviewed during 2013**

**Reasons for declining**

The Northern B HDEC is required to clearly identify the ethical standard(s) that it considers not to be met by an application. These ethical standards are contained in the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (GFUR), Ethical Guidelines for Observational Studies (EGOS) and Ethical Guidelines for Intervention Studies (EGIS)*. The references in the tables below are to paragraph numbers in these documents.

**Reference:** 13/NTB/10  
**Review Type:** Intervention

**Short title:** A Phase 2 Randomized, Double Blind, Placebo Controlled, Parallel Arm Study to Investigate the Efficacy and Safety of Inhaled Laninamivir Octanoate TwinCaps® Dry Powder Inhaler in Adults with Symptomatic Influenza A or B Infection

**Co-ordinating Investigator:** Professor Murray Barclay

|  |  |
| --- | --- |
| **Reference** | **Reason** |
| 3.11 *EGIS* | It was not clear to the Committee that the risks of the research were proportional to the benefits of the research. The researcher needs to be more explicit about the possible benefits of this study and how the risks might be mitigated. |
| 5.30 *EGIS* | Intervention studies should not be performed with vulnerable groups if they can be adequately performed with other groups. |
| 6.66 *EGIS* | The investigators have an obligation to ensure the availability of health care services that are essential to the safe conduct of a study, for participants, study team and for the wider population. |

**Reference:** 13/NTB/128  
**Review Type:** Intervention

**Short title:** Metacognitive Therapy for Anorexia Nervosa: An open trial in the South Island Eating Disorder Service

**Co-ordinating Investigator:** Associate Professor Janet Carter

|  |  |
| --- | --- |
| **Reference** | **Reason** |
| 5.4 *EGIS* | The committee is unclear about the study design and therefore is unable to judge whether the protocol and information provided best answers the study question. It is not clear that the study minimises risk. |
| 6.56 *EGIS* | An independent Data Monitoring Committee should also be considered in early phase studies, whether or not randomised, of a high-risk intervention; for example: where vulnerable populations, such as children or people with mental illness, are studied |
| 4.22 *EGIS* | The potential conflict of interest between participant and researcher is not adequately covered, as well as any justification for recruiting during the first visit to the rehabilitation center. |

**Reference:** 13/NTB/145  
**Review Type:** Intervention

**Short title:** The Dynamic Patterns of Thinking in Attention-Deficit/Hyperactive Disorder (ADHD): Diagnostic accuracy of Euclidean, multifractal and lacunarity measures

**Co-ordinating Investigator:** Dr Fabian Labra-Sprohnle

|  |  |
| --- | --- |
| **Reference** | **Reason** |
| 6.22 *EGIS* | Insufficient information to adequately review the informed consent process |
| 6.2 *EGIS* | There is a lack of processes in place to mitigate risk of recruitment in a vulnerable context |
| 2.8 *EGIS* | There is insufficient information on the control group |

**Reference:** 13/NTB/159  
**Review Type:** Intervention

**Short title:** The effectiveness of The Novaco Anger Programme with a Forensic Mental Health Population.

**Co-ordinating Investigator:** Miss Ashleigh Clarke

|  |  |
| --- | --- |
| **Reference** | **Reason** |
| 4.9 *EGIS* | Any potential cultural and ethical issues pertaining to Māori must be addressed through appropriate engagement with Māori, which may include discussions with appropriate representatives of specific whānau, hapū and iwi as determined by the scope and method of the study. |
| 5.5 *EGIS* | Scientific soundness is ethically important. Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources |
| 5.6 *EGIS* | The intended number of participants in an intervention study should be sufficient to generate reliable study findings, and the consequent recruitment targets should be realistic. Statistical issues relating to trial design, sample size and analysis can be complex, and usually require expert advice. |
| 5.7 *EGIS* | The study protocol should contain an overview of the planned statistical analyses, and these planned analyses should be adhered to in conducting the study. |
| 6.12 *EGIS* | Investigators should effectively communicate to participants the purpose and practical implications of all key study features, including any randomisation, placebo control or blinding (see also ‘Features of intervention studies’, paragraphs 2.7–2.11). |
| 6.22 *EGIS* | Informed consent is essentially a matter of good communication between people. Information should be provided to potential participants in a form and in a way that assists their informed decision-making. Please view 6.22 of the Ethical Guidelines for Intervention Studies for further information. |

# Issues and complaints

This section outlines issues faced by the Committee during 2013.

**Issues causing difficulty in review**

* Online system issues
* Lack of appropriate peer review
* Provisional responses not being submitted in tracked changes format.

# Action taken

* New online system updates have been drafted, tested and implemented
* Peer review template developed and published on HDEC website
* Newsletter containing reminder to track changes was published on HDEC website.

### Issues referred to NEAC and/or the HRC Ethics Committee

NIL

## Complaints received

* An official complaint was received from the Breast Cancer Aotearoa Coalition (BCAC) against ‘The Synergism Or Long Duration (SOLD) Study’ (MEC/08/03/033). Study approval was reviewed at a full meeting and was re-confirmed.
* Official complaint from Children's Oncology Group (COG). COG has requested that their applications be considered by the Central HDEC. The HDEC Secretariat informed the NTB HDEC about the complaint and the researchers’ preference to have future applications reviewed by the Central HDEC.

**Overdue review**

During 2013 there were 38 instances where the review period was over 35 days for full applications and 25 where the review period was over 15 days for expedited applications.

See Appendix 1 for more information.

**Issues causing delays in reported review times**

The issues causing a delayed response time are as follows:

* Online system issues prevented Committee members from reviewing effectively.
* The online system clock that records time taken to receive a decision includes all *calendar* days which results in public holidays and weekends being included in the timeframes.
* The standard operating procedures state that the HDEC review should be paused over the period 25 December to 15 January the following year. This does not occur automatically and as a result, any applications awaiting review during this period have been identified and are not considered overdue.

**Action taken**

* The online system issues have been addressed with the latest system update
* Any applications that were running over the public holidays have been identified in Appendix 1.

