

Northern B Health and Disability Ethics Committee

Annual Report
2017

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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.

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# Chairperson’s report

Ms Kate O’Connor was appointed as chairperson of Northern B in December 2015 taking over from Mr Raewyn Sporle after a period of 8 years. Northern B has performed consistently well with no significant issues. Long serving member Phyllis Huitema retired in May at the conclusion of her term of office and was replaced by Jane Wylie. The committee continues to function well and is evenly balanced with four lay and four non-lay members. The committee encourages and welcomes researchers to present in person or to teleconference in to meetings.

Ms O’Connor led the joint submission process for all four HDEC Chairs submitting to the HDC Code of Rights Review of Right 7.4. The HDECs continue to be caught up in the legal complexity when reviewing adult non-consensual studies and researchers express their frustration at the lack of policy movement in this area.

HDECs participated in the development 2016 and launch of NZ’s first Health Research Strategy in 2017 and welcome a national unified direction for health research.

The volume of ethics applications submitted for review continue to rise such that meeting agendas are consistently full. Students are encouraged to attend with their supervisors and for supervisors to take an active hands-on role in ensuring studies are ethical and scientifically justifiable and that the study design is appropriate to the objective of the study.

The committee is concerned that students are not always sufficiently supervised or their application reviewed and supported when presenting for the first time to an HDEC. While the process is not designed to be intimidating, appearing before an eight-person committee and having to present a study and answer questions about the purpose and study design, is nevertheless a challenging process for newcomers.

It continues to be a challenge to recruit male members to the Committee and the low fees paid in relation to the level of expert review required for the performance of duties impacts on suitable candidates being available for appointment.

The committee is seeing an increasing number of adaptive trial designs with multiple arms in some cases delivering real time data earlier to investigators allowing for the study to be adapted as results inform the research. Such designs impact on the committee’s workload, as they often involve multiple amendments.

The committee is well supported by the Ministry of Health Ethics team for secretariat support and advice. The Ethics team, under instruction of the committee and in liaison with the HDEC Chair, is taking a more active role in monitoring annual progress reports, in situations of non-compliance as per the SOPs.

# Membership and attendance

## Membership

### List of EC members within the reporting period.

**Mrs Kate O’Connor (Chair)**

Membership category: Ethical and Moral Reasoning

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Kate O'Connor (M.A., PGDipBus) is the Executive Manager of the AUT Ethics Committee (AUTEC). Previously she was a Senior Research Contracts Specialist in AUT's Research Office, a Contracts Manager for UniServices Ltd. in the University of Auckland's School of Population Health, and Secretary for the University of Auckland's Human Participants Ethics Committee, and Biological Safety Committee. She has been a member of NZ Branch Executive of the Australasian Research Management Society and the executive committee of the Auckland branch of the Federation of Graduate Women. She is a PhD candidate researching the history of informed consent.

**Mrs Lessa Russell**

Membership category: Observational and Interventional Studies

Date of appointment: 14th December 2015

Current term expires: 1st July 2018

Leesa Russell is currently coordinator the the New Zealand Cardiac Network, the National Cardiac Surgical Clinical Network and the Cancer Treatments Advisory Group Hematology Oncology Working Group. 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 as part of the Cardiovascular Research Laboratory at the University of Auckland and on behalf of Respiratory physicians at Middlemore Hospital. She has worked at the Health Research Council as Executive Secretary to the HRC Ethics Committee and Data Monitoring Committee and also in an evaluation capacity in quality improvement. 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 which was prompted by a change in legislation requiring the destruction of frozen reproductive material which was stored for 10 years or longer, and required contact with 2000 patients and obtained a managment 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 is a First Responder (Waiuku Station). She previously held a role in the NZACRES executive and membership of the Cardiac Society of New Zealand and is currently studying towards a Post Graduate Diploma in Quality Systems.

**Mrs Mali Erick**

Membership category: Community Representative

Date of appointment: 24th July 2017

Current term expires: 24th July 2018

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.

**Miss Tangihaere Macfarlane**

Membership category: Community Representative

Date of appointment: 19th May 2014

Current term expires: 19th May 2017

Miss Macfarlane (Te Arawa, Ngāti Whakaue, Ngāti Pikiao, Ngāti Rangiwewehi) is a Health Sector Auditor 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.

**Mrs Stephanie Pollard**

Membership category: Intervention Studies

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Mrs Stephanie Pollard is currently employed as an independent Clinical Research Consultant. With a 25 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.

**Dr Nora Lynch**

Membership category: Intervention Studies

Date of appointment: 24th July 2015

Current term expires: 24th July 2018

Dr Nora Lynch MBChB (1979) MMed (1987 ) PG CertPH (2016) FRACP (1986). Nora is a physician specialising in rheumatology who worked in both the public and private sectors from 1987-2014. She is currently studying towards a Graduate Diploma in History. 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 )and member on the Australasian 3e panel (Evidence, Expertise and Exchange) which prepared treatment guidelines for local specialist use(2010-2013).

**Mr John Hancock**

Membership category: The Law

Date of appointment: 14th December 2015

Current term expires: 14th December 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

**Mrs Jane Wylie**

Membership category: Intervention Studies

Date of appointment: 20th May 2017

Current term expires: 20th May 2020

Mrs Jane Wylie has experience in interventional research and genetics with qualifications in medical laboratory science, post graduate qualifications in social science and health sciences, ethics and law. She is employed by the University of Auckland.

##

## Attendance

|  |
| --- |
| **LEGEND:** **\*** After name indicates Māori member**Y** = Present **A** = Apology**X** = Meeting cancelled / No meeting scheduled **/** = Not a member of committee during this time |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | ***Membership category*** ***(L/NL)*** | **Jul** | **Aug** | Sep | **Oct** | **Nov** | **Dec** | **Jan** | **Feb** | **Mar** | **Apr** | **May** | **Jun** | **Total** |
| Mrs Kate O’Connor | L | **Y** | **Y** | A | **Y** | **Y** | X | X | **Y** | **Y** | **Y** | **Y** | **Y** | 9 |
| Mrs Lessa Russell | NL | A | **Y** | **Y** | **Y** | **Y** | X | X | Y | A | A | **Y** | **Y** | 7 |
| Mrs Mali Erick | L | **Y** | **Y** | **Y** | A | **Y** | X | X | **Y** | **Y** | **Y** | **Y** | **Y** | 9 |
| Miss Tangihaere Macfarlane\* | L | **Y** | **Y** | **Y** | Y | **Y** | X | X | **Y** | **Y** | **Y** | **Y** | **Y** | 10 |
| Mrs Stephanie Pollard | NL | A | **Y** | **Y** | Y | **Y** | X | X | A | **Y** | **Y** | **Y** | **Y** | 8 |
| Dr Nora Lynch | NL | Y | **Y** | **Y** | Y | **Y** | X | X | **Y** | **Y** | **Y** | **Y** | **Y** | 10 |
| Mr John Hancock | L | **Y** | **Y** | **Y** | A | **Y** | X | X | **Y** | **Y** | **Y** | **Y** | **Y** | 9 |
| Mrs Jane Wylie | NL | / | / | / | / | / | X | X | / | / | / | / | **Y** | 1 |
| Mrs Phyllis Huitema\* | L | **Y** | **Y** | A | **Y** | **Y** | X | X | **Y** | **Y** | **Y** | A | / | 8 |
| Dr Melissa Cragg | NL | **Y** | / | / | / | / | X | X | / | / | / | / | / | 1 |
| Dr Patries Herst | NL | **Y** | / | / | / | / | X | X | / | / | / | / | / | 1 |
| Dr Kate Parker  | NL | / | / | **Y** | / | / | X | X | / | / | / | / | / | 1 |
| Dr Brian Fergus | L | / | / | / | **Y** | / | X | X | / | / | / | / | / | 1 |
| Dr Nicola Swain | NL | / | / | / | / | / | X | X | **Y** | / | / | / | / | 1 |
| Dr Catherine Jackson  | NL | / | / | / | / | / | X | X | / | / | **Y** | / | / | 1 |
| **Total no. of members present** |  | **8** | **8** | **7** | **7** | **8** | **X** | **X** | **8** | **7** | **7** | **7** | **8** |  |
| **No. of applications considered** |  | **10** | **8** | **12** | **12** | **11** | **X** | **X** | **12** | **7** | **12** | **7** | **12** |  |

## Training and conferences

### Specify the training undergone by new members

New member training for 1 member.

### Specify the on-going training for EC members

GCP training.

Maori bio-banking and genomics training (1 attendee).

Training was conducted before a number of meetings throughout the year on relevant topics, privacy, use of portal, ACC (8 attendees).

# Applications reviewed

### Summary of applications received by full EC

|  |  |
| --- | --- |
| No. of applications approved | 90 |
| No. of applications approved subject to conditions / pending | 1 |
| No. of applications deferred and subsequently approved | 0 |
| No. of applications deferred as at time of report | 0 |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | 0 |
| No. of applications that were declined because of no/insufficient consultation with appropriate cultural group | 0 |
| No. of applications declined (This excludes those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group)  | 9 |
| No. of applications which do not require ethics committee approval  | 29 |
| No. of studies withdrawn by researcher | 1 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC  | - |
| **Total number of applications received by full EC**  | **130** |

### Summary of applications received under expedited / low risk review.

|  |  |
| --- | --- |
| No. of applications approved | 60 |
| No. of applications approved subject to conditions / pending | 0 |
| No. of applications which do not require ethics committee approval  | 5 |
| No. of applications referred for full committee review | 0 |
| No of applications which were withdrawn by HDEC EXP | 2 |
| **Total number of applications received under expedited/low risk review** | **77** |

|  |  |
| --- | --- |
| Total number of applications received: | 197 |

#

# Complaints and overdue application summary

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

## Complaints received

No complaints for Northern B in the reporting period.

## Overdue review

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. Average review times exclude time taken for researchers to respond to requests for further information.

Average review time was 17 days for expedited applications. Target timeframe for expedited applications is 15 calendar days

Average review time was 32 days for full applications. Target timeframe for full applications is 35 calendar days

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

## Applications reviewed by full committee

| **Reference no.** | **Protocol title** | **Name of principal****investigator** | **Date****received** | **Date of first review** | **Outcome of first review** | **Status at time of report** | **Date of final outcome** | **Locality** | **Funder** | **Consultation undertaken** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 16/NTB/124 | HCV reactivity Northland | Dr Arlo Upton | 21/07/2016 | 12/08/2016 |  | Withdrawn by Researcher | 24/08/2016 |  | no sponsor | Locality |
| 16/NTB/125 | Bulbospongiosus function | Dr Omid Yassaie | 6/07/2016 | 19/07/2016 | Provisionally Approve | Approve | 3/10/2016 |  | no sponsor | Locality |
| 16/NTB/126 | REMOVAL-HD trial | Dr Colin Hutchison | 21/07/2016 | 15/08/2016 | Provisionally Approve | Approve | 12/12/2016 | Hawke's Bay District Health Board | collaborative research | Locality |
| 16/NTB/127 | Human genetic susceptibility to Legionella Infection | Dr Sandy Slow | 21/07/2016 | 15/08/2016 | Provisionally Approve | Approve | 17/10/2016 | University of Otago, Christchurch | no sponsor | Locality |
| 16/NTB/128 | Superficial infection rate between proud and buried K-wire fixation for distal humerus supracondylar fracture. | Dr Chuan Kong Koh | 21/07/2016 |  |  | Decline | 15/08/2016 |  | no sponsor | Locality |
| 16/NTB/129 | 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 | 21/07/2016 | 15/08/2016 | Provisionally Approve | Approve | 23/09/2016 | Middlemore Clinical Trials | pharmaceutical company | Locality |
| 16/NTB/130 | INSIGHT | Dr Michelle Wilson | 15/07/2016 | 19/07/2016 |  | Approve | 24/07/2016 |  | no sponsor | Locality |
| 16/NTB/132 | A study evaluating how GS-9674 is cleared by the body, in adults with normal and reduced liver function. | Prof Edward Gane | 21/07/2016 | 12/08/2016 |  | Approve | 30/08/2016 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 16/NTB/133 | LTI01-1001; Phase 1 LTI­01 study in CPE/Empyema patients | Professor John Kolbe | 21/07/2016 | 15/08/2016 | Provisionally Approve | Approve | 5/09/2016 | Auckland District Health Board | pharmaceutical company | Locality |
| 16/NTB/135 | iCST | Dr Gary Cheung | 21/07/2016 | 12/08/2016 | Provisionally Approve | Approve | 31/08/2016 | The University of Auckland | academic institution | Locality |
| 16/NTB/136 | Regional analysis of the accuracy of the SkinVision smartphone application in recognising skin cancer lesions | Assoc Prof Amanda Oakley | 26/07/2016 | 12/08/2016 | Provisionally Approve | Approve | 26/10/2016 | Waikato DHB | medical device company | Locality |
| 16/NTB/137 | Psychosocial impact of nasograstric tube feeding in the adolescent oncology patient | Doctor Awras Majeed | 28/07/2016 | 12/08/2016 | Provisionally Approve | Approve | 3/11/2016 |  | no sponsor | Locality |
| 16/NTB/138 | Isolation and Stimulation of iNKT cells in Diabetes and Obesity | Associate Professor Jeremy Krebs | 3/08/2016 | 29/08/2016 | Provisionally Approve | Approve | 26/09/2016 | University of Otago, Wellington | no sponsor | Locality |
| 16/NTB/139 | Measurement of nivolumab and pembrolizumab in patients | Dr. Robert Matthew Strother | 1/08/2016 | 12/08/2016 | Provisionally Approve | Approve | 23/09/2016 |  | no sponsor | Locality |
| 16/NTB/140 | A rapid non drug treatment for anxiety- the rapid symptom shifting therapy | Professor Bruce Arroll | 25/08/2016 | 14/09/2016 |  | Approve | 20/09/2016 |  | academic institution | Locality |
| 16/NTB/141 | Genomic mechanisms underlying long‐term response to treatment in serous ovarian cancer. | Doctor Bryony Simcock | 25/08/2016 | 14/09/2016 | Provisionally Approve | Approve | 16/11/2016 |  | no sponsor | Locality |
| 16/NTB/143 | Evaluation of MORSim (Multidisciplinary Operating Room Simulation). | Dr Peter Beaver | 25/08/2016 | 14/09/2016 | Provisionally Approve | Approve | 3/10/2016 | The University of Auckland | academic institution | Locality |
| 16/NTB/145 | Antibiotic Timing and Culture Yields in Paediatric Musculoskeletal Infection | Mr Matthew Boyle | 25/08/2016 |  |  | Decline | 14/09/2016 | Auckland City Hospital | no sponsor | Locality |
| 16/NTB/148 | CARE 2 | Dr Fiona Miles | 23/08/2016 | 31/08/2016 |  | Approve | 5/09/2016 |  | no sponsor | Locality |
| 16/NTB/150 | DESIGNING The SCORECARD Project | Mr Steve Waqanivavalagi | 25/08/2016 | 14/09/2016 | Provisionally Approve | Withdrawn by HDEC | 14/12/2016 | University of Auckland | academic institution | Locality |
| 16/NTB/151 | THRIVER-F | Professor Alan F Merry | 25/08/2016 | 14/09/2016 |  | Approve | 27/09/2016 | The University of Auckland | medical device company, academic institution | Locality |
| 16/NTB/152 | MK-8521 Phase IIa Trial in Subjects with Type 2 Diabetes Mellitus (protocol MK-8521-004) | Dr Simon Carson | 25/08/2016 | 14/09/2016 | Provisionally Approve | Approve | 4/11/2016 | Southern Clinical Trials | pharmaceutical company | Locality |
| 16/NTB/153 | The FAB study | Dr Rachael Parke | 25/08/2016 | 14/09/2016 | Provisionally Approve | Approve | 27/09/2016 | Auckland District Health Board | no sponsor | Locality |
| 16/NTB/154 | A study to evaluate safety and tolerability of GS -5801 in healthy subjects | Prof Edward Gane | 25/08/2016 | 14/09/2016 |  | Approve | 19/09/2016 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 16/NTB/155 | Comparison of the blood levels of two forms of clobazam suspension in healthy male and female volunteers under fasting conditions | Dr Noelyn Hung | 25/08/2016 |  |  | Approve | 14/09/2016 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 16/NTB/156 | Comparison of the blood levels of two forms of clobazam suspension in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | 25/08/2016 |  |  | Approve | 15/09/2016 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 16/NTB/157 | The prognostic significance of immune cell infiltrates in meningioma | Dr Clinton Turner | 25/08/2016 | 15/09/2016 | Provisionally Approve | Approve | 10/11/2016 | Auckland District Health Board | no sponsor | Locality |
| 16/NTB/160 | Characterizing lung mechanics in mechanically ventilated neonates. | Doctor Bronwyn Dixon | 26/08/2016 | 5/09/2016 |  | Approve | 13/09/2016 | Canterbury District Health Board | academic institution | Locality |
| 16/NTB/161 | PaNTS Study | Ms Silvia Marinone | 31/08/2016 | 12/09/2016 | Provisionally Approve | Approve | 23/09/2016 | Auckland District Health Board | no sponsor | Locality |
| 16/NTB/163 | 5 year outcome of CMDHB Grave’s disease patients | Dr Hee Jong (Jessica) Lee | 14/09/2016 | 27/09/2016 | Provisionally Approve | Approve | 13/12/2016 | Middlemore Hospital | no sponsor | Locality |
| 16/NTB/164 | Communicating bad news in health: Improving the experiences of patients, patients’ family/whānau and health professionals | Ms Tamyra Matthews | 16/09/2016 | 27/09/2016 |  | Approve | 12/10/2016 |  | no sponsor | Locality |
| 16/NTB/165 | Māori Engagement with Mental Health Services | Miss Amelia Backhouse-Smith | 15/09/2016 | 27/09/2016 | Provisionally Approve | Approve | 31/10/2016 | Massey University | no sponsor | Locality |
| 16/NTB/166 | Denosumab in addition to ULT for Bone Erosions in Gout | Prof Nicola Dalbeth | 22/09/2016 | 11/10/2016 | Provisionally Approve | Approve | 13/12/2016 | University of Auckland | academic institution | Locality |
| 16/NTB/167 | Increasing retention in an alcohol and other drug therapeutic community | Mrs Jo Willcocks | 22/09/2016 |  |  | Decline | 11/10/2016 | University of Canterbury | no sponsor | Locality |
| 16/NTB/168 | A Global Study Characterising the Safety and Tolerability of Anifrolumab in Participants with Active Systemic Lupus Erythematosus | Dr Alan Doube | 22/09/2016 | 11/10/2016 | Provisionally Approve | Withdrawn by HDEC | 31/01/2017 | Waikato Hospital | pharmaceutical company | Locality |
| 16/NTB/171 | MK-3475-365 | Dr Peter Fong | 22/09/2016 | 11/10/2016 |  | Approve | 31/10/2016 | Auckland District Health Board | pharmaceutical company | Locality |
| 16/NTB/172 | PROMOTE-SAH Study | Ms Lynette Newby | 22/09/2016 | 11/10/2016 | Provisionally Approve | Approve | 1/02/2017 | Auckland District Health Board | no sponsor | Locality |
| 16/NTB/173 | Work-related risk factors for CVD | Prof Jeroen Douwes | 22/09/2016 |  |  | Approve | 11/10/2016 | Massey University | academic institution | Locality |
| 16/NTB/174 | Developing HABITs | Professor Sally N. Merry | 22/09/2016 |  |  | Approve | 11/10/2016 | University of Auckland | academic institution | Locality |
| 16/NTB/175 | E-screening in pregnancy | Dr Tanya Wright | 20/09/2016 | 27/09/2016 | Provisionally Approve | Approve | 11/12/2016 |  | no sponsor | Locality |
| 16/NTB/176 | A Phase 1a/1b study of ABI-H0731 in healthy volunteers and patients with chronic hepatitis B | Professor Ed Gane | 22/09/2016 | 11/10/2016 |  | Approve | 25/10/2016 | Auckland District Health Board | pharmaceutical company | Locality |
| 16/NTB/177 | Filgotinib in Combination With Methotrexate in Adults With Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Methotrexate. | Dr Daniel Ching | 22/09/2016 | 11/10/2016 |  | Approve | 22/11/2016 | Timaru Medical Specialists Ltd | pharmaceutical company | Locality |
| 16/NTB/178 | MK-3682-041: Study of Efficacy and Safety of MK-3682 + MK-8408 in Subjects with Chronic HCV | Prof Edward Gane | 22/09/2016 | 11/10/2016 | Provisionally Approve | Approve | 1/11/2016 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 16/NTB/179 | Filgotinib + MTX vs Filgotinib alone vs MTX alone | Dr Daniel Ching | 22/09/2016 | 11/10/2016 |  | Approve | 16/11/2016 | Timaru Medical Specialists Ltd | pharmaceutical company | Locality |
| 16/NTB/180 | DAy DREaMS | Ms. Gayl Humphrey | 29/09/2016 |  |  | Approve | 12/10/2016 | The University of Auckland | other government agency | Locality |
| 16/NTB/181 | CO39262: Vemurafenib, cobimetinib & atezolizumab triplet combination in advanced melanoma | Dr Richard North | 22/09/2016 | 11/10/2016 | Provisionally Approve | Approve | 4/11/2016 | Bay of Plenty Clinical School | pharmaceutical company | Locality |
| 16/NTB/183 | Mindfulness phone app for patients with brain tumours | Dr Claudio De Tommasi | 3/10/2016 |  |  | Approve | 12/10/2016 | Canterbury District Health Board | no sponsor | Locality |
| 16/NTB/184 | ProFood Study | Dr Thorsten Stanley | 5/10/2016 | 17/10/2016 | Provisionally Approve | Approve | 30/11/2016 | University of Otago, Wellington | no sponsor | Locality |
| 16/NTB/186 | Tackling Preterm | Dr Beverley Lawton | 27/10/2016 |  |  | Approve | 17/11/2016 | University of Otago | academic institution | Locality |
| 16/NTB/187 | Antibiotic education | Dr Stephen Ritchie | 11/10/2016 | 25/10/2016 | Provisionally Approve | Approve | 16/11/2016 |  | no sponsor | Locality |
| 16/NTB/188 | Quality of Vision | Dr. Dean Corbett | 17/10/2016 | 25/10/2016 |  | Approve | 10/11/2016 | Auckland Eye | medical device company | Locality |
| 16/NTB/189 | The costs of eating disorders in New Zealand | Dr Jennifer Jordan | 17/10/2016 | 26/10/2016 |  | Approve | 7/11/2016 | University of Otago, Christchurch | no sponsor | Locality |
| 16/NTB/190 | Nasal Mesh Nebulizer Study | A/ Prof Richard Douglas | 27/10/2016 | 17/11/2016 | Provisionally Approve | Approve | 13/12/2016 | University of Auckland | pharmaceutical company | Locality |
| 16/NTB/191 | Do diagnoses change between admission and discharge? | Dr Laura Chapman | 17/10/2016 | 26/10/2016 | Provisionally Approve | Approve | 30/11/2016 | University of Auckland + Waitemata DHB | academic institution | Locality |
| 16/NTB/192 | D5290C00003 | Dr. Thorsten Villiers Stanley | 27/10/2016 | 17/11/2016 | Provisionally Approve | Approve | 1/02/2017 | Wellington Hospital | pharmaceutical company | Locality |
| 16/NTB/193 | Measuring changes in vaginal pressure before and after prolapse surgery | Dr Jennifer Kruger | 27/10/2016 |  |  | Approve | 17/11/2016 | University of Auckland | academic institution | Locality |
| 16/NTB/194 | Pupillometry, EEG and postoperative pain | Dr Amy Gaskell | 20/10/2016 | 28/10/2016 |  | Approve | 7/11/2016 | Waikato DHB | no sponsor | Locality |
| 16/NTB/196 | High-Resolution Mapping of Gastrointestinal Electrical Activity | Professor Ian Bissett | 21/10/2016 | 1/11/2016 |  | Approve | 10/11/2016 | The University of Auckland | academic institution | Locality |
| 16/NTB/197 | A study to examine the safety and tolerability of the trial drug Brincidofovir in healthy adults and in adults. | Dr Chris Wynne | 27/10/2016 |  |  | Approve | 17/11/2016 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company | Locality |
| 16/NTB/199 | 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 | 27/10/2016 | 17/11/2016 |  | Approve | 28/11/2016 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company | Locality |
| 16/NTB/201 | The value of periwound LA for post-operative anaelgesia of patients undergoing total hip joint replacement | Dr David Kieser | 27/10/2016 | 17/11/2016 | Provisionally Approve | Approve | 24/02/2017 | CDHB | no sponsor | Locality |
| 16/NTB/202 | Local anesthetic administration in NOF# closed reduction and internal fixation | Dr David Kieser | 27/10/2016 | 17/11/2016 | Provisionally Approve | Approve | 24/02/2017 | CDHB | no sponsor | Locality |
| 16/NTB/205 | XPEDITE | Associate Professor Andrew Holden | 27/10/2016 | 17/11/2016 | Provisionally Approve | Approve | 1/02/2017 | Auckland District Health Board | medical device company | Locality |
| 16/NTB/207 | NHF vs NIV in COPD patients with chronic respiratory failure | Dr James Fingleton | 27/10/2016 | 4/11/2016 |  | Approve | 16/11/2016 | Medical Research Institute of New Zealand | other | Locality |
| 16/NTB/208 | CHYLD Study at 9 years | Professor Jane Harding | 27/10/2016 | 17/11/2016 | Provisionally Approve | Approve | 24/01/2017 | The University of Auckland | academic institution | Locality |
| 16/NTB/209 | A study to evaluate safety and tolerability of GS-9688 in healthy subjects | Prof Edward Gane | 27/10/2016 | 17/11/2016 |  | Approve | 21/11/2016 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 16/NTB/213 | Concussion and whiplash: a comparison of neck magnetic resonance imaging features | Dr Ewan Kennedy | 21/11/2016 | 9/12/2016 | Provisionally Approve | Approve | 22/12/2016 | University of Otago | academic institution | Locality |
| 16/NTB/214 | Incidence of forearm diaphyseal fracture in the Auckland population. | Dr Rushi chandar Penumarthy | 21/11/2016 | 11/12/2016 | Provisionally Approve | Withdrawn by HDEC | 23/03/2017 |  | no sponsor | Locality |
| 16/NTB/215 | Mitochondrial Disease: The NZ Experience. | Dr Sarah Missen | 21/11/2016 | 11/12/2016 | Provisionally Approve | Approve | 18/01/2017 | ADHB | no sponsor | Locality |
| 16/NTB/216 | An Assessment of Antenatal Corticosteroids in Women with Diabetes in Pregnancy | Dr Jeremy Tuohy | 24/11/2016 | 11/12/2016 | Provisionally Approve | Approve | 25/01/2017 | University of Auckland | academic institution | Locality |
| 16/NTB/217 | SCATBI NZ Norms | Mrs Jessica Gardiner | 28/11/2016 |  |  | Decline | 12/12/2016 |  | non-governmental organisation (NGO), other | Locality |
| 16/NTB/218 | Abdominal Tuberculosis | Dr Simon Dalton | 29/11/2016 | 12/12/2016 | Provisionally Approve | Approve | 18/01/2017 |  | no sponsor | Locality |
| 16/NTB/219 | Identification of cardiovascular disease biomarkers in New Zealand | Associate Professor Greg Jones | 5/12/2016 | 12/12/2016 | Provisionally Approve | Approve | 15/03/2017 | University of Otago | no sponsor | Locality |
| 16/NTB/223 | Multiple Myeloma in the Midland cancer region. Are there ethnic differences ? | Dr Myra Ruka | 12/12/2016 |  |  | Approve | 10/01/2017 | Waikato DHB | no sponsor | Locality |
| 17/NTB/10 | Synovial Chondrodromatosis/Synovial Osteochondromatosis of the Hand and Wrist. | Dr Amanda Peacock | 24/01/2017 | 30/01/2017 | Provisionally Approve | Approve | 22/03/2017 | CMDHB | no sponsor | Locality |
| 17/NTB/103 | PURPLE registry | Dr Katriona Clarke | 1/06/2017 | 13/06/2017 | Provisionally Approve | Approve | 7/07/2017 | Capital & Coast District Health Board | academic institution | Locality |
| 17/NTB/104 | Vitamin C for vitality | Professor Margreet Vissers | 31/05/2017 | 13/06/2017 |  | Approve | 28/06/2017 |  | no sponsor | Locality |
| 17/NTB/106 | Refractory Ulcerative Colitis | A/Prof Dr Michael G. Schultz | 6/06/2017 |  |  | Approve | 13/06/2017 | Southern District Health Board | academic institution | Locality |
| 17/NTB/107 | Effect if chewing on glycaemic response | Dr Esther Kim | 6/06/2017 | 13/06/2017 | Provisionally Approve | Approve | 5/07/2017 | Plant & Food Research Ltd | other government agency | Locality |
| 17/NTB/109 | Validation of CLASSIC | Professor Ian Bissett | 7/06/2017 | 20/06/2017 | Provisionally Approve | Approve | 18/08/2017 | The University of Auckland | academic institution | Locality |
| 17/NTB/11 | Measles Management in Māori | Dr Karen Wright | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 3/03/2017 | Waikato DHB | district health board (DHB) | Locality |
| 17/NTB/110 | Evaluation of a point of care capillary full blood count analyser. | Doctor Nilofer D'Sousa | 12/06/2017 | 23/06/2017 |  | Approve | 7/09/2017 | Palmerston North Hospital | no sponsor | Locality |
| 17/NTB/111 | RESTORES Trial | Dr Peter Sandiford | 13/06/2017 | 26/06/2017 |  | Approve | 5/07/2017 | Waitemata District Health Boarad | other government agency | Locality |
| 17/NTB/117 | A study of MGA012 in patients with advanced solid tumors | Dr Anne O'Donnell | 22/06/2017 | 12/07/2017 | Provisionally Approve | Approve | 5/09/2017 | Capital and Coast District Health Board | pharmaceutical company | Locality |
| 17/NTB/118 | The Health of New Zealand Veterans | Dr David McBride | 16/06/2017 | 26/06/2017 | Provisionally Approve | Approve | 22/09/2017 | University of Otago | academic institution | Locality |
| 17/NTB/119 | Spleen Registry | Doctor Zahra Al-khudairi | 14/06/2017 |  |  | Decline | 28/06/2017 |  | no sponsor | Locality |
| 17/NTB/120 | Cervical screening HPV self-test | Dr Naomi Brewer | 22/06/2017 | 12/07/2017 |  | Provisionally approve | Massey University | academic institution, other | Locality |  |
| 17/NTB/121 | iCST delivered by trained volunteers | Dr Gary Cheung | 22/06/2017 | 12/07/2017 | Provisionally Approve | Approve | 22/09/2017 | The University of Auckland | academic institution | Locality |
| 17/NTB/124 | M15-925 | Dr Daniel Ching | 22/06/2017 | 12/07/2017 | Provisionally Approve | Approve | 6/09/2017 | Timaru Rheumatology Studies | pharmaceutical company | Locality |
| 17/NTB/125 | Proof of Concept Study of Etrasimod in Patients with Pyoderma Gangrenosum | Assoc. Prof Marius Rademaker | 22/06/2017 | 12/07/2017 | Provisionally Approve | Approve | 11/08/2017 | Clinical Trials New Zealand Ltd | pharmaceutical company | Locality |
| 17/NTB/127 | Efficacy of intravenous and submucosal dexamethasone in third molar surgery | Ms Adelyn Lau | 22/06/2017 | 12/07/2017 | Provisionally Approve | Approve | 14/08/2017 | Faculty of Dentistry, University of Otago | no sponsor | Locality |
| 17/NTB/128 | A study of AL-034 in healthy participants | Prof Edward Gane | 22/06/2017 | 12/07/2017 | Provisionally Approve | Approve | 14/08/2017 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 17/NTB/129 | Haemophilia Live | mr Brian Ramsay | 22/06/2017 |  |  | Decline | 14/07/2017 | CCDHB | pharmaceutical company | Locality |
| 17/NTB/13 | Study of the Safety and Efficacy of Lemborexant in Subjects With Insomnia Disorder | Dr Dean Quinn | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 12/04/2017 |  | pharmaceutical company | Locality |
| 17/NTB/130 | Pau te Hau. High-intensity interval training for young adolescents | Dr Nigel Harris | 22/06/2017 | 12/07/2017 | Provisionally Approve | Decline | 25/07/2017 | Auckland University of Technology | academic institution | Locality |
| 17/NTB/131 | A study to examine the safety and tolerability of multiple doses of the trial drug Brincidofovir in healthy adults. | Dr Chris Wynne | 22/06/2017 |  |  | Approve | 12/07/2017 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company | Locality |
| 17/NTB/133 | Effects of Shuzi Technology on Pain and Quality of Life | Dr Anna Goodwin | 22/06/2017 | 11/07/2017 | Provisionally Approve | Approve | 17/10/2017 | New Zealand Centre of Integrated Health | other | Locality |
| 17/NTB/134 | T2NOW | Dr. Brandon Orr-Walker | 22/06/2017 | 12/07/2017 | Provisionally Approve | Approve | 19/09/2017 | Middlemore Hospital | pharmaceutical company | Locality |
| 17/NTB/136 | TAKe Cohort Study | Mr Andrew Waa | 30/06/2017 | 14/07/2017 | Provisionally Approve | Approve | 29/09/2017 | University of Otago (Wellington) | no sponsor | Locality |
| 17/NTB/137 | ANZpHOD | Dr Emma Best | 27/06/2017 |  |  | Decline | 14/07/2017 | The University of Auckland | no sponsor | Locality |
| 17/NTB/14 | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis | Dr. David Orr | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 30/03/2017 | Grafton | pharmaceutical company | Locality |
| 17/NTB/15 | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis (NASH) | Dr. David Orr | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 28/03/2017 | Grafton | pharmaceutical company | Locality |
| 17/NTB/16 | LOTUS Study | A/P Catherine Byrnes | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 15/03/2017 | The University of Auckland & Starship Children's Hospital | non-governmental organisation (NGO) | Locality |
| 17/NTB/18 | A 3-Year Follow-up Study in participants previously treated with Odalasvir and AL-335 With or Without Simeprevir for Hepatitis C Virus (HCV) Infection. | Dr Catherine Stedman | 26/01/2017 |  |  | Approve | 17/02/2017 | Christchurch Clinical Studies Trust (CCST) Ltd and Christchurch Public Hospital | pharmaceutical company | Locality |
| 17/NTB/19 | Improving Management of Atrial Fibrillation in Primary Care | Prof Ralph Stewart | 26/01/2017 | 17/02/2017 | Provisionally Approve | Decline | 15/03/2017 | Auckland Cit Hospital Green Lane Cardiovascular Services | no sponsor | Locality |
| 17/NTB/2 | Effects of glucocorticoids in pregnant women with diabetes | Dr Ryan Paul | 16/01/2017 | 18/01/2017 | Provisionally Approve | Approve | 3/02/2017 | Waikato DHB | no sponsor | Locality |
| 17/NTB/20 | TextNudge for Activity | Ms Nicola Saywell | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 8/03/2017 | Auckland University of Technology | academic institution | Locality |
| 17/NTB/21 | The effect of cold pressed snack bars on appetite in healthy adults | Dr Christine Butts | 26/01/2017 |  |  | Approve | 17/02/2017 | Plant and Food Research Ltd | other government agency | Locality |
| 17/NTB/22 | (duplicate) A pilot randomised control trial (RCT) of group Cognitive Behaviour Therapy (CBT)to assist prisoners with symptoms of Traumatic Brain Injury (TBI). | Ms Tracey Mitchell | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 12/04/2017 | Serco/AUT | no sponsor | Locality |
| 17/NTB/23 | Pacific children’s hospital admissions in New Zealand; the parents’ perspectives. | Mrs Ellaine Ete-Rasch | 30/01/2017 | 8/02/2017 | Provisionally Approve | Approve | 24/04/2017 | Victoria University of Wellington | no sponsor | Locality |
| 17/NTB/24 | Malignant Pertussis | Dr Anusha Ganeshalingham | 9/02/2017 | 16/02/2017 | Provisionally Approve | Approve | 2/03/2017 |  | no sponsor | Locality |
| 17/NTB/25 | Development of a thymidylate synthase biomarker using blood cells | Dr Nuala Helsby | 10/02/2017 | 16/02/2017 |  | Approve | 28/02/2017 | University of Auckland | academic institution | Locality |
| 17/NTB/26 | Haemophilia Live | mr Brian Ramsay | 16/02/2017 |  |  | Decline | 1/03/2017 | CCDHB | pharmaceutical company | Locality |
| 17/NTB/27 | The effects of preterm birth & subsequent diet. | Dr Clint Gray | 14/02/2017 | 20/02/2017 | Provisionally Approve | Approve | 10/05/2017 | University of Otago (Wellington) | no sponsor | Locality |
| 17/NTB/28 | Multi-dimensional Approach to Improve Exercise Compliance in Patients with Inflammatory Bowel Disease | Miss Georgina Fagan | 15/02/2017 | 1/03/2017 |  | Decline | 2/03/2017 | Univerisity of Otago | academic institution | Locality |
| 17/NTB/29 | Psychosocial experiences of Pasifika and Māori peoples with a cardiac inherited disease in New Zealand | Mr Jessee Tanu Fia'Ali'i | 15/02/2017 | 21/02/2017 | Provisionally Approve | Approve | 13/03/2017 | The University of Auckland | academic institution | Locality |
| 17/NTB/3 | Women's experiences of footwear in rheumatoid arthritis | Miss Trish Morpeth | 16/01/2017 |  |  | Approve | 8/02/2017 | The University of Auckland | academic institution | Locality |
| 17/NTB/30 | Newton 2 - EG-01-1962-03: Comparison of EG-1962 to oral nimodipine in aSAH | Dr Edward Mee | 23/02/2017 | 10/03/2017 | Provisionally Approve | Approve | 4/05/2017 | Auckland DHB | pharmaceutical company | Locality |
| 17/NTB/31 | eCoin for OAB | Dr Sharon English | 23/02/2017 | 10/03/2017 | Provisionally Approve | Approve | 20/04/2017 | Urology Associates | medical device company | Locality |
| 17/NTB/35 | A Study to Determine Potential Drug Interactions with ACH-0144471 in Healthy Subjects | Dr Paul Hamilton | 23/02/2017 | 10/03/2017 | Provisionally Approve | Approve | 7/04/2017 | Auckland Clinical Studies Ltd | pharmaceutical company | Locality |
| 17/NTB/36 | A Phase 1b study to evaluate safety and tolerability of GS-9688 in Patients with Chronic Hepatitis B | Prof Edward Gane | 23/02/2017 | 14/03/2017 | Provisionally Approve | Approve | 4/04/2017 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 17/NTB/37 | The Benzathine Penicillin G Pharmacokinetics Study | Dr Dianne Sika-Paotonu | 23/02/2017 | 10/03/2017 | Provisionally Approve | Approve | 5/07/2017 | Victoria University of Wellington | academic institution | Locality |
| 17/NTB/38 | Comparison of the blood levels of two forms of ferrous sulfate/ascorbic acid in healthy male volunteers under fasting conditions with diet control | Dr Noelyn Hung | 23/02/2017 |  |  | Approve | 10/03/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTB/39 | The effect of 1,3-butanediol on immunity in athletes | Mr David Shaw | 23/02/2017 | 10/03/2017 | Provisionally Approve | Approve | 21/04/2017 |  | academic institution | Locality |
| 17/NTB/4 | International Takotsubo Registry (InterTAK Registry) | Dr Jen-Li Looi | 17/01/2017 |  |  | Decline | 1/02/2017 |  | no sponsor | Locality |
| 17/NTB/40 | Humidification Needs | Miss Irene Cheung | 2/03/2017 | 8/03/2017 | Provisionally Approve | Approve | 4/04/2017 | Fisher & Paykel Healthcare | medical device company | Locality |
| 17/NTB/41 | Non type B Haemophilus influenzae disease in New Zealand children | Dr Emma Best | 2/03/2017 | 14/03/2017 |  | Approve | 22/03/2017 | Starship Children's Health | no sponsor | Locality |
| 17/NTB/42 | Body Composition Monitor v clinical fluid assessment | Dr Sarah Gleeson | 13/03/2017 | 21/03/2017 | Provisionally Approve | Decline | 4/04/2017 |  | no sponsor | Locality |
| 17/NTB/43 | Psychological distress and clinical burden of diabetes in youth and young adults | Dr Joanna McClintock | 14/03/2017 |  |  | Approve | 21/03/2017 |  | no sponsor | Locality |
| 17/NTB/44 | Multi-dimensional Approach to Improve Exercise Compliance in Patients with Inflammatory Bowel Disease - A Pilot Study | Miss Georgina Fagan | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 10/05/2017 |  | academic institution | Locality |
| 17/NTB/45 | Anticoagulation in the Obese - Prospective Registry | Dr Eileen Merriman | 23/03/2017 |  |  | Decline | 13/04/2017 |  | no sponsor | Locality |
| 17/NTB/46 | Biomechanical analyses of myocardial diseases: Pilot Study | Prof Martyn Nash | 21/03/2017 | 30/03/2017 |  | Approve | 12/04/2017 | University of Auckland | academic institution | Locality |
| 17/NTB/49 | Prophylactic early PN in HPT | Dr Andrew Butler | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 26/05/2017 | Canterbury District Health Board | academic institution | Locality |
| 17/NTB/50 | Quantification of intranasal topical gadolinium distribution | Dr James Johnston | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 27/08/2017 |  | academic institution, district health board (DHB) | Locality |
| 17/NTB/53 | A study on the effects of oral BEZ235 and/or RAD001 on respiratory tract infections in elderly subjects. | Dr Dean Quinn | 23/03/2017 | 13/04/2017 |  | Approve | 5/05/2017 |  | pharmaceutical company | Locality |
| 17/NTB/54 | Comparison of the blood levels of two forms of acamprosate tablets in healthy male and female volunteers under fasting conditions | Dr Noelyn Hung | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 7/07/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTB/55 | Comparison of the blood levels of two forms of acamprosate tablets in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 7/07/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTB/56 | LADAMO study | Dr David Squirrell | 23/03/2017 | 13/04/2017 | Provisionally Approve | Withdrawn by HDEC | 30/08/2017 | ADHB | academic institution | Locality |
| 17/NTB/57 | Community Pharmacists Educating to Reduce risk of Acute Kidney Injury | Ms Di Vicary | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 7/06/2017 | Hawke's Bay District Health Board | district health board (DHB) | Locality |
| 17/NTB/58 | PRONTO-T1D | Dr John Baker | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 26/05/2017 | Middlemore Clinical Trials | pharmaceutical company | Locality |
| 17/NTB/59 | Staphylococcus capitis colonisation of neonates at Dunedin Hospital | Miss Louise Thorn | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 26/05/2017 | University of Otago | no sponsor | Locality |
| 17/NTB/60 | A study to determine the safety, antiviral activity and pharmacokinetics of ARB-1740. | Prof Edward Gane | 23/03/2017 | 13/04/2017 | Provisionally Approve | Approve | 10/05/2017 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 17/NTB/61 | Infra-slow neurofeedback for food addiction | Professor Dirk De Ridder | 31/03/2017 | 7/04/2017 |  | Approve | 19/04/2017 | University of Otago | no sponsor | Locality |
| 17/NTB/62 | Focussed physical health needs assessment | Dr Sheryl Jury | 24/03/2017 | 4/04/2017 | Provisionally Approve | Approve | 5/05/2017 | Auckland and Waitemata District Health Boards | no sponsor | Locality |
| 17/NTB/63 | Aging with Stroke and Polio in New Zealand (ASPINZ) | Dr Kelly Jones | 28/03/2017 | 12/04/2017 |  | Approve | 24/04/2017 | Auckland University of Technology | academic institution | Locality |
| 17/NTB/64 | Refractory Ulcerative Colitis | A/Prof Dr Michael G. Schultz | 4/04/2017 | 12/04/2017 |  | Decline | 27/04/2017 | Southern District Health Board | academic institution | Locality |
| 17/NTB/65 | People’s experiences in the year after having tests for a Cardiac Inherited Disease. | Ms Claire O'Donovan | 20/04/2017 | 11/05/2017 | Provisionally Approve | Approve | 12/06/2017 | University of Auckland | academic institution | Locality |
| 17/NTB/66 | Recovery of movement and sensation after stroke | Associate Professor Cathy Stinear | 20/04/2017 | 11/05/2017 | Provisionally Approve | Approve | 31/05/2017 |  | academic institution | Locality |
| 17/NTB/68 | Fish oil in gout | Professor Lisa Stamp | 20/04/2017 | 11/05/2017 | Provisionally Approve | Approve | 31/05/2017 | University of Otag, Christchurch | no sponsor | Locality |
| 17/NTB/7 | Preterm Qual | Dr Fiona Cram | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 27/04/2017 | Katoa Ltd | academic institution | Locality |
| 17/NTB/70 | The SANTA Trial: Shoulder Arthroplasty Necessitating Tranexamic Acid | Dr Ryan Gao | 20/04/2017 | 11/05/2017 | Provisionally Approve | Approve | 9/06/2017 | Orthopaedic Surgery | no sponsor | Locality |
| 17/NTB/71 | Staphylococcus aureus prevalence | Dr Ayesha Verrall | 20/04/2017 | 11/05/2017 | Provisionally Approve | Approve | 7/06/2017 | University of Otago Wellington | academic institution | Locality |
| 17/NTB/72 | PEARL-CF | Professor Andrew S Day | 20/04/2017 | 11/05/2017 | Provisionally Approve | Approve | 13/06/2017 | University of Otago Christchurch | academic institution | Locality |
| 17/NTB/76 | Tonsil Analysis of Amoxicillin and Clavulanic Acid Study (TAACS) | Dr James Johnston | 20/04/2017 | 12/05/2017 | Provisionally Approve | Approve | 6/10/2017 |  | academic institution | Locality |
| 17/NTB/77 | Cognitive Impairment Pathway Study | Dr Michal Boyd | 20/04/2017 | 11/05/2017 | Provisionally Approve | Decline | 15/05/2017 | The University of Auckland | academic institution | Locality |
| 17/NTB/79 | Retrospective analysis of looking at pre-transplantation hepatitis B virus as a risk factor for hepato-cellular carcinoma recurrence following liver transplantation | Dr Clare Russell | 24/04/2017 | 5/05/2017 | Provisionally Approve | Withdrawn by HDEC | 19/09/2017 |  | no sponsor | Locality |
| 17/NTB/8 | Prolonged neonatal hypoglycaemia | Dr Chris McKinlay | 20/01/2017 | 30/01/2017 | Provisionally Approve | Decline | 19/04/2017 | University of Auckland | academic institution | Locality |
| 17/NTB/80 | The usefulness of a Brain Computer Interface for rehabilitation after stroke. | Mrs Sharon Olsen | 1/05/2017 | 8/05/2017 |  | Approve | 31/05/2017 | AUT University | academic institution | Locality |
| 17/NTB/81 | Women's experiences of breast reconstruction after mastectomy | Dr Marianne Lill | 2/05/2017 | 5/05/2017 | Provisionally Approve | Approve | 23/06/2017 | Whanganui DHB | no sponsor | Locality |
| 17/NTB/82 | Timing of cord clamping (T.O.C.C). An observational study of umbilical cord clamping practice in a New Zealand maternity hospital. | Mrs Tina Hewitt | 3/05/2017 | 9/05/2017 |  | Approve | 19/05/2017 | Canterbury District Health Board | academic institution | Locality |
| 17/NTB/84 | (duplicate) Prolonged neonatal hypoglycaemia | Dr Chris McKinlay | 9/05/2017 |  |  | Approve | 15/05/2017 | University of Auckland | academic institution | Locality |
| 17/NTB/85 | What works? Individuals’ experiences and knowledge of suicide prevention interventions in Aotearoa / New Zealand. | Miss Behiye (Becky) Ali | 25/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 14/07/2017 | University of Auckland | no sponsor | Locality |
| 17/NTB/86 | Oral Prednisone for the Treatment of Acute Sore throat | Dr Ivan Koay | 25/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 18/10/2017 | Navicular 619Ltd | no sponsor | Locality |
| 17/NTB/87 | SAFRON II | Dr Giuseppe Sasso | 25/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 6/07/2017 | Auckland District Health Board | collaborative research | Locality |
| 17/NTB/88 | Glycaemic potency of potatoes | Dr John Monro | 18/05/2017 | 31/05/2017 |  | Approve | 8/06/2017 | The New Zealand Institute for Plant and Food research | no sponsor | Locality |
| 17/NTB/89 | Does a Femoral or Saphenous (Adductor canal) nerve block affect strength and function of the knee at 6 months and 12 months following anterior cruciate ligament reconstruction? A retrospective analysi | Dr Julius Dale-Gandar | 18/05/2017 | 31/05/2017 | Provisionally Approve | Approve | 14/07/2017 |  | collaborative research | Locality |
| 17/NTB/9 | The genetics of digestive function | Professor Stephen P Robertson | 26/01/2017 | 17/02/2017 | Provisionally Approve | Approve | 12/04/2017 | Otago University | no sponsor | Locality |
| 17/NTB/90 | Effect of Intravenous compared with oral supplement on the quality of life in patients with inflammatory bowel disease | Dr Stephen Inns | 19/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 5/07/2017 | Hutt Valley District Health Board | no sponsor | Locality |
| 17/NTB/91 | Evaluation of Community Interventions for Unhealthy Weight Pre-schoolers in the South Island | Professor Barry Taylor | 25/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 11/08/2017 | University of Otago | no sponsor | Locality |
| 17/NTB/92 | Vitamin D in SUFE | Dