

Northern B Health and Disability Ethics Committee

Annual Report
2016

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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

It is with great pleasure that I submit the 2016 Annual Report for Northern B HDEC. This was my first year as the Committee’s Chairperson. I extend my grateful thanks to our previous Chairperson Raewyn Sporle, who guided the committee throughout her term with great care and expertise. The other 3 HDEC Chairs continue to benefit me with the wisdom of their experience, thank you.

2016 was another busy and successful year for Northern B. We have welcomed two new members to the group, John Hancock and Leesa Russell. Both quickly made a very valuable contribution. I sincerely thank all of the members for their dedication and hard work; it is great working with you all. I am particularly grateful to our lay-members for their perseverance in reviewing research involving complex science with first-and-foremost regard to the well-being of potential participants. In addition, my sincere thanks go to Stephanie Pollard and Nora Gillies for carrying substantial extra responsibilities for reviewing new applications and amendments in the on-line system.

Across all of the HDECs a total of 652 applications were validated in 2016. While this total was slightly down on the previous year, the overall trend is of increasing application volume. We expect this growth to continue, especially as the new research funding made available through the strategic refresh of the HRC comes on-stream. It is likely that changes in the regulatory arrangements for therapeutic products will contribute further to HDECs’ workload, and it is imperative that NZ’s ethical review system is adequately resourced to meet this challenge.

The HDEC Secretariat, led by Philippa Bascand, continues to support Northern B with a very responsive and expert level of service, and have initiated a number of highly successful improvements. Of particular note is the screening and support processes with respect to questions about the impact of research on Māori, and the requirements for consultation. As a result the quality of responses to the cultural section of the applications has improved tremendously. The re-design of the template for Annual Reports now allows Co-ordinating Investigators to report on their activities in much richer detail. The new member training, and on-going pre-meeting member training is extremely valuable.

In the past year a particular challenge has arisen with respect to research in emergency settings or where participants possess a diminished capacity to consent. We acknowledge the work done by researchers working in these areas to refine their protocols to meet both the law and the required ethical standards. We encourage further review of the guidelines to address this important area. We also note that some post-graduate researchers would benefit from deeper engagement with their academic supervisors, and encourage tertiary institutions to take a more active role as Sponsor of their student researchers.

Finally, we give thanks to our applicants for their lively and open dialogue with us, and their commitment to continuous ethical reflection and practice. We wish them every research success.



Mrs Kate O’Connor

Chairperson

Northern B Health and Disability Ethics Committee

# Membership and attendance

No meetings were postponed or cancelled due to inability to make quorum. No new members were appointed to the Committee during 2016.

## Membership

**Lay members**

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| **Mrs Kate O’Connor (Chair)**  |
| Membership category:  |  Ethics and moral reasoning |
| Date of appointment:  | 14 Dec 2015  |
| Current term expires:  | 14 Dec 2018  |

Kate O'Connor is the Chair of Northern B, HDEC, and is the Executive Manager of the AUT Ethics Committee. She is a Master of Arts (Philosophy) and holds a Post Graduate Diploma in Business Administration. Kate’s current doctoral inquiry is of research governmentality, using Michel Foucault’s theories of power and resistance.

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| **Mrs Maliaga Erick** |
| Membership category:  | Consumer / Community Representative |
| Date of appointment:  | 24 July 2015 |
| Current term expires:  | 24 July 2018 |

Maliaga Erick is currently working for the Werry Workforce Wharaurau 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.

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| **Mrs Phyllis Huitema** |
| Membership category: | Consumer / Community representative |
| Date of appointment: | 19 May 2014 |
| Current term expires: | 19 May 2017 |

Mrs Huitema works as Convenor /Chair of Professional Conduct Committees who work under the Health Practitioners Competence Act 2003, a role she has had since 1996. She also had a Community Liaison role with the Neurological Foundation of New Zealand and has been a lay member of the Dr Mercia Barnes Trust since 2002. Mrs Huitema has been a Justice of the Peace since 1999 and has also held roles on a number of national and local health-related Ethics Committees.

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| **Miss Tangihaere MacFarlane** |
| Membership category: | Consumer / Cultural representative |
| Date of appointment: | 19 May 2014 |
| Current term expires: | 19 May 2017 |

Miss Macfarlane (Te Arawa, Ngāti Whakaue, Ngāti Pikiao, Ngāti Rangiwewehi) is Quality and Risk Manager, Complaints Officer and Privacy Officer at Te Roopu Taurima O Manukau Trust (2011 – present). She has previously held positions on the Lakes District Health Board Community & Public Health Advisory Committee (2001 – 2007), Te Kotahitanga o Te Arawa Fisheries Trust (2004 – 2013), and Te Roopu Hauora o Te Arawa Trust (2001 – 2007). Miss Macfarlane has completed a Bachelor of Health Science (2007) and a Diploma in Māori Business (2004), among other studies.

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| **Mr John Hancock** |
| Membership category: | The Law |
| Date of appointment: | 14 Dec 2015 |
| Current term expires: | 14 Dec 2018 |

John Hancock is an Auckland lawyer who specialises in child, youth and human rights related law and public policy. He was formally Principal Solicitor at YouthLaw in Auckland, Principal Advisor (Legal) at the Office of the Children's Commissioner and a Youth Advocate practising in the Auckland Youth Court. He is currently Senior Legal Adviser at the Human Rights Commission. He also has held advocacy, governance and leadership roles in non-government and community-based organisations and statutory committees.

### Non-lay members

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| **Mrs Stephanie Pollard** |
| Membership category: | Health researcher |
| Date of appointment: | 14 Dec 2015  |
| Current term expires: | 14 Dec 2018  |

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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| **Mrs Lessa Russell** |
| Membership category: | Intervention / Observation studies  |
| Date of appointment: | 14 Dec 2015 |
| Current term expires: | 14 Dec 2018 |

Leesa Russell is currently Quality Lead for Specialist Medicine and Health of Older People at Waitemata District Health Board and is studying towards a Post-Graduate Diploma in Quality Systems at Massey University. She has previously worked with the New Zealand Cardiac Network, the National Cardiac Surgical Clinical Network and the Cancer Treatments Advisory Group Hematology Oncology Working Group as national coordinator. She completed a BA (2002) and MA (2004) at University of Auckland, focusing on Sociology of Medicine and writing on the effect of policy changes on the personal and professional lives of General Practitioners in Auckland. Mrs Russell has been involved in clinical research, quality improvement and at the Health Research Council as Executive Secretary to the HRC Ethics Committee and Data Monitoring Committee. In 2006 she received Research Fellowship for her work on the cognitive affects of elective surgery on older adults. On return from maternity leave in 2013, Mrs Russell managed a year long national implementation project in the fertility industry prompted by a change in legislation and obtained a management position in quality and process improvement as a result. She went on to manage Clinical Audit at St John. She holds (lapsed) accreditation for Spirometery and Phlebotomy competencies and has previously volunteered as a First Responder (Waiuku Station). She previously held a role in the NZACRES executive and membership of the Cardiac Society of New Zealand.

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| **Dr Nora Lynch** |
| Membership category: | Intervention studies  |
| Date of appointment: | 1 July 2015 |
| Current term expires: | 1 July 2018 |

Dr Nora Lynch MBChB (Auckland 1979) MMed (Melb. 1987) FRACP 1986, PGCert Public Health (Auckland 2016). Nora is a physician specialising in rheumatology who consulted in both the public and private sectors until 2014. She has held a number of professional advisory roles and leadership positions including member of the Core Services Consensus Development Panel for hip and knee replacement (1995),member of the Royal Australasian College Physicians Specialist Advisory Committee for rheumatology training (1998-2004), executive member (1995–2006) and President (2006–2008) of the New Zealand Rheumatology Association, member PTAC Rheumatology Subcommittee (2010–2014 ), member on the Australasian 3e panel (Evidence, Expertise and Exchange) that prepared treatment guidelines for local specialist use (2010–2013) and member of the North Shore CMA governance team 2015-present. She returned to Auckland University in 2015 where she completed a Postgraduate Certificate in Public Health and is currently undertaking a Graduate Diploma in History.

## Attendance

The Northern B HDEC held 9 meetings in 2016.

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| **Members** | **Meetings (Northern B HDEC) Jan – Dec 2016** | **Total** |
| Jan | Feb | March | Apr | May | June | July | Aug | Sept | Oct | Nov | Dec |  |
| Lay members | E | Mrs Kate O’Connor |  | **✓** | **✓** | **✓** |  | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** |  | 8/9 |
| Cm | Mrs Maliaga Erick |  | ***A*** | ***A*** | ***A*** |  | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** |  | 5/9 |
| Cn | Mrs Phyllis Huitema |  | **✓** | **✓** | **✓** |  | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** |  | 8/9 |
| Cn  | Ms Tangihare MacFarlane |  | **✓** | **✓** | **✓** |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 9/9 |
| L | Mr John Hancock |  | **✓** | **✓** | **✓** |  | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** |  | 8/9 |
| Cn | Dr Kate Parker (Co-opted from NTA Committee) |  | **✓** |  |  |  |  |  |  | **✓** |  |  |  | 2/2 |
| Cm | Shamim Chagani (Co-opted from NTA Committee) |  |  |  |  |  |  |  | **✓** |  |  |  |  | 1/1 |
| Cm | Brian Fergus (Co-Opted from NTA Committee) |  |  |  |  |  |  |  |  |  | **✓** |  |  | 1/1 |
| Non-lay members | HR | Mrs Stephanie Pollard |  | **✓** | ***A*** | **✓** |  | **✓** | ***A*** | ***A*** | **✓** | **✓** | **✓** |  | 6/9 |
| HR | Mrs Leesa Russell |  | **✓** | **✓** | **✓** |  | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** |  | 8/9 |
| HP | Dr Nora Lynch |  | **✓** | ***A*** | **✓** |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 7/9 |
| HR | Dr Nicola Swain (Co-opted from STH HDEC) |  |  | **✓** |  |  |  |  |  |  |  |  |  | 1/1 |
| HR | Dr Patries Herst (Co-opted from CEN Committee) |  |  |  |  |  |  | **✓** |  |  |  |  |  | 1/1 |
| HR | Dr Melissa Cragg (Co-opted from CEN 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

HDEC members were invited to attend the following conferences in 2016:

* Annual Conference of the New Zealand Association of Clinical Research

New Member Training was held in March 2016.

This training day covered the following topics:

• Why do we need ethics committees? A history of health research ethics in New Zealand and the current ethics landscape

• Ethical principles and underlying ethical considerations

• The HDEC Processes

• Use of Health Information

• Use of Tissue and Bio-banking

• Future Unspecified Research

• Informed Consent

• Non-consensual Research

• Vulnerable Populations and Studies Involving Children

• Māori and Indigenous Health Development

• Scientific Merit and Peer Review.

Contributors included:

• Associate Professor Martin Wilkinson (National Ethics Advisory Committee)

• Dr Karen Bartholomew (Member, Northern A Committee)

• Dr Angela Ballantyne (Member, Central Committee)

• Nic Aagaard and Philippa Bascand (Ministry of Health)

• Dr Helen Wihongi (ADHB Research Office).

A handbook was developed for new members and sent out prior to the new member training.

### Details of on-going training for EC members

Pre-meeting training was conducted before a number of meetings throughout the year.

Topics covered included:

• Ethical Features of Health Research

• Use of Health Information for Research

• Non-consensual Research.

## Chairpersons’ meetings

There were two Chairs’ day meetings in 2016. The first meeting was on 29 May and the second meeting was on 1 November. The meetings were held at the Ministry of Health offices in Freyberg Building and Molesworth Street in Wellington. Mrs O’Connor attended two meetings.

# Applications reviewed

The Northern B HDEC received 151 applications in 2016. From the 151 applications 84 applications were reviewed by the full committee and 67 were reviewed through the expedited pathway.

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| --- | --- | --- |
| Full | Approved | 68 |
| Declined | 9 |
| Provisional Approval (as at 31 December 2016) | 7 |
| *Total (with a decision at 31 December 2016)* | 84 |
| Expedited | Approved | 60 |
| Declined | 2 |
| Provisional Approval (as at 31 December 2016) | 5 |
| *Total (with a decision at 31 December 2016)* | 67 |
| **Total applications reviewed** | **151** |

A summary of these applications can be found in Appendix 1.

**Complaints and overdue application summary**

This section outlines complaints about decisions made by the Committee during 2016.

## Complaints received

**Ethics reference:** 16/NTB/36

**Study title:** Hepatitis C sero prevalence study in Northland

**Co-ordinating Investigator:** Dr Arlo Upton

Following a decline decision Northern B HDEC received a complaint in April 2016 about the process of review by the committee for a Hepatitis C sero prevalence study in Northland. The complaint centered on natural justice provisions and impartiality. The complaint also raised the question of whether the committee was quorate at the time of meeting when issuing its decision.

Northern B HDEC was quorate on the day of the meeting and when issuing its decision. The committee had co-opted a non-lay member, Dr Nicola Swain, who attended by telephone. The committee undertook a review of the application decision and the information supplied to the committee, including meeting with the researcher and inviting in writing the researcher to re-submit the application for further review.

The researcher re-submitted the application to Northern B for further review with additional information. The application was provisionally approved by the committee. The researcher later decided to withdraw the study due to the conditions attached to the provisional approval.

## Overdue review

During 2016 there were 24 instances where the review time was over 35 days for full applications and 22 where the review time was over 15 days for expedited applications.

See Appendix 1 for more information.

# Appendix 1: Details of applications reviewed[[1]](#footnote-1)

## Applications reviewed by full committee

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study reference | Study status | Short title | Co-ordinating investigator | Application type | Date application validated | Date of first decision | Provisional response received | Date of final decision |
| 16/NTB/12 | Approve | Lactoferrin Infant Feeding Trial | Dr Nicola Austin | Intervention | 21/01/2016 | 10/02/2016 | 7/03/2016 | 21/03/2016 |
| 16/NTB/13 | Approve | TicToc | Dr John McMenamin | Intervention | 21/01/2016 | 10/02/2016 | 14/03/2016 | 21/03/2016 |
| 16/NTB/15 | Approve | TARGET3D | Prof Edward Gane | Intervention | 21/01/2016 | 10/02/2016 | 15/03/2016 | 21/03/2016 |
| 16/NTB/18 | Approve | Community-based group anxiety treatment | Dr Jennifer Jordan | Intervention | 21/01/2016 |  |  | 10/02/2016 |
| 16/NTB/23 | Approve | ATHENA | Dr Stephen Best | Intervention | 21/01/2016 | 10/02/2016 | 8/04/2016 | 18/04/2016 |
| 16/NTB/24 | Approve | A Phase 2 Study of Abemaciclib in Patients with Brain Metastases Secondary to Hormone Receptor Positive Breast Cancer, Non-Small Cell Lung Cancer or Melanoma | Dr Rosalie Fisher | Intervention | 21/01/2016 | 10/02/2016 | 19/02/2016 | 1/03/2016 |
| 16/NTB/4 | Approve | Immune effects of Oral Insulin (TN20) | Professor Russell Scott | Intervention | 21/01/2016 | 10/02/2016 | 10/05/2016 | 20/05/2016 |
| 16/NTB/33 | Approve | ASD2 Study | Dr Ian Crozier | Intervention | 18/02/2016 | 14/03/2016 | 7/04/2016 | 18/04/2016 |
| 16/NTB/35 | Approve | FibUpFront PPH | Dr Joreline (Jay) Van Der Westhuizen | Intervention | 18/02/2016 | 14/03/2016 | 24/03/2016 | 7/04/2016 |
| 16/NTB/36 | Decline | HCV sero-prevalence in Northland | Dr Arlo Upton | Observational | 18/02/2016 |  |  | 14/03/2016 |
| 16/NTB/37 | Approve | Outcomes Study of Persona Knee System in Total Knee Arthroplasty | Mr Neville Strick | Observational | 18/02/2016 |  |  | 14/03/2016 |
| 16/NTB/38 | Approve | Impact of Charcot-Marie-Tooth disease in the Auckland Region of New Zealand (ImpactCMT) | Dr Alice Theadom | Observational | 18/02/2016 | 14/03/2016 | 15/03/2016 | 18/04/2016 |
| 16/NTB/48 | Approve | Study of the Investigational Drug Avelumab in Patients with Advanced Renal Cell Carcinoma | Dr Alvin Tan | Intervention | 23/03/2016 | 13/04/2016 | 4/07/2016 | 19/07/2016 |
| 16/NTB/50 | Decline | Consolidation of the Four Breast Cancer Registers | Dr Reena Ramsaroop | Observational | 23/03/2016 | 13/04/2016 | 12/07/2016 | 25/07/2016 |
| 16/NTB/55 | Decline | Wellington Stroke Outcomes Study - have patient outcomes after stroke changed in 18 years? | Dr Harry McNaughton | Observational | 23/03/2016 |  |  | 13/04/2016 |
| 16/NTB/57 | Approve | PREVARID- Prevention of Respiratory Infections with Vitamin D | Associate Professor Cameron Grant | Intervention | 23/03/2016 | 13/04/2016 | 17/05/2016 | 18/05/2016 |
| 16/NTB/60 | Approve | Comparison of the blood levels of two forms of imatinib tablet in healthy male volunteers under fed conditions | Dr Noelyn Hung | Intervention | 23/03/2016 |  |  | 15/04/2016 |
| 16/NTB/61 | Approve | Comparison of the blood levels of two forms of buprenorphine 20 mcg/hr transdermal patch in healthy male and female volunteers over 22 days in each study period | Dr Noelyn Hung | Intervention | 23/03/2016 | 15/04/2016 | 22/04/2016 | 11/05/2016 |
| 16/NTB/62 | Approve | PLUS Study - Plasma-Lyte 148® versus Saline Study | Dr Paul Young | Intervention | 23/03/2016 |  |  | 15/04/2016 |
| 16/NTB/63 | Approve | M13-542 A study comparing ABT-494 to Placebo in subjects with moderately to severe Rheumatoid Arthritis with Inadequate response to Biologic Disease Modifying Anti-Rheumatic Drugs (bDMARDS) | Dr Daniel Ching | Intervention | 23/03/2016 | 13/04/2016 | 11/05/2016 | 30/05/2016 |
| 16/NTB/64 | Approve | Persistent airflow limitation and the airway microbiome in childhood asthma | Prof Jeroen Douwes | Observational | 23/03/2016 | 15/04/2016 | 13/06/2016 | 27/06/2016 |
| 16/NTB/82 | Approve | 64294178HPC2001: A Phase 2 study of Different Treatment Combinations of AL-335, odalasvir and simeprevir in subjects with chronic hepatitis C virus infection | Prof Edward Gane | Intervention | 25/05/2016 | 13/06/2016 | 4/07/2016 | 26/07/2016 |
| 16/NTB/96 | Approve | A Study of ALN-HBV in Healthy Adult Subjects and Non-cirrhotic Patients with Chronic Hepatitis B Virus | Prof. Edward Gane | Intervention | 25/05/2016 | 13/06/2016 | 20/07/2016 | 15/08/2016 |
| 16/NTB/98 | Approve | SuDDICU-ANZ | Dr Paul Young | Intervention | 25/05/2016 | 13/06/2016 | 17/06/2016 | 26/07/2016 |
| 16/NTB/86 | Approve | Holter recording in long QT syndrome | Dr Kathryn Waddell-Smith | Observational | 26/05/2016 | 13/06/2016 | 27/06/2016 | 6/07/2016 |
| 16/NTB/89 | Approve | Feasibility study of an oral device to promote weight loss | Prof. Paul Brunton | Intervention | 26/05/2016 | 13/06/2016 | 21/07/2016 | 24/07/2016 |
| 16/NTB/91 | Approve | Comparison of the blood levels of two forms of tadalafil 20 mg tablets in healthy male volunteers under fed conditions | Dr Noelyn Hung | Intervention | 26/05/2016 | 13/06/2016 | 1/07/2016 | 25/07/2016 |
| 16/NTB/92 | Approve | STAR-120-SIES | Dr Trevor B Gray | Intervention | 26/05/2016 | 13/06/2016 | 29/06/2016 | 24/07/2016 |
| 16/NTB/93 | Approve | Study of Avelumab in Patients with Locally Advanced or Metastatic Urothelial Cancer | Dr Peter Fong | Intervention | 26/05/2016 | 13/06/2016 | 9/08/2016 | 30/08/2016 |
| 16/NTB/94 | Approve | A study to evaluate the long-term safety and efficacy of intravenous Alphal-Proteinase Inhibitor in adults with emphysema | Dr Jeffrey Garrett | Intervention | 26/05/2016 |  |  | 13/06/2016 |
| 16/NTB/95 | Approve | Te Ara Hā: Asthma Self-Management Programme | Dr Tristram Ingham | Intervention | 26/05/2016 | 13/06/2016 | 1/07/2016 | 3/08/2016 |
| 16/NTB/97 | Approve | Sentimag use for sentinel node biopsy | Dr Ahrin Anna Morrow | Intervention | 26/05/2016 | 13/06/2016 | 6/09/2016 | 28/09/2016 |
| 16/NTB/99 | Decline | Study to Improve Adherence to Type 2 Diabetes Oral Medications Through Personalised Multi-Channel Interventions | Dr Jodie Main | Intervention | 26/05/2016 |  |  | 13/06/2016 |
| 16/NTB/111 | Approve | HET vs RBL Trial | Dr Rhys Filgate | Intervention | 23/06/2016 | 13/07/2016 | 2/08/2016 | 19/08/2016 |
| 16/NTB/113 | Decline | (duplicate) A rapid non drug treatment for anxiety- the rapid symptom shifting therapy | Professor Bruce Arroll | Intervention | 23/06/2016 |  |  | 13/07/2016 |
| 16/NTB/114 | Decline | Effect of not fasting prior to coronary angiography and/or percutaneous coronary intervention on the incidence of vomiting and aspiration during the procedure | Prof Mark Webster | Intervention | 23/06/2016 |  |  | 13/07/2016 |
| 16/NTB/115 | Approve | A Novel Nanosensor array for Heart Failure diagnosis | Dr Patrick Gladding | Observational | 23/06/2016 | 13/07/2016 | 20/07/2016 | 22/08/2016 |
| 16/NTB/116 | Approve | LSFACT | A/Prof Jonathan Koea | Intervention | 23/06/2016 | 13/07/2016 | 25/07/2016 | 23/08/2016 |
| 16/NTB/117 | Approve | A study to determine the relative bioavailability of ACH-0144471 after administration of a tablet or softgel capsule vs. a liquid filled capsule in healthy volunteers | Dr Paul Hamilton | Intervention | 23/06/2016 | 13/07/2016 | 14/07/2016 | 26/07/2016 |
| 16/NTB/119 | Approve | Efficacy of neutral electrolytically activated water use in patients with chronic rhino sinusitis | Dr James Johnston | Intervention | 23/06/2016 |  |  | 13/07/2016 |
| 16/NTB/120 | Approve | MAKO RAPTOR study (Robot Assisted Partial vs. Total knee Replacement) | Mr Simon Young | Intervention | 23/06/2016 | 13/07/2016 | 12/10/2016 | 4/11/2016 |
| 16/NTB/121 | Approve | The CogEx Trial | Miss Elizabeth Binns | Intervention | 23/06/2016 | 13/07/2016 | 2/08/2016 | 23/08/2016 |
| 16/NTB/122 | Approve | A multi-site, open-label extension trial of RPC1063 in relapsing MS | Dr Deborah F Mason | Intervention | 23/06/2016 |  |  | 13/07/2016 |
| 16/NTB/126 | Approve | REMOVAL-HD trial | Dr Colin Hutchison | Intervention | 21/07/2016 | 15/08/2016 | 15/11/2016 | 12/12/2016 |
| 16/NTB/127 | Approve | Human genetic susceptibility to Legionella Infection | Dr Sandy Slow | Observational | 21/07/2016 | 15/08/2016 | 30/09/2016 | 17/10/2016 |
| 16/NTB/128 | Decline | Superficial infection rate between proud and buried K-wire fixation for distal humerus supracondylar fracture | Dr Chuan Kong Koh | Intervention | 21/07/2016 |  |  | 15/08/2016 |
| 16/NTB/129 | Approve | Open-label, randomised trial to evaluate the efficacy and safety of MOR00208 with bendamustine (BEN) versus rituximab (RTX) with BEN in adult patients with R-R DLBCL | Dr Samar Issa | Intervention | 21/07/2016 | 15/08/2016 | 14/09/2016 | 23/09/2016 |
| 16/NTB/132 | Approve | A study evaluating how GS-9674 is cleared by the body, in adults with normal and reduced liver function | Prof Edward Gane | Intervention | 21/07/2016 | 12/08/2016 | 23/08/2016 | 30/08/2016 |
| 16/NTB/133 | Approve | LTI01-1001; Phase 1 LTI­01 study in CPE/Empyema patients | Professor John Kolbe | Intervention | 21/07/2016 | 15/08/2016 | 31/08/2016 | 5/09/2016 |
| 16/NTB/135 | Approve | iCST | Dr Gary Cheung | Intervention | 21/07/2016 | 12/08/2016 | 18/08/2016 | 31/08/2016 |
| 16/NTB/140 | Approve | A rapid non drug treatment for anxiety- the rapid symptom shifting therapy | Professor Bruce Arroll | Intervention | 25/08/2016 | 14/09/2016 | 19/09/2016 | 20/09/2016 |
| 16/NTB/141 | Approve | Genomic mechanisms underlying long‐term response to treatment in serous ovarian cancer | Doctor Bryony Simcock | Observational | 25/08/2016 | 14/09/2016 | 9/11/2016 | 16/11/2016 |
| 16/NTB/143 | Approve | Evaluation of MORSim (Multidisciplinary Operating Room Simulation) | Dr Peter Beaver | Observational | 25/08/2016 | 14/09/2016 | 22/08/2016 | 3/10/2016 |
| 16/NTB/145 | Decline | Antibiotic Timing and Culture Yields in Paediatric Musculoskeletal Infection | Mr Matthew Boyle | Observational | 25/08/2016 |  | 17/08/2016 | 14/09/2016 |
| 16/NTB/151 | Approve | THRIVER-F | Professor Alan F Merry | Intervention | 25/08/2016 | 14/09/2016 | 16/09/2016 | 27/09/2016 |
| 16/NTB/152 | Approve | MK-8521 Phase IIa Trial in Subjects with Type 2 Diabetes Mellitus (protocol MK-8521-004) | Dr Simon Carson | Intervention | 25/08/2016 | 14/09/2016 | 17/10/2016 | 4/11/2016 |
| 16/NTB/153 | Approve | The FAB study | Dr Rachael Parke | Intervention | 25/08/2016 | 14/09/2016 | 16/09/2016 | 27/09/2016 |
| 16/NTB/154 | Approve | A study to evaluate safety and tolerability of GS -5801 in healthy subjects | Prof Edward Gane | Intervention | 25/08/2016 | 14/09/2016 | 16/09/2016 | 19/09/2016 |
| 16/NTB/155 | Approve | Comparison of the blood levels of two forms of clobazam suspension in healthy male and female volunteers under fasting conditions | Dr Noelyn Hung | Intervention | 25/08/2016 |  |  | 14/09/2016 |
| 16/NTB/156 | Approve | Comparison of the blood levels of two forms of clobazam suspension in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | Intervention | 25/08/2016 |  |  | 15/09/2016 |
| 16/NTB/157 | Approve | The prognostic significance of immune cell infiltrates in meningioma | Dr Clinton Turner | Observational | 25/08/2016 | 15/09/2016 | 4/11/2016 | 10/11/2016 |
| 16/NTB/166 | Approve | Denosumab in addition to ULT for Bone Erosions in Gout | Prof Nicola Dalbeth | Intervention | 22/09/2016 | 11/10/2016 | 9/12/2016 | 13/12/2016 |
| 16/NTB/167 | Decline | Increasing retention in an alcohol and other drug therapeutic community | Mrs Jo Willcocks | Intervention | 22/09/2016 |  |  | 11/10/2016 |
| 16/NTB/168 | Provisionally approve | A Global Study Characterising the Safety and Tolerability of Anifrolumab in Participants with Active Systemic Lupus Erythematosus | Dr Alan Doube | Intervention | 22/09/2016 | 11/10/2016 |  |  |
| 16/NTB/171 | Approve | MK-3475-365 | Dr Peter Fong | Intervention | 22/09/2016 | 11/10/2016 | 31/10/2016 | 31/10/2016 |
| 16/NTB/172 | Provisionally approve | PROMOTE-SAH Study | Ms Lynette Newby | Observational | 22/09/2016 | 11/10/2016 |  |  |
| 16/NTB/173 | Approve | Work-related risk factors for CVD | Prof Jeroen Douwes | Observational | 22/09/2016 |  |  | 11/10/2016 |
| 16/NTB/174 | Approve | Developing HABITs | Professor Sally N. Merry | Observational | 22/09/2016 |  |  | 11/10/2016 |
| 16/NTB/176 | Approve | A Phase 1a/1b study of ABI-H0731 in healthy volunteers and patients with chronic hepatitis B | Professor Ed Gane | Intervention | 22/09/2016 | 11/10/2016 | 19/10/2016 | 25/10/2016 |
| 16/NTB/177 | Approve | Filgotinib in Combination With Methotrexate in Adults With Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Methotrexate | Dr Daniel Ching | Intervention | 22/09/2016 | 11/10/2016 | 8/11/2016 | 22/11/2016 |
| 16/NTB/178 | Approve | MK-3862-041: Study of Efficacy and Safety of MK-3682 + MK-8408 in Subjects with Chronic HCV | Prof Edward Gane | Intervention | 22/09/2016 | 11/10/2016 | 25/10/2016 | 1/11/2016 |
| 16/NTB/179 | Approve | Filgotinib + MTX vs Filgotinib alone vs MTX alone | Dr Daniel Ching | Intervention | 22/09/2016 | 11/10/2016 | 8/11/2016 | 16/11/2016 |
| 16/NTB/181 | Approve | CO39262: Vemurafenib, cobimetinib & atezolizumab triplet combination in advanced melanoma | Dr Richard North | Intervention | 22/09/2016 | 11/10/2016 | 31/10/2016 | 4/11/2016 |
| 16/NTB/186 | Approve | Tackling Preterm | Dr Beverley Lawton | Observational | 27/10/2016 |  |  | 17/11/2016 |
| 16/NTB/190 | Approve | Nasal Mesh Nebulizer Study | A/ Prof Richard Douglas | Intervention | 27/10/2016 | 17/11/2016 | 24/11/2016 | 13/12/2016 |
| 16/NTB/192 | Provisionally approve | D5290C00003 | Dr. Thorsten Villiers Stanley | Intervention | 27/10/2016 | 17/11/2016 | 19/12/2016 |  |
| 16/NTB/193 | Approve | Measuring changes in vaginal pressure before and after prolapse surgery | Dr Jennifer Kruger | Observational | 27/10/2016 |  |  | 17/11/2016 |
| 16/NTB/197 | Approve | A study to examine the safety and tolerability of the trial drug Brincidofovir in healthy adults and in adults | Dr Chris Wynne | Intervention | 27/10/2016 |  |  | 17/11/2016 |
| 16/NTB/199 | Approve | A study to examine the safety and tolerability of the trial drugs REGN2477 alone and in combination with REGN1033 in healthy postmenopausal women | Dr Chris Wynne | Intervention | 27/10/2016 | 17/11/2016 | 21/11/2016 | 28/11/2016 |
| 16/NTB/201 | Provisionally approve | The value of periwound LA for post-operative anaelgesia of patients undergoing total hip joint replacement | Dr David Kieser | Intervention | 27/10/2016 | 17/11/2016 |  |  |
| 16/NTB/202 | Provisionally approve | Local anesthetic administration in NOF# closed reduction and internal fixation | Dr David Kieser | Intervention | 27/10/2016 | 17/11/2016 |  |  |
| 16/NTB/205 | Provisionally approve | XPEDITE | Associate Professor Andrew Holden | Intervention | 27/10/2016 | 17/11/2016 | 8/12/2016 |  |
| 16/NTB/208 | Provisionally approve | CHYLD Study at 9 years | Professor Jane Harding | Observational | 27/10/2016 | 17/11/2016 | 16/12/2016 |  |
| 16/NTB/209 | Approve | A study to evaluate safety and tolerability of GS-9688 in healthy subjects | Prof Edward Gane | Intervention | 27/10/2016 | 17/11/2016 | 18/11/2016 | 21/11/2016 |

## Applications reviewed by expedited review

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| Study reference | Study status | Short title | Co-ordinating investigator | Application type | Date application validated | Date of first decision | Provisional response received | Date of final decision |
| 16/NTB/10 | Approve | Cancer stem cells and regulatory systems in urological cancers | Dr Tinte Itinteang | Observational | 18/01/2016 |  |  | 1/02/2016 |
| 16/NTB/100 | Approve | Review of Newborn Screening for Cystic Fibrosis in New Zealand | Dr Catherine Byrnes | Observational | 26/05/2016 |  |  | 5/06/2016 |
| 16/NTB/101 | Approve | Ka Mau Te Wehi: Weight Loss: Eating Healthy & Increasing Exercise | Associate Professor Marewa Glover | Intervention | 3/06/2016 | 20/06/2016 | 1/07/2016 | 5/07/2016 |
| 16/NTB/102 | Approve | RA video joint count training | Dr Rebecca Grainger | Intervention | 8/06/2016 | 20/06/2016 | 1/07/2016 | 5/07/2016 |
| 16/NTB/105 | Approve | Mobile Mindfulness Meditation in Student Health Services Users | Ms Jayde Flett | Intervention | 10/06/2016 |  |  | 20/06/2016 |
| 16/NTB/107 | Approve | Enhanced DRP identification and improved outcomes at discharge | Dr Rhiannon Braund | Intervention | 14/06/2016 | 24/06/2016 | 12/08/2016 | 15/08/2016 |
| 16/NTB/11 | Approve | Health care utilisation of people with severe COPD | Prof. Tim Stokes | Observational | 18/01/2016 |  |  | 21/01/2016 |
| 16/NTB/110 | Decline | Effects of Shuzi Technology on Inflammation | Ms Desiree De Spong | Intervention | 15/06/2016 | 22/06/2016 | 21/07/2016 | 25/07/2016 |
| 16/NTB/123 | Approve | An Investigation of Human Papillomavirus in disease of the prostate | Dr Brian Damian Pethica | Observational | 28/06/2016 | 5/07/2016 | 7/07/2016 | 11/07/2016 |
| 16/NTB/125 | Approve | Bulbospongiosus function | Dr Omid Yassaie | Observational | 6/07/2016 | 19/07/2016 | 29/09/2016 | 3/10/2016 |
| 16/NTB/130 | Approve | INSIGHT | Dr Michelle Wilson | Observational | 15/07/2016 | 19/07/2016 | 21/07/2016 | 24/07/2016 |
| 16/NTB/136 | Approve | Regional analysis of the accuracy of the SkinVision smartphone application in recognising skin cancer lesions | Assoc Prof Amanda Oakley | Observational | 26/07/2016 | 12/08/2016 | 25/10/2016 | 26/10/2016 |
| 16/NTB/137 | Approve | Psychosocial impact of nasograstric tube feeding in the adolescent oncology patient | Doctor Awras Majeed | Observational | 28/07/2016 | 12/08/2016 | 1/11/2016 | 3/11/2016 |
| 16/NTB/138 | Approve | Isolation and Stimulation of iNKT cells in Diabetes and Obesity | Associate Professor Jeremy Krebs | Observational | 3/08/2016 | 29/08/2016 | 23/09/2016 | 26/09/2016 |
| 16/NTB/139 | Approve | Measurement of nivolumab and pembrolizumab in patients | Dr. Robert Matthew Strother | Observational | 1/08/2016 | 12/08/2016 | 16/09/2016 | 23/09/2016 |
| 16/NTB/148 | Approve | CARE 2 | Dr Fiona Miles | Observational | 23/08/2016 | 31/08/2016 | 2/09/2016 | 5/09/2016 |
| 16/NTB/160 | Approve | Characterizing lung mechanics in mechanically ventilated neonates | Doctor Bronwyn Dixon | Observational | 26/08/2016 | 5/09/2016 | 7/09/2016 | 13/09/2016 |
| 16/NTB/161 | Approve | PaNTS Study | Ms Silvia Marinone | Observational | 31/08/2016 | 12/09/2016 | 16/09/2016 | 23/09/2016 |
| 16/NTB/163 | Approve | 5 year outcome of CMDHB Grave’s disease patients | Dr Hee Jong (Jessica) Lee | Observational | 14/09/2016 | 27/09/2016 | 12/12/2016 | 13/12/2016 |
| 16/NTB/164 | Approve | Communicating bad news in health: Improving the experiences of patients, patients’ family/whānau and health professionals | Ms Tamyra Matthews | Observational | 16/09/2016 | 27/09/2016 | 11/10/2016 | 12/10/2016 |
| 16/NTB/165 | Approve | Māori Engagement with Mental Health Services | Miss Amelia Backhouse-Smith | Observational | 15/09/2016 | 27/09/2016 | 25/10/2016 | 31/10/2016 |
| 16/NTB/175 | Approve | E-screening in pregnancy | Dr Tanya Wright | Observational | 20/09/2016 | 27/09/2016 | 1/12/2016 | 11/12/2016 |
| 16/NTB/180 | Approve | DAy DREaMS | Ms. Gayl Humphrey | Observational | 29/09/2016 |  |  | 12/10/2016 |
| 16/NTB/183 | Approve | Mindfulness phone app for patients with brain tumours | Dr Claudio De Tommasi | Intervention | 3/10/2016 |  |  | 12/10/2016 |
| 16/NTB/184 | Approve | ProFood Study | Dr Thorsten Stanley | Intervention | 5/10/2016 | 17/10/2016 | 18/11/2016 | 30/11/2016 |
| 16/NTB/187 | Approve | Antibiotic education | Dr Stephen Ritchie | Observational | 11/10/2016 | 25/10/2016 | 11/11/2016 | 16/11/2016 |
| 16/NTB/188 | Approve | Quality of Vision | Dr. Dean Corbett | Observational | 17/10/2016 | 25/10/2016 | 4/11/2016 | 10/11/2016 |
| 16/NTB/189 | Approve | The costs of eating disorders in New Zealand | Dr Jennifer Jordan | Observational | 17/10/2016 | 26/10/2016 | 2/11/2016 | 7/11/2016 |
| 16/NTB/191 | Approve | Do diagnoses change between admission and discharge? | Dr Laura Chapman | Observational | 17/10/2016 | 26/10/2016 | 21/11/2016 | 30/11/2016 |
| 16/NTB/194 | Approve | Pupillometry, EEG and postoperative pain | Dr Amy Gaskell | Observational | 20/10/2016 | 28/10/2016 | 1/11/2016 | 7/11/2016 |
| 16/NTB/196 | Approve | High-Resolution Mapping of Gastrointestinal Electrical Activity | Professor Ian Bissett | Observational | 21/10/2016 | 1/11/2016 | 4/11/2016 | 10/11/2016 |
| 16/NTB/2 | Approve | The impact of the introduction of a point of care haematology analyser at Rawene Hospital | Dr Katharina Blattner | Observational | 18/01/2016 | 21/01/2016 | 25/01/2016 | 1/02/2016 |
| 16/NTB/207 | Approve | NHF vs NIV in COPD patients with chronic respiratory failure | Dr James Fingleton | Intervention | 27/10/2016 | 4/11/2016 | 11/11/2016 | 16/11/2016 |
| 16/NTB/213 | Approve | Concussion and whiplash: a comparison of neck magnetic resonance imaging features | Dr Ewan Kennedy | Observational | 21/11/2016 | 9/12/2016 | 19/12/2016 | 22/12/2016 |
| 16/NTB/214 | Provisionally approve | Incidence of forearm diaphyseal fracture in the Auckland population | Dr Rushi chandar Penumarthy | Observational | 21/11/2016 | 11/12/2016 |  |  |
| 16/NTB/215 | Provisionally approve | Mitochondrial Disease: The NZ Experience | Dr Sarah Missen | Observational | 21/11/2016 | 11/12/2016 |  |  |
| 16/NTB/216 | Provisionally approve | An Assessment of Antenatal Corticosteroids in Women with Diabetes in Pregnancy | Dr Jeremy Tuohy | Observational | 24/11/2016 | 11/12/2016 |  |  |
| 16/NTB/217 | Decline | SCATBI NZ Norms | Mrs Jessica Gardiner | Observational | 28/11/2016 |  |  | 12/12/2016 |
| 16/NTB/218 | Provisionally approve | Abdominal Tuberculosis | Dr Simon Dalton | Observational | 29/11/2016 | 12/12/2016 |  |  |
| 16/NTB/219 | Provisionally approve | Identification of cardiovascular disease biomarkers in New Zealand | Associate Professor Greg Jones | Observational | 5/12/2016 | 12/12/2016 |  |  |
| 16/NTB/22 | Approve | Pelvimetric measurements variations between Māori and European Males | Dr Rajeev Patel | Observational | 22/01/2016 | 1/02/2016 | 4/03/2016 | 8/03/2016 |
| 16/NTB/26 | Approve | PneumoINSPIRE | Dr Paul Young | Observational | 25/01/2016 | 2/02/2016 | 2/02/2016 | 10/02/2016 |
| 16/NTB/27 | Approve | The Newborn Ethnicity Project | Dr Lynn Sadler | Observational | 5/02/2016 |  |  | 22/02/2016 |
| 16/NTB/28 | Approve | Huarahi Hauora | MR RICKY BELL | Intervention | 12/02/2016 | 24/02/2016 | 8/04/2016 | 12/04/2016 |
| 16/NTB/29 | Approve | Whānau experiences of adverse perinatal events | Ms Kendall Stevenson | Observational | 12/02/2016 | 26/02/2016 | 15/03/2016 | 21/03/2016 |
| 16/NTB/3 | Approve | Examining the factors influencing decision-making amongst End-Stage Renal Disease (ESRD) patients considering asking family and friends for a kidney | Ms Merryn Jones | Observational | 18/01/2016 | 21/01/2016 | 10/03/2016 | 21/03/2016 |
| 16/NTB/34 | Approve | Prevalence of Obstructive Sleep Apnoea in an Inpatient Stroke Rehabilitaiton setting in Canterbury, NZ | dr sarah hawkins | Observational | 15/02/2016 |  |  | 29/02/2016 |
| 16/NTB/41 | Approve | Qualitative research on perceptions of maternal mental health services | Dr Ian Soosay | Observational | 17/02/2016 | 29/02/2016 | 1/03/2016 | 3/03/2016 |
| 16/NTB/43 | Approve | Exploration of why people do not complete pulmonary rehabilitation | Mrs Sarah Candy | Observational | 7/03/2016 | 21/03/2016 | 12/04/2016 | 18/04/2016 |
| 16/NTB/44 | Approve | Blood levels of lidocaine following topical application in the laryngopharynx | Dr Jacqueline Allen | Observational | 29/02/2016 |  |  | 10/03/2016 |
| 16/NTB/46 | Approve | Allogeneic and autologous serum eye drops | Dr Krishna Badami | Observational | 11/03/2016 | 22/03/2016 | 5/04/2016 | 7/04/2016 |
| 16/NTB/47 | Approve | Rhinothermy in the common cold: a feasibility study | Dr James Fingleton | Intervention | 11/03/2016 |  |  | 21/03/2016 |
| 16/NTB/49 | Approve | The incidence, demographics and diagnostic clinical manifestations Juvenile Idiopathic Arthritis in Māori and Pacific Island children | Dr Anthony Concannon | Observational | 16/03/2016 |  |  | 29/03/2016 |
| 16/NTB/51 | Approve | SPRINT-SARI | Dr Colin McArthur | Observational | 16/03/2016 |  |  | 29/03/2016 |
| 16/NTB/53 | Approve | Implementation of the Safe Sleep Calculator in General Practice | Dr Christine McIntosh | Intervention | 16/03/2016 | 29/03/2016 | 11/04/2016 | 12/04/2016 |
| 16/NTB/59 | Approve | ISMV 2016 | Dr Rachael Parke | Observational | 23/03/2016 | 31/03/2016 | 18/04/2016 | 22/04/2016 |
| 16/NTB/67 | Approve | Blood ropivacaine levels following local infiltration analgesia for knee replacement | Dr Nicholas Lightfoot | Observational | 4/04/2016 |  |  | 18/04/2016 |
| 16/NTB/68 | Approve | Effect of maternal sleep position in small for gestational age pregnancy | Professor Peter R Stone | Observational | 6/04/2016 | 18/04/2016 | 21/04/2016 | 26/04/2016 |
| 16/NTB/70 | Approve | Generating Human Cell Models of Genetic Eye Disease | Dr. Andrea Vincent | Observational | 15/04/2016 | 22/04/2016 | 17/06/2016 | 24/06/2016 |
| 16/NTB/72 | Approve | A Retrospective review of Lupus Nephritis in Greater Auckland area | Dr Fei Xiong | Observational | 10/05/2016 | 16/05/2016 | 5/06/2016 | 7/06/2016 |
| 16/NTB/77 | Approve | HPV Self-Testing Acceptability | Dr Beverley Lawton | Observational | 2/05/2016 | 6/05/2016 | 10/05/2016 | 13/05/2016 |
| 16/NTB/78 | Approve | Prognostic importance of HbA1c in acute coronary syndrome | Dr Carl Peters | Observational | 3/05/2016 |  |  | 9/05/2016 |
| 16/NTB/79 | Approve | Brain Imaging in Obesity | A/Prof Patrick Manning | Observational | 5/05/2016 | 9/05/2016 | 18/05/2016 | 23/05/2016 |
| 16/NTB/80 | Approve | MAIT cells in HIV infection | Dr James Ussher | Observational | 5/05/2016 | 9/05/2016 | 13/05/2016 | 16/05/2016 |
| 16/NTB/81 | Approve | PREM NZ | Dr Alison Jackson | Observational | 13/05/2016 | 16/05/2016 | 20/05/2016 | 23/05/2016 |
| 16/NTB/84 | Approve | Shingles Burden: Older People South Auckland | Dr Elizabeth Tizzard | Observational | 16/05/2016 |  |  | 20/05/2016 |
| 16/NTB/85 | Approve | CEFS | \A/P Dr R Ross Kennedy | Observational | 18/05/2016 |  |  | 20/05/2016 |

## Overdue full applications

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| Reference | Short title | CI name | Review type | Decision | Days overdue | Reason overdue |
| 16/NTB/111 | HET vs RBL Trial | Dr Rhys Filgate | HDEC-Full Review | Approve | 2 | Committee Member Delay |
| 16/NTB/115 | A Novel Nanosensor array for Heart Failure diagnosis | Dr Patrick Gladding | HDEC-Full Review | Approve | 18 | Committee Member Delay |
| 16/NTB/116 | LSFACT | A/Prof Jonathan Koea | HDEC-Full Review | Approve | 14 | Committee Member Delay |
| 16/NTB/120 | MAKO RAPTOR study (Robot Assisted Partial vs. Total knee Replacement) | Mr Simon Young | HDEC-Full Review | Approve | 8 | Committee Member Delay |
| 16/NTB/121 | The CogEx Trial | Miss Elizabeth Binns | HDEC-Full Review | Approve | 6 | Committee Member Delay |
| 16/NTB/126 | REMOVAL-HD trial | Dr Colin Hutchison | HDEC-Full Review | Approve | 17 | Committee Member Delay |
| 16/NTB/127 | Human genetic susceptibility to Legionella Infection | Dr Sandy Slow | HDEC-Full Review | Approve | 7 | Committee Member Delay |
| 16/NTB/152 | MK-8521 Phase IIa Trial in Subjects with Type 2 Diabetes Mellitus (protocol MK-8521-004) | Dr Simon Carson | HDEC-Full Review | Approve | 3 | Committee Member Delay |
| 16/NTB/190 | Nasal Mesh Nebulizer Study | A/ Prof Richard Douglas | HDEC-Full Review | Approve | 5 | Committee Member Delay |
| 16/NTB/33 | ASD2 Study | Dr Ian Crozier | HDEC-Full Review | Approve | 1 | Committee Member Delay |
| 16/NTB/35 | FibUpFront PPH | Dr Joreline (Jay) Van Der Westhuizen | HDEC-Full Review | Approve | 4 | Committee Member Delay |
| 16/NTB/38 | Impact of Charcot-Marie-Tooth disease in the Auckland Region of New Zealand (ImpactCMT) | Dr Alice Theadom | HDEC-Full Review | Approve | 24 | Committee Member Delay |
| 16/NTB/48 | Study of the Investigational Drug Avelumab n Patients With Advanced Renal Cell Carcinoma | Dr Alvin Tan | HDEC-Full Review | Approve | 1 | Committee Member Delay |
| 16/NTB/61 | Comparison of the blood levels of two forms of buprenorphine 20 mcg/hr transdermal patch in healthy male and female volunteers over 22 days in each study period | Dr Noelyn Hung | HDEC-Full Review | Approve | 7 | Committee Member Delay |
| 16/NTB/63 | M13-542 A study comparing ABT-494 to Placebo in subjects with moderately to severe Rheumatoid Arthritis with Inadequate response to Biologic Disease Modifying Anti-Rheumatic Drugs (bDMARDS) | Dr Daniel Ching | HDEC-Full Review | Approve | 5 | Committee Member Delay |
| 16/NTB/64 | Persistent airflow limitation and the airway microbiome in childhood asthma | Prof Jeroen Douwes | HDEC-Full Review | Approve | 2 | Committee Member Delay |
| 16/NTB/82 | 64294178HPC2001: A Phase 2 study of Different Treatment Combinations of AL-335, odalasvir and simeprevir in subjects with chronic hepatitis C virus infection | Prof Edward Gane | HDEC-Full Review | Approve | 6 | Committee Member Delay |
| 16/NTB/91 | Comparison of the blood levels of two forms of tadalafil 20 mg tablets in healthy male volunteers under fed conditions | Dr Noelyn Hung | HDEC-Full Review | Approve | 7 | Committee Member Delay |
| 16/NTB/92 | STAR-120-SIES | Dr Trevor B Gray | HDEC-Full Review | Approve | 8 | Committee Member Delay |
| 16/NTB/93 | Study of Avelumab in Patients with Locally Advanced or Metastatic Urothelial Cancer | Dr Peter Fong | HDEC-Full Review | Approve | 4 | Committee Member Delay |
| 16/NTB/95 | Te Ara Hā: Asthma Self-Management Programme | Dr Tristram Ingham | HDEC-Full Review | Approve | 16 | Committee Member Delay |
| 16/NTB/96 | A Study of ALN-HBV in Healthy Adult Subjects and Non-cirrhotic Patients with Chronic Hepatitis B Virus | Prof. Edward Gane | HDEC-Full Review | Approve | 10 | Committee Member Delay |
| 16/NTB/97 | Sentimag use for sentinel node biopsy | Dr Ahrin Anna Morrow | HDEC-Full Review | Approve | 5 | Committee Member Delay |
| 16/NTB/98 | SuDDICU-ANZ | Dr Paul Young | HDEC-Full Review | Approve | 23 | Committee Member Delay |

## Overdue expedited applications

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| Reference | Short title | CI name | Review type | Decision | Days overdue | Reason overdue |
| 16/NTB/101 | Ka Mau Te Wehi: Weight Loss: Eating Healthy & Increasing Exercise | Associate Professor Marewa Glover | HDEC-Expedited Review | Approve | 6 | Committee Member Delay |
| 16/NTB/102 | RA video joint count training | Dr Rebecca Grainger | HDEC-Expedited Review | Approve | 1 | Secretariat Delay |
| 16/NTB/125 | Bulbospongiosus function | Dr Omid Yassaie | HDEC-Expedited Review | Approve | 2 | Incomplete Provisional Approval Response |
| 16/NTB/136 | Regional analysis of the accuracy of the SkinVision smartphone application in recognising skin cancer lesions | Assoc Prof Amanda Oakley | HDEC-Expedited Review | Approve | 3 | Committee Member Delay |
| 16/NTB/137 | Psychosocial impact of nasograstric tube feeding in the adolescent oncology patient | Doctor Awras Majeed | HDEC-Expedited Review | Approve | 2 | Committee Member Delay |
| 16/NTB/138 | Isolation and Stimulation of iNKT cells in Diabetes and Obesity | Associate Professor Jeremy Krebs | HDEC-Expedited Review | Approve | 14 | Committee Member Delay |
| 16/NTB/139 | Measurement of nivolumab and pembrolizumab in patients | Dr. Robert Matthew Strother | HDEC-Expedited Review | Approve | 3 | Committee Member Delay |
| 16/NTB/160 | Characterizing lung mechanics in mechanically ventilated neonates | Doctor Bronwyn Dixon | HDEC-Expedited Review | Approve | 1 | Committee Member Delay |
| 16/NTB/161 | PaNTS Study | Ms Silvia Marinone | HDEC-Expedited Review | Approve | 4 | Committee Member Delay |
| 16/NTB/165 | Māori Engagement with Mental Health Services | Miss Amelia Backhouse-Smith | HDEC-Expedited Review | Approve | 3 | Secretariat Delay |
| 16/NTB/175 | E-screening in pregnancy | Dr Tanya Wright | HDEC-Expedited Review | Approve | 2 | Secretariat Delay |
| 16/NTB/184 | ProFood Study | Dr Thorsten Stanley | HDEC-Expedited Review | Approve | 9 | Secretariat Delay |
| 16/NTB/187 | Antibiotic education | Dr Stephen Ritchie | HDEC-Expedited Review | Approve | 4 | Secretariat Delay |
| 16/NTB/191 | Do diagnoses change between admission and discharge? | Dr Laura Chapman | HDEC-Expedited Review | Approve | 3 | Committee Member Delay |
| 16/NTB/196 | High-Resolution Mapping of Gastrointestinal Electrical Activity | Professor Ian Bissett | HDEC-Expedited Review | Approve | 2 | Secretariat Delay |
| 16/NTB/213 | Concussion and whiplash: a comparison of neck magnetic resonance imaging features | Dr Ewan Kennedy | HDEC-Expedited Review | Approve | 6 | Holiday Shut Down - Not Overdue |
| 16/NTB/26 | PneumoINSPIRE | Dr Paul Young | HDEC-Expedited Review | Approve | 1 | Secretariat Delay |
| 16/NTB/27 | The Newborn Ethnicity Project | Dr Lynn Sadler | HDEC-Expedited Review | Approve | 2 | Secretariat Delay |
| 16/NTB/28 | Huarahi Hauora | Mr Ricky Bell | HDEC-Expedited Review | Approve | 1 | Committee Member Delay |
| 16/NTB/29 | Whānau experiences of adverse perinatal events | Ms Kendall Stevenson | HDEC-Expedited Review | Approve | 5 | Committee Member Delay |
| 16/NTB/43 | Exploration of why people do not complete pulmonary rehabilitation | Mrs Sarah Candy | HDEC-Expedited Review | Approve | 5 | Committee Member and Secretariat Delay |
| 16/NTB/68 | Effect of maternal sleep position in small for gestational age pregnancy | Professor Peter R Stone | HDEC-Expedited Review | Approve | 2 | Secretariat Delay |

1. Data is directly reported from the online system. Any errors in spelling reflects errors made by the applicant. [↑](#footnote-ref-1)