# Appendix 1: Details of applications reviewed

## Applications reviewed by full committee

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study reference** | **Study status** | **Short title** | **Co-ordinating Investigator** | **Other Investigators** | **Locality/ies** | **Application type** |
| 12/NTB/2 | Approve | Trial of a brief treatment for common mental health syndromes in primary care | Ms Fiona Mathieson |  |  | Intervention |
| 13/NTB/10 | Decline | A Phase 2 Randomized, Double Blind, Placebo Controlled, Parallel Arm Study to Investigate the Efficacy and Safety of Inhaled Laninamivir Octanoate TwinCaps® Dry Powder Inhaler in Adults | Prof Murray Barclay |  | Primorus | Intervention |
| 13/NTB/102 | Approve | Early life determinants of long term outcomes in cystic fibrosis (CF FAB) | Professor Claire Wainwright |  |  | Observational |
| 13/NTB/103 | Approve | Engaging in stroke rehabilitation | Ms Felicity Bright | Dr Nicola Kayes,Professor Kathryn McPherson | Dr Samantha Everitt (CMDHB) | Observational |
| 13/NTB/104 | Approve | Outcome from general anaesthesia in infants with cystic fibrosis ( CF GAIN) | Professor Claire Wainwright |  |  | Observational |
| 13/NTB/105 | Approve | SONAR | Dr Helen Linda Pilmore | Dr Kannaiyan Rabindranath | Auckland District Health Board,Frances McNulty,Health Research South | Intervention |
| 13/NTB/107 | Approve | COMBAT CF: Can azithromycin prevent bronchiectasis in infants with CF | Dr Catherine Byrnes |  |  | Intervention |
| 13/NTB/11 | Approve | Nutritional therapy and gut inflammation in Crohn's disease | Mrs Catherine Wall | Professor Andrew Day,Assoc. Prof. Richard Gearry | CDHB Research Office | Intervention |
| 13/NTB/116 | Approve | Redesigning Daily Occupations | Dr Kirk Reed |  | Kate O'Connor | Intervention |
| 13/NTB/120 | Approve | 3D Imaging of Neonatal And Paediatric Subjects | Dr Michael Meyer |  | Dr Samantha Everitt (CMDHB) | Observational |
| 13/NTB/123 | Approve | 178-CL-101.To find out in patients with overactive bladder (OAB) if combinations of two drugs (Solifenacin Succinate and Mirabegron) are safe, well tolerated and have efficacy, compared to placebo and | Mr Stephen Mark |  | Canterbury Urology Research Trust,Cardinal Points Research Ltd,John Tuckey,michael holmes,Patrick James Meffan,Tauranga Urology Research Ltd | Intervention |
| 13/NTB/124 | Approve | Type 2 diabetes in dialysis patients | Dr Jasmine Tan | Clinical A/Prof John Collins,Professor Tim Cundy | Auckland District Health Board | Observational |
| 13/NTB/125 | Approve | MDMA (3,4-methylenedioxy-N-methylamphetamine) and tinnitus | Dr Grant Searchfield |  |  | Intervention |
| 13/NTB/126 | Approve | OPTIMIST A | Prof Peter Dargaville | Dr Mariam Buksh |  | Intervention |
| 13/NTB/128 | Decline | Metacognitive Therapy for Anorexia Nervosa | Associate Professor Janet Carter |  |  | Intervention |
| 13/NTB/129 | Approve | An investigation into the tolerability of Manuka CyclopowerTM chewable tablets | Dr Lynne Chepulis |  |  | Intervention |
| 13/NTB/130 | Approve | Evaluation of TAF vs TDF in patients with HBeAg positive Chronic HBV | Prof Edward Gane |  | Auckland Clinical Studies Limited,Christopher David Moyes | Intervention |
| 13/NTB/131 | Approve | Evaluation of TAF vs TDF in patients with HBeAg negative Chronic HBV | Prof Edward Gane |  | Auckland Clinical Studies Limited,Christopher David Moyes | Intervention |
| 13/NTB/143 | Approve | Effectiveness and Safety of FG-4592 for the treatment of anaemia in people with CKD not on dialysis | Dr David M. Voss | Dr Kannaiyan Rabindranath | Dr Samantha Everitt (CMDHB),Jan Adams, COO | Intervention |
| 13/NTB/144 | Provisionally approve | Aspiration therapy for treating obesity | Dr Dinesh Lal |  |  | Intervention |
| 13/NTB/145 | Decline | The Dynamic Patterns of Thinking in Attention-Deficit/Hyperactive Disorder (ADHD) | Dr Fabian Labra-Sprohnle |  |  | Intervention |
| 13/NTB/146 | Approve | (ANZ 1201 / BIG 6-11) NeoPHOEBE: Pi3k inhibition in Her2 OverExpressing Breast CancEr | Dr Marion Kuper-Hommel |  |  | Intervention |
| 13/NTB/147 | Provisionally approve | Zoledronic acid in DMD | Dr Craig Jefferies |  |  | Intervention |
| 13/NTB/148 | Approve | A study to Evaluate the Safety, Tolerability, and Activity of NGM282 in patients with Type 2 Diabetes. | Dr Ajith Dissanayake | Dr Dean Quinn,Dr Edward Watson,Dr Paul Noonan,Prof Russell Scott | Dr Jinny Willis,Dr Samantha Everitt (CMDHB),Prof Richard Stubbs, P3 Research Ltd,Prof Richard Stubbs. P3 Research Ltd,South Pacific Clinical Trials Ltd | Intervention |
| 13/NTB/151 | Approve | Chart review of renal biopsies in type 2 diabetic patients | Dr Jasmine Tan | Clinical A/Prof John Collins,Dr Jonathan Zwi | Auckland District Health Board,Dr Samantha Everitt (CMDHB),Waitemata DHB | Observational |
| 13/NTB/155 | Approve | Abnormal Scaring and Fibrotic Conditions | Professor Swee T Tan |  | Hutt Valley DHB | Observational |
| 13/NTB/156 | Approve | OPEN-LABEL DUPILUMAB IN PARTICIPANTS OF PREVIOUS DUPILUMAB CLINICAL TRIALS. | Dr. Gordon Dean Miller Coote |  | G D Millar-Coote | Intervention |
| 13/NTB/159 | Decline | Novaco Anger Management Study | Miss Ashleigh Clarke |  |  | Intervention |
| 13/NTB/163 | Approve | Positive Psychology for Suicidal Behaviour (PPSB) | Mr Kosta Tabakakis |  |  | Intervention |
| 13/NTB/165 | Approve | EGFR Testing in New Zealand | A/Prof Mark McKeage |  | Auckland District Health Board | Observational |
| 13/NTB/168 | Approve | Effects of low dose everolimus and/or BEZ235 on vaccine response in the elderly | Dr Dean Richard Quinn |  | Barney Montgomery,Clinical Trials at Riccarton Clinic ltd,Dr Dean Quinn P3 Research Wellington Unit,Dr Jinny Willis,Dr Phillipa Murray ,Dr Samantha Everitt (CMDHB),Dr Simon Carson,G D Millar-Coote,Greshame Carr,Prof Richard Stubbs, P3 Research Tauranga,South Pacific Clinical Trials Limited,Southern Clinical Trails - Waitemata Ltd | Intervention |
| 13/NTB/170 | Provisionally approve | MK 431A 289 A Study of the Safety and Efficacy of MK-0431A XR in Pediatric Participants With Type 2 Diabetes Mellitus Inadequate Glycemic Control on Metformin | Dr Craig Jefferies |  | Wayne Cutfield | Intervention |
| 13/NTB/172 | Approve | Aged Residential Care Healthcare Implementation Project (ARCHIP) | Professor Martin Connolly |  |  | Intervention |
| 13/NTB/173 | Approve | NETwork! Genomics retrospective project | Dr Benjamin Lawrence |  |  | Observational |
| 13/NTB/175 | Approve | Dosing of busulfan and methotrexate | Dr Lochie Teague |  | Auckland District Health Board | Intervention |
| 13/NTB/180 | Approve | Predictive value of airway response to aspiration | Dr Anna Miles |  |  | Observational |
| 13/NTB/181 | Approve | Prenatal Environment and Neurodevelopment (PEN) Pilot Study | Dr Suzanne Stevens |  | Auckland District Health Board, Westwives midwifery centre | Observational |
| 13/NTB/183 | Approve | Population reference ranges for periostin | Professor Richard Beasley |  | Medical Research Institute of New Zealand | Observational |
| 13/NTB/184 | Approve | Periostin sampling time variation study | Dr Richard Beasley |  | Medical Research Institute of New Zealand | Observational |
| 13/NTB/185 | Approve | Longitudinal study of serum periostin levels in asthma | Dr Richard Beasley |  |  | Observational |
| 13/NTB/186 | Approve | Serum periostin level in patients with bone fractures | Dr Richard Beasley |  |  | Observational |
| 13/NTB/187 | Approve | Serum periostin levels in participants undergoing dental extractions | Dr Richard Beasley |  |  | Observational |
| 13/NTB/19 | Approve | A Study to Test if Ibrutinib is Safe and Works Well in Patient’s with Certain Types of Leukaemia | Dr W. Nigel Patton |  | ADHB,CDHB Research Office | Intervention |
| 13/NTB/190 | Approve | Periostin levels in those of Chinese descent | Dr Richard Beasley |  | Medical Research Institute of New Zealand | Observational |
| 13/NTB/191 | Approve | Change in serum periostin level in severe exacerbation of asthma | Professor Richard Beasley |  | CCDHB | Observational |
| 13/NTB/192 | Approve | NeuroVISION | Dr Douglas Campbell |  | Auckland District Health Board | Observational |
| 13/NTB/193 | Approve | A validation study. | Dr. CC Grant | Ms Rajneeta Saraf |  | Observational |
| 13/NTB/194 | Approve | A long term, follow-up clinical trial studying the effects of GLPG0634 given to participants with Rheumatoid Arthritis | Dr Daniel Ching |  | Timaru Rheumatology Studies | Intervention |
| 13/NTB/20 | Approve | FENICE trial | Mrs Rachael Parke | Dr Bruce KING,Ms Jennifer Goodson | Auckland District Health Board,Bay of Plenty DHB,CDHB Research Office | Observational |
| 13/NTB/23 | Approve | Walking up and down ramps in children with CP | Miss Meghan Edmonston | Dr Mark Boocock,Dr Denise Taylor,Dr susan stott,Ms Nada Signal,Professor Peter McNair | Auckland District Health Board | Observational |
| 13/NTB/24 | Approve | MK-3475 vs Ipilimumab for advanced Melanoma | Dr Bernie Fitzharris |  | CCDHB,CDHB | Intervention |
| 13/NTB/25 | Approve | A Phase 2 Randomized, Double Blind, Placebo Controlled, Parallel Arm Study to Investigate the Efficacy and Safety of Inhaled Laninamivir Octanoate TwinCaps® Dry Powder Inhaler in Adults | Prof Murray Barclay |  | Barney Montgomery,Clinical Trials NZ Ltd,Guy Graham Currie,Kylie Haaima,Primorus,Southern Clinical Trials Remuera | Intervention |
| 13/NTB/26 | Approve | Asthma Health Literacy | Mrs Bernadette Jones |  | Cheryl Davies,Workbase Education Trust | Observational |
| 13/NTB/33 | Approve | Unpasteurised milk: protective for allergies and asthma? | Prof Jeroen Douwes |  | Centre for Public Health Research, Massey University | Observational |
| 13/NTB/34 | Approve | Advance Care Planning and Intellectual Disability | Ms S Brandford | Dr Brigit Mirfin-Veitch,Ms Jennifer Conder | IDEA Services Tracey Ramsay | Observational |
| 13/NTB/35 | Approve | MRDR | Dr Hilary Blacklock |  | CMDHB Research Office | Observational |
| 13/NTB/36 | Approve | Cultural Adaptation of the QPS Battery and GICS | Ms Karen Hayman |  |  | Observational |
| 13/NTB/37 | Approve | The effect of BCL2, BCL 6, and MYC expression,copy number and rearrangements by FISH and IHC on Event free survival and Overall survival in patients with de novo Diffuse large B-cell lymphoma. | Dr Samar Issa | Dr Lesley Overend | CMDHB Research Office | Observational |
| 13/NTB/38 | Approve | The effects of non-invasive brain stimulation on chronic arm pain | Dr Gwyn Lewis | Mr David Rice,Professor Peter McNair | Auckland District Health Board,Auckland University of Technology | Intervention |
| 13/NTB/47 | Approve | Does pre-emptive sciatic nerve block prevent phantom limb pain? | Dr Kelly Byrne |  | Jan Adams, COO | Intervention |
| 13/NTB/48 | Approve | Post Market enVista Toric IOL Evaluation | Dr Dean Corbett |  |  | Intervention |
| 13/NTB/49 | Approve | Baby Brain Waves | Professor Alistair Gunn |  | Auckland District Health Board | Observational |
| 13/NTB/5 | Approve | MELVAC | Dr Catherine Barrow |  | CCDHB,Malaghan INstitute of Medical Research | Intervention |
| 13/NTB/52 | Approve | Frequency of eating disorders in teenagers with type 1 diabetes | Dr Stephanie Cox | Dr Juliet Berkeley | CDHB Research Office | Observational |
| 13/NTB/54 | Approve | CAAN-AF | Dr Martin Stiles |  | BOPDHB,CCDHB,Jan Adams, COO | Intervention |
| 13/NTB/55 | Approve | A clinical trial studying the effects of GLPG0634 and methotrexate given to participants with Rheumatoid Arthritis | Dr Daniel Ching | Dr alan doube,Dr Joe Singh | Jan Adams, COO,Timaru Rheumatology Studies,Waitemata DHB | Intervention |
| 13/NTB/56 | Approve | ADMINISTRATOR DO NOT USE - A clinical trial studying the effects of GLPG0634 given to participants with Rheumatoid Arthritis. | Dr Daniel Ching |  | Timaru Rheumatology Studies | Intervention |
| 13/NTB/6 | Approve | MELVAC Dose Escalation | Dr Catherine Barrow |  | CCDHB,Malaghan Institute of Medical Research | Intervention |
| 13/NTB/62 | Approve | PT003006 A 24 week Efficacy and Safety study of inhaled glycopyrrolate and formoterol fumarate compared to Placebo MDI in individuals with moderate to very severe COPD. | Dr Dean Richard Quinn |  | Carol Veale,CMDHB Research Office,Jan Adams, COO,Prof Richard Stubbs, P3 Research,RMC Medical Research Ltd | Intervention |
| 13/NTB/64 | Approve | SUDDICU inception cohort study | Dr paul young |  | CCDHB | Observational |
| 13/NTB/65 | Approve | A randomized, double blind, placebo controlled, dose ranging study to evaluate dupilumab in patients with moderate to severe, uncontrolled asthma. | Dr Richard Beasley | Associate Professor Jim Reid | Cate Tyrer, Manager, Quality & Risk ,Medical Research Institute of New Zealand,RMC Medical Research | Intervention |
| 13/NTB/66 | Approve | AAA study | Dr David Squirrell |  |  | Intervention |
| 13/NTB/67 | Approve | The effect of statins on circulating concentrations of NTproCNP | A/Prof Richard Troughton |  | CDHB Research Office | Intervention |
| 13/NTB/68 | Approve | A Study to collect blood biomarker samples from patients with Chronic Hepatitis B who received treatment with Pegasys (Peginterferon Alpha-2a) ±Nucleo(s)tide Analogue | Prof Edward Gane |  | Auckland District Health Board | Intervention |
| 13/NTB/69 | Approve | Can Amino Acids in Combination with Exercise Training Improve Glycaemic Control and Cardiovascular Health in Type-2 Diabetics? | Mr Kim Gaffney |  | CCDHB,Sally Lark, Massey University | Intervention |
| 13/NTB/7 | Approve | A Clinical Trial to test different doses of a new medication IPI145 given with Methotrexate to treat Rheumatoid Arthritis | Dr Sunil Kumar |  | CMDHB Research Office | Intervention |
| 13/NTB/71 | Approve | A Study to Evaluate Cardiovascular Outcomes in Patients with Type 2 Diabetes Treated with ITCA 650 | Dr John Baker | Dr Edmond Walford,Dr Gordon Dean Millar-Coote,Dr Jocelyne Benatar,Prof Russell Scott | Auckland District Health Board,CMDHB Research Office,G D Millar-Coote,Lipid & Diabetes Research Group,Prof Richard Stubbs, P3 Research,Waitemata DHB | Intervention |
| 13/NTB/72 | Approve | Non high risk chest pain patients are safe for discharge | Dr Andrew Munro |  |  | Observational |
| 13/NTB/73 | Decline | A study to determine if adding canagliflozin to metformin therapy is effective, safe and well tolerated in patients with Type 2 Diabetes Mellitus who are unable to control their blood sugar with die | Dr Michael Williams | Dr Dean Quinn,Dr Jeremy Krebs,Dr Gordon Dean Millar-Coote | G D Millar-Coote,Lakeland Clinical Trials,Prof Richard Stubbs from P3 Research Ltd | Intervention |
| 13/NTB/76 | Approve | Early Treatment of Chronic Hepatitis B. | Dr. William Abbott |  |  | Observational |
| 13/NTB/78 | Approve | Early Results of SUFE Treatment | Mr Andrew Graydon |  |  | Observational |
| 13/NTB/8 | Approve | An investigation into safety and tolerability of Manuka Cyclopower | Dr Lynne Chepulis | Ms Evelyn Francis |  | Intervention |
| 13/NTB/80 | Approve | Investigating the microbiological contamination of drugs adMinistered for anaesthesia in the operating theatre | Mrs Derryn Gargiulo | Professor Alan Merry,Dr Craig Webster,Associate Professor Janie Sheridan | Auckland District Health Board | Intervention |
| 13/NTB/81 | Approve | AI452016 | Prof Edward Gane |  | Auckland District Health Board | Observational |
| 13/NTB/82 | Approve | TEAM: A pilot Trial of Early Activity and Mobility in ICU | dr paul young |  | Auckland District Health Board,CCDHB | Intervention |
| 13/NTB/83 | Approve | ConSEPT: A PREDICT study. | Dr Stuart Dalziel |  | Auckland District Health Board | Intervention |
| 13/NTB/84 | Approve | ProVIDe: Protein intake in early life and later development | Ms Barbara Cormack | Professor Frank Bloomfield | Auckland District Health Board,Jan Adams, COO | Intervention |
| 13/NTB/85 | Approve | A screening study to identify adult and adolescent individuals with Down Syndrome for eligibiity to participate in a future Drug Treatment Research Study. | Professor Ed Mitchell |  | Auckland Clinical Studies Ltd,CCDHB,Health Research South | Intervention |
| 13/NTB/92 | Approve | (duplicate) A clinical trial studying the effects of GLPG0634 given to participants with Rheumatoid Arthritis. | Dr Daniel W T Ching | Dr Joe Singh | Timaru Rheumatology Studies,Waitemata DHB | Intervention |
| 13/NTB/96 | Approve | NOCTURNAL HYPOXAEMIA AND GOUT: A Feasibility Study | Miss Christine Little | Miss Shyama Abraham | CMDHB Research Office | Intervention |
| 13/NTB/97 | Approve | An Investigation of Apremilast in Psoriatic Arthritis Subjects | Dr Daniel W T Ching |  | CMDHB Research Office ,Jan Adams, COO,Timaru Rheumatology Studies. | Intervention |
| 13/NTB/98 | Approve | An Investigation of Cabozantinib in Hepatocellular Carcinoma Patients previously treated with Sorafenib | Prof Edward Gane |  | Auckland District Health Board | Intervention |
| 13/NTB/99 | Approve | COG ANBL12P1: High Risk Neuroblastoma | Dr Mark Winstanley |  | Auckland District Health Board | Intervention |

## Applications reviewed by expedited review

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| **Study reference** | **Study status** | **Short title** | **Co-ordinating Investigator** | **Other Investigators** | **Locality/ies** | **Application type** |
| 13/NTB/1 | Approve | SMART | Professor Valery L. Feigin | Dr Alice Theadom,Dr Rita Krishnamurthi | Dr Kenneth Clark,Jan Adams, COO,Waitemata DHB | Intervention |
| 13/NTB/100 | Approve | Comparison of different patient pathways to the diagnosis of melanomas in Waikato, New Zealand | Prof Mark Elwood |  | Jan Adams, COO,Tristram Clinic | Observational |
| 13/NTB/101 | Approve | CAFE NZ | Dr Rachel Vicars |  |  | Intervention |
| 13/NTB/110 | Approve | The fish spike study | Ms Hannah Collins |  | CMDHB Research Office | Intervention |
| 13/NTB/117 | Approve | Invasive GAS disease in New Zealand, 2002 - 2012 | Dr Deborah Williamson |  |  | Observational |
| 13/NTB/118 | Approve | The burden of Haemophilus influenzae meningitis in the post vaccine era | Dr Yeri Ahn |  | Dr Samantha Everitt (CMDHB) | Observational |
| 13/NTB/121 | Approve | Development of Type 2 diabetes Mellitus following Gestational Diabetes Mellitus | Dr Shekhar Sehgal | Dr John Baker |  | Observational |
| 13/NTB/132 | Approve | Kiwifruit Extract for the alleviation of constipation | Prof Sally D Poppitt | Mr Wilson Yip | Prof. Gillian Lewis | Intervention |
| 13/NTB/133 | Approve | Differentiated Thyroid Cancer Outcomes in the Auckland Region: A 5-Year Cohort 2003-2007 | Dr James Johnston | Dr Laura Hill | CMDHB Research Office | Observational |
| 13/NTB/134 | Approve | Cardiac disease in kidney failure | Associate Professor Helen Pilmore |  |  | Observational |
| 13/NTB/136 | Approve | Mindfuness based pain intervention | Miss Jessica Leov |  |  | Intervention |
| 13/NTB/137 | Approve | Case based cohort study of Sawmill workers exposed to persistent organic pollutants | Doctor Grahame Jelley | Mr Hohepa Joseph Harawira | Dr Grahame Jelley | Observational |
| 13/NTB/138 | Approve | METS Study | Dr Kathryn Hagen | Dr Doug Campbell | Auckland District Health Board | Observational |
| 13/NTB/141 | Approve | Efficacy of “InterRAI” and “SCREEN” for detecting suboptimal dietary intake in the elderly | Dr Hamish Jamieson |  | cdhb | Observational |
| 13/NTB/15 | Approve | Intergenerational Communication Practices and Themes within Whanau Maori | Dr Stephanie Palmer | Ms Rachel McClintock |  | Observational |
| 13/NTB/150 | Approve | Merino Encircle Compression Stockings in patients requiring compression stockings | Dr Janine Pilcher | Mrs Angela Bayley |  | Intervention |
| 13/NTB/152 | Approve | Qualitative analysis of the psychological impact of pre-operative halo traction in paediatric scoliosis patients | Dr Sanka Bambarawana |  |  | Observational |
| 13/NTB/158 | Approve | Nasal flora and Staphylococcus aureus | Dr Stephen Ritchie |  | University of Auckland | Intervention |
| 13/NTB/164 | Approve | Screening and brief intervention for substance misuse in mental health | Dr David Newcombe | Dr Susanna Galea | Waitemata DHB | Observational |
| 13/NTB/169 | Approve | Diabetes retinal screening cohort study | Dr. Tom Robinson |  | Auckland District Health Board | Observational |
| 13/NTB/17 | Approve | Written emotional disclosure and surgery | Dr Elizabeth Broadbent |  | Auckland District Health Board,Dr Samantha Everitt (CMDHB) | Intervention |
| 13/NTB/174 | Approve | Epidemiology Cohort Study on Severe Sepsis in Waikato Region | Dr Prashanth Hari Dass |  |  | Observational |
| 13/NTB/178 | Provisionally approve | Growth and Bone Mineral Density 5 years post Paediatric Liver Transplant | Dr Amin Sheikh |  |  | Observational |
| 13/NTB/18 | Approve | The Gestational Diabetes Mellitus Study of Detection Thresholds (GEMS) | Professor Caroline Crowther |  |  | Intervention |
| 13/NTB/195 | Approve | Alcohol and Other Drug Treatment Court Evaluation | Ms Gabrielle Clezy | Mr Julian King |  | Observational |
| 13/NTB/196 | Provisionally approve | Cellulitis in children: A QI collaborative | Dr Jennifer Njenga |  |  | Observational |
| 13/NTB/198 | Approve | Rheumatic Fever M/emm typing in Children | Professor Diana Lennon |  |  | Observational |
| 13/NTB/199 | Approve | Mortality and morbidity following sub-massive PE | Dr Chinthaka Samaranayake |  | Dr Samantha Everitt (CMDHB) | Observational |
| 13/NTB/200 | Provisionally approve | A study of the lived world of the patient with Borderline Personality Disorder | Ms Marlene Dor |  |  | Observational |
| 13/NTB/202 | Provisionally approve | Bony Mallet Fracture study | Ms Karen Smith | Miss Clara Miller |  | Observational |
| 13/NTB/204 | Approve | Notes review to evaluate an educational intervention | AP Jennifer Weller | Professor Alan Merry,Dr David Cumin,Mr Ian Civil,Dr Matt Boyd |  | Observational |
| 13/NTB/207 | Approve | Epidemiology of Non-Melanoma Skin Cancers (NMSC) in the Auckland Region | Mr Richard Martin |  | Waitemata District Health Board | Observational |
| 13/NTB/21 | Approve | Use of the STOPP criteria to identify potentially inappropriate prescribing | Dr Sarah Gray | Dr Mary Seddon | Samantha Everitt (CMDHB) | Observational |
| 13/NTB/22 | Approve | Treatment Goals and the Influence of Pharmacist Counselling | Doctor Peter Sizeland | Mr Rajan Ragupathy | Jan Adams, COO | Intervention |
| 13/NTB/27 | Approve | Description of adenovirus lower respiratory tract infection in children and outcomes | Dr Geetika Badkar |  | Dr Samantha Everitt (CMDHB) | Observational |
| 13/NTB/4 | Approve | Thyrotoxicosis in Maori | Dr Jade Tamatea |  |  | Observational |
| 13/NTB/41 | Approve | PREVIEW:NZ | Prof Sally D Poppitt | Dr Anne-Thea McGill,Dr Lisa Te Morenga | SBS HOD Biological Sciences Gillian Lewis | Intervention |
| 13/NTB/63 | Approve | CPAP: Evaluation of Therapy Comfort | Dr Rachel Vicars |  |  | Intervention |
| 13/NTB/79 | Approve | EPOCH | Dr Susan Wells | Associate Professor Chris Bullen,Dr Natasha Rafter | Manaia Primary Health Organisation,Te Tai Tokerau PHO | Intervention |
| 13/NTB/88 | Approve | Developmental Screening of Refugee Children Under 5 Years Old Arriving in New Zealand (NZ) | Dr Santuri Rungan |  |  | Observational |
| 13/NTB/89 | Approve | Paediatric acute pain audit - a pilot study | Dr Andrew Liley |  | Auckland District Health Board | Observational |
| 13/NTB/91 | Approve | Incidence and outcome of renal transplant recipients with BK viraemia and/or virus nephropathy. | Dr Chun-Yuan Hsiao |  | Auckland District Health Board,Waitemata DHB | Observational |

## Minimal dataset form applications

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| **Study reference** | **Study status** | **Short title** | **Co-ordinating Investigator** |
| AKL/2001/184 WAI/43/01/772 | Invalid Application | BCIRG 006 | Dr Michael Jameson |
| CEN/12/03/005 | Approve | Maori mental health recovery: a hermeneutic study | Ms Inez Awatere-Walker |
| CEN/12/EXP/007 | Approve | Living with multiple long-term health conditions | Ms Helen Francis |
| LRS/12/06/019 | Approve | Cardiac Biomarkers in COPD | Dr Eskandarain Shafuddin |
| MEC 10/01/005 | Invalid Application | Trial assigning individualised options for treatment - the TAILORx trial | Dr Marion Kuper-Hommel |
| MEC/06/05/048 | Approve | New Zealand Heart Failure Registry | Dr Gerald Devlin |
| MEC/07/10/194 | Approve | Femara versus Anastrozole Clinical Evaluation trial | A/Prof Ian Campbell |
| MEC/07/58/EXP | Approve | Paediatric Pulmonary Hypertension Database | Dr Clare O'Donnell |
| MEC/08/01/011 | Invalid Application | Ig NextGen 16% in PID | Dr Penny Fitzharris |
| MEC/08/10/123 | Invalid Application | First Study Protocol Number: CC-5013-MM-020/IFM 07-01 (Celgene) | Mrs Fay Sommerville |
| MEC/09/04/037 | Approve | Fetal Anaemia Study | Dr Alexandra Wallace |
| MEC/09/11/130 | Invalid Application | A Study to Evaluate the Long Term Effects of Repeated Administration of Adalimumab in Participants with Ulcerative Colitis | Dr Ian Wallace |
| MEC/09/28/EXP | Approve | ICU PPP | Dr Colin McArthur |
| MEC/10/01/005 | Approve | Trial assigning individualised options for treatment - the TAILORx trial | Dr Marion Kuper-Hommel |
| MEC/10/07/062 | Approve | PALLAS | Dr Martin Stiles |
| MEC/10/11/116 | Approve | A study on the effectiveness and safety of ocrelizumab in adults with Primary Progressive Multiple Sclerosis | Dr Christopher Lynch |
| MEC/10/12/128 | Approve | Valor Study | Dr Gillian Corbett |
| MEC/11/03/032 | Approve | A 52 weeks extension to: A Phase IIb Study of MK-4618 in Patients with OAB | Dr Helen Roberts |
| MEC/11/04/033 | Approve | Efficacy and Safety of Extended-Release Niacin/Laropiprant in patients with Primary Hypercholesterolaemia or mixed Dyslipidaemia-MK-118. | Dr Raewyn Fisher |
| MEC/11/12/103 | Approve | Study of Rindopepimut/GM-CSF with Temozolomide in Patients with a Newly Diagnosed, Surgically Resected, Brain Tumour (EGFRvIII-positive Glioblastoma | Dr Michael Tills |
| MEC/11/EXP/123 | Approve | Collaborative practice in palliative care | ms Christine McDonald |
| MEC/12/EXP/038 | Approve | Health literacy: gout; skin infections and GDM | Miss Susan Reid |
| MEC/12/EXP/077 | Approve | Epidemiology of important congenital heart disease in New Zealand:Perinatal diagnosis and outcomes. | Dr Luke Eckersley |
| NTX/07/09/100 | Approve | Double blind randomised controlled trial of methylphenidate versus placebo for the treatment of methamphetamine dependence | Associate Professor Sylvester Wayne MILES |
| NTX/08/11/112 | Approve | How does microbial metabolism of our food affect gut health? | Dr Shanthi Parkar |
| NTX/10/05/043 | Approve | The Heparin Citrate study | Dr Shay McGuinness |
| NTX/10/07/060 | Approve | Mindfulness based stress reduction with patients who have rheumatoid arthritis | Associate Professor Nathan Consedine |
| NTX/10/08/077 | Approve | Femoral tunnel placement in ACL reconstruction | Mr Mark Clatworthy |
| NTX/11/04/029 | Approve | OMIVI Study | Dr Nikki Mills |
| NTX/11/05/043 | Approve | Stem cells from bone marrow | Mr Jonathan Wheeler |
| NTX/12/02/003 | Approve | Non-invasive measurement of Neural Respiratory Drive (NRD) in Children. | Dr David McNamara |
| NTX/12/04/029 | Approve | PegIFN alpha plus ribavirin post treatment problems | Mr Brett Knock |
| NTX/12/06/054 | Approve | Gastrografin in ileus | Associate Professor Ian Bissett |
| NTX/12/EXP/018 | Approve | Development of radiological algorithms | Dr Alys Clark |
| NTX/12/EXP/088 | Invalid Application | Nutrition and ECMO | Mrs Eileen Gilder |
| NTY 11/05/047 | Invalid Application | SUPREMO trial | Dr Michael Tills |
| NTY 25/98/520 | Invalid Application | Exemestane compared to Tamoxifen for breast cancer | A/Prof Ian Campbell |
| NTY 25/98/520 | Invalid Application | Exemestane compared to Tamoxifen for breast cancer | A/Prof Ian Campbell |
| NTY/05/11/092 | Approve | Sentinel Lymph Node Biopsy versus Axillary Clearance in Operable Breast Cancer (SNAC 2) | A/Prof Ian Campbell |
| NTY/07/05/044 | Invalid Application | Isotretinoin 5mg capsules (once daily) in the treatment of persistent low grade adult acne. Post Study Follow-up. | Professor Marius Rademaker |
| NTY/08/01/011 | Approve | ANZ 0501 LATER | A/Prof Ian Campbell |
| NTY/08/95/EXP | Approve | SOURCE Registry | Dr Sanjeevan Pasupati |
| NTY/09/06/051 | Approve | PILLAR II Study | Professor Peter Browett |
| NTY/09/111/EXP | Approve | Waikato Mortality Data Linkage | Dr Nicholas Barnes |
| NTY/09/74/EXP | Approve | Shock-Less | Dr Martin Stiles |
| NTY/09/84/EXP | Approve | Levosimendan vs other inotropes | Dr Nicholas Barnes |
| NTY/10/01/002 | Approve | Patient satisfaction following primary total hip replacement for osteoarthritis: a randomised controlled trial of posterior versus lateral approaches | Dr Jonathan Manson |
| NTY/10/05/044 | Approve | Spiritual Self Schema (3S)Therapy in the treatment of comorbid anxiety or depression and substance abuse or dependence | Ms Carlene Bone |
| NTY/10/08/065 | Approve | Selenium effects on cancer treatments in normal and malignant cells | Dr Michael Jameson |
| NTY/10/10/086 | Approve | Propranolol Versus Placebo for Infantile Haemangioma (IH) | Professor Marius Rademaker |
| NTY/10/11/094 | Approve | What is the best dose of prostatic Botox for men in urinary retention? | Mr Michael Holmes |
| NTY/11/02/016 | Approve | The Consequences of Brain Injury in Children (COBIC) | Dr Nicola Starkey |
| NTY/11/04/041 | Approve | Bridging the intention-action gap in rehabilitation | Associate Professor Paula Kersten |
| NTY/11/05/047 | Approve | SUPREMO trial | Dr Michael Tills |
| NTY/11/06/063 | Approve | Chiropractic and sensorimotor function | Dr Kelly Holt |
| NTY/11/07/073 | Approve | The cardiovascular effects of calcium supplementation | Dr Loretta Radford |
| NTY/11/07/083 | Approve | Analysis of Lean Six Sigma as a method for developing a falls prevention programme in a geriatric rehabilitation setting | Mr Richard Benfell |
| NTY/11/08/084 | Approve | How nurses work in partnership with Maori and other patients | Ms Christine BAKER |
| NTY/11/11/109 | Approve | Improving the inflammatory health benefits of a New Zealand diet – a prospective two-arm pilot dietary intervention study. | Prof Lynnette R. Ferguson |
| NTY/11/EXP/073 | Approve | How well is intrathecal morphine managed by health care professionals | Ms Jennifer Boudreau |
| NTY/11/EXP/083 | Approve | Smoking cessation in a general practice: barriers and enablers to cessation | Mrs Mary McLean |
| NTY/11/EXP/088 | Invalid Application | Mapping gastro-oesophageal cancer in the Auckland-Northland region | Doctor Soizick Mesnage |
| NTY/11/EXP/088 | Approve | Mapping gastro-oesophageal cancer in the Auckland-Northland region | Doctor Soizick Mesnage |
| NTY/12/01/003 | Approve | Tramadol vs. Morphine for refractory postoperative pain in the recovery room | Dr Kelly Byrne |
| NTY/12/01/011 | Approve | Study Evaluating the Neuropsychiatric Safety and Efficacy of 12 Weeks Varenicline Tartrate 1mg BID and Bupropion Hydrochloride 150mg BID for Smoking Cessation in Subjects With and Without a History of | Dr Michael Williams |
| NTY/12/02/019 | Approve | Iodine contrast-induced thyrotoxicosis | Dr Kim Simcox |
| NTY/12/05/034 | Approve | AMICI | Dr Gerald Devlin |
| NTY/12/05/039 | Approve | Cardiac Assessments after Treatment Study - CATS | Dr Michael Williams |
| NTY/12/06/050 | Approve | Evaluation of adding the Incredible Years Specialist Service for high risk families | Ms Dianne Lees |
| NTY/12/5/034 | Invalid Application | AMICI | Dr Gerald Devlin |
| NTY/12/5/034 | Invalid Application | AMICI | Dr Gerard Devlin |
| NTY/12/EXP/018 | Approve | Psoriasis and lichen sclerosus | Dr Harriet Cheng |
| NTY/12/EXP/026 | Approve | Real life Correlates | Dr. Sangeeta Dey |
| NTY/72/96/382 | Invalid Application | International Breast Cancer Intervention Study | A/Prof Ian Campbell |
| NTY/72/96/382 | Approve | International Breast Cancer Intervention Study | A/Prof Ian Campbell |
| URA/11/10/063 | Approve | Can Macitentan reduce finger ulceration in people with systemic sclerosis? | Dr Kamal Solanki |
| WAI/25/98/250 | Invalid Application | Exemestane compared to Tamoxifen for breast cancer | A/Prof Ian Campbell |
| WAI/25/98/520 | Approve | Exemestane compared to Tamoxifen for breast cancer | A/Prof Ian Campbell |
| WAI/39/98/541 | Approve | Rituximab in remission induction and maintenance treatment of relapsed/resistant follicular non-Hodgkin's lymphoma: a phase III randomized clinical trial | Dr Michael Jameson |
| WAI/42/01/771 | Approve | BCIRG 005 | Dr Michael Jameson |
| WAI/43/01/772 | Approve | BCIRG 006 | Dr Michael Jameson |
| WAI/5/98/500 | Approve | Long-term Anastrozole vs Tamoxfen Treatment Effects (LATTE) | A/Prof Ian Campbell |
| AKY/03/03/065 | Invalid Application | The New Zealand Mental Health Survey | Dr Kate Scott |

## Overdue full applications

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| --- | --- | --- | --- | --- |
| **Reference** | **Short Title** | **Co-ordinating Investigator** | **Days overdue** | **Reason** |
| 13/NTB/102 | Early life determinants of long term outcomes in cystic fibrosis (CF FAB) | Professor Claire Wainwright | 49 | Public Holidays |
| 13/NTB/105 | SONAR | Dr Helen Linda Pilmore | 5 | Committee Response Overdue |
| 13/NTB/107 | COMBAT CF: Can azithromycin prevent bronchiectasis in infants with CF | Dr Catherine Byrnes | 24 | Committee Response Overdue |
| 13/NTB/11 | Nutritional therapy and gut inflammation in Crohn's disease | Mrs Catherine Wall | 3 | Committee Response Overdue |
| 13/NTB/120 | 3D Imaging of Neonatal And Paediatric Subjects | Dr Michael Meyer | 11 | Committee Response Overdue |
| 13/NTB/123 | 178-CL-101.To find out in patients with overactive bladder (OAB) if combinations of two drugs (Solifenacin Succinate and Mirabegron) are safe, well tolerated and have efficacy, compared to placebo and | Mr Stephen Mark | 23 | Committee Response Overdue |
| 13/NTB/125 | MDMA (3,4-methylenedioxy-N-methylamphetamine) and tinnitus | Dr Grant Searchfield | 12 | Committee Response Overdue |
| 13/NTB/126 | OPTIMIST A | Prof Peter Dargaville | 7 | Committee Response Overdue |
| 13/NTB/130 | Evaluation of TAF vs TDF in patients with HBeAg positive Chronic HBV | Prof Edward Gane | 13 | Committee Response Overdue |
| 13/NTB/143 | Effectiveness and Safety of FG-4592 for the treatment of anaemia in people with CKD not on dialysis | Dr David M. Voss | 4 | Committee Response Overdue |
| 13/NTB/146 | (ANZ 1201 / BIG 6-11) NeoPHOEBE: Pi3k inhibition in Her2 OverExpressing Breast CancEr | Dr Marion Kuper-Hommel | 13 | Committee Response Overdue |
| 13/NTB/148 | A study to Evaluate the Safety, Tolerability, and Activity of NGM282 in patients with Type 2 Diabetes. | Dr Ajith Dissanayake | 20 | Committee Response Overdue |
| 13/NTB/155 | Abnormal Scaring and Fibrotic Conditions | Professor Swee T Tan | 43 | Public Holidays |
| 13/NTB/156 | OPEN-LABEL DUPILUMAB IN PARTICIPANTS OF PREVIOUS DUPILUMAB CLINICAL TRIALS. | Dr. Gordon Dean Miller Coote | 13 | Public Holidays |
| 13/NTB/163 | Positive Psychology for Suicidal Behaviour (PPSB) | Mr Kosta Tabakakis | 33 | Public Holidays |
| 13/NTB/180 | Predictive value of airway response to aspiration | Dr Anna Miles | 26 | Public Holidays |
| 13/NTB/184 | Periostin sampling time variation study | Dr Richard Beasley | 18 | Public Holidays |
| 13/NTB/185 | Longitudinal study of serum periostin levels in asthma | Dr Richard Beasley | 18 | Public Holidays |
| 13/NTB/186 | Serum periostin level in patients with bone fractures | Dr Richard Beasley | 18 | Public Holidays |
| 13/NTB/187 | Serum periostin levels in participants undergoing dental extractions | Dr Richard Beasley | 18 | Public Holidays |
| 13/NTB/19 | A Study to Test if Ibrutinib is Safe and Works Well in Patient’s with Certain Types of Leukaemia | Dr W. Nigel Patton | 7 |  |
| 13/NTB/190 | Periostin levels in those of Chinese descent | Dr Richard Beasley | 18 | Public Holidays |
| 13/NTB/191 | Change in serum periostin level in severe exacerbation of asthma | Professor Richard Beasley | 18 | Public Holidays |
| 13/NTB/194 | A long term, follow-up clinical trial studying the effects of GLPG0634 given to participants with Rheumatoid Arthritis | Dr Daniel Ching | 14 | Public Holidays |
| 13/NTB/24 | MK-3475 vs Ipilimumab for advanced Melanoma | Dr Bernie Fitzharris | 6 | Committee Response Overdue |
| 13/NTB/34 | Advance Care Planning and Intellectual Disability | Ms S Brandford | 3 | Committee Response Overdue |
| 13/NTB/38 | The effects of non-invasive brain stimulation on chronic arm pain | Dr Gwyn Lewis | 2 | Committee Response Overdue |
| 13/NTB/47 | Does pre-emptive sciatic nerve block prevent phantom limb pain? | Dr Kelly Byrne | 17 | Committee Response Overdue |
| 13/NTB/49 | Baby Brain Waves | Professor Alistair Gunn | 2 | Committee Response Overdue |
| 13/NTB/5 | MELVAC | Dr Catherine Barrow | 5 | Committee Response Overdue |
| 13/NTB/52 | Frequency of eating disorders in teenagers with type 1 diabetes | Dr Stephanie Cox | 1 | Committee Response Overdue |
| 13/NTB/55 | A clinical trial studying the effects of GLPG0634 and methotrexate given to participants with Rheumatoid Arthritis | Dr Daniel Ching | 6 | Committee Response Overdue |
| 13/NTB/56 | ADMINISTRATOR DO NOT USE - A clinical trial studying the effects of GLPG0634 given to participants with Rheumatoid Arthritis. | Dr Daniel Ching | 6 | Committee Response Overdue |
| 13/NTB/6 | MELVAC Dose Escalation | Dr Catherine Barrow | 5 | Committee Response Overdue |
| 13/NTB/66 | AAA study | Dr David Squirrell | 10 | Committee Response Overdue |
| 13/NTB/7 | A Clinical Trial to test different doses of a new medication IPI145 given with Methotrexate to treat Rheumatoid Arthritis | Dr Sunil Kumar | 3 | Committee Response Overdue |
| 13/NTB/76 | Early Treatment of Chronic Hepatitis B. | Dr. William Abbott | 15 | Committee Response Overdue |
| 13/NTB/98 | An Investigation of Cabozantinib in Hepatocellular Carcinoma Patients previously treated with Sorafenib | Prof Edward Gane | 4 | Committee Response Overdue |

## Overdue expedited applications

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| **Study reference** | **Short Title** | **Co-ordinating Investigator** | **Days Overdue** | **Reason** |
| 13/NTB/1 | SMART | Professor Valery L. Feigin | 23 | Committee Response Overdue |
| 13/NTB/101 | CAFE NZ | Dr Rachel Vicars | 1 | Committee Response Overdue |
| 13/NTB/118 | The burden of Haemophilus influenzae meningitis in the post vaccine era | Dr Yeri Ahn | 5 | Committee Response Overdue |
| 13/NTB/132 | Kiwifruit Extract for the alleviation of constipation | Prof Sally D Poppitt | 15 | Committee Response Overdue |
| 13/NTB/133 | Differentiated Thyroid Cancer Outcomes in the Auckland Region: A 5-Year Cohort 2003-2007 | Dr James Johnston | 6 | Committee Response Overdue |
| 13/NTB/136 | Mindfuness based pain intervention | Miss Jessica Leov | 2 | Committee Response Overdue |
| 13/NTB/137 | Case based cohort study of Sawmill workers exposed to persistent organic pollutants | Doctor Grahame Jelley | 11 | Committee Response Overdue |
| 13/NTB/141 | Efficacy of “InterRAI” and “SCREEN” for detecting suboptimal dietary intake in the elderly | Dr Hamish Jamieson | 14 | Committee Response Overdue |
| 13/NTB/152 | Qualitative analysis of the psychological impact of pre-operative halo traction in paediatric scoliosis patients | Dr Sanka Bambarawana | 20 | Committee Response Overdue |
| 13/NTB/158 | Nasal flora and Staphylococcus aureus | Dr Stephen Ritchie | 18 | Committee Response Overdue |
| 13/NTB/164 | Screening and brief intervention for substance misuse in mental health | Dr David Newcombe | 10 | Committee Response Overdue |
| 13/NTB/169 | Diabetes retinal screening cohort study | Dr. Tom Robinson | 24 | Committee Response Overdue |
| 13/NTB/174 | Epidemiology Cohort Study on Severe Sepsis in Waikato Region | Dr Prashanth Hari Dass | 4 | Committee Response Overdue |
| 13/NTB/18 | The Gestational Diabetes Mellitus Study of Detection Thresholds (GEMS) | Professor Caroline Crowther | 7 | Committee Response Overdue |
| 13/NTB/195 | Alcohol and Other Drug Treatment Court Evaluation | Ms Gabrielle Clezy | 35 | Public Holidays |
| 13/NTB/198 | Rheumatic Fever M/emm typing in Children | Professor Diana Lennon | 32 | Public Holidays |
| 13/NTB/199 | Mortality and morbidity following sub-massive PE | Dr Chinthaka Samaranayake | 28 | Public Holidays |
| 13/NTB/204 | Notes review to evaluate an educational intervention | AP Jennifer Weller | 18 | Public Holidays |
| 13/NTB/207 | Epidemiology of Non-Melanoma Skin Cancers (NMSC) in the Auckland Region | Mr Richard Martin | 13 | Public Holidays |
| 13/NTB/21 | Use of the STOPP criteria to identify potentially inappropriate prescribing | Dr Sarah Gray | 1 | Committee Response Overdue |
| 13/NTB/22 | Treatment Goals and the Influence of Pharmacist Counselling | Doctor Peter Sizeland | 16 | Committee Response Overdue |
| 13/NTB/63 | CPAP: Evaluation of Therapy Comfort | Dr Rachel Vicars | 16 | Committee Response Overdue |
| 13/NTB/79 | EPOCH | Dr Susan Wells | 2 | Committee Response Overdue |
| 13/NTB/88 | Developmental Screening of Refugee Children Under 5 Years Old Arriving in New Zealand (NZ) | Dr Santuri Rungan | 7 | Committee Response Overdue |
| 13/NTB/89 | Paediatric acute pain audit - a pilot study | Dr Andrew Liley | 7 | Committee Response Overdue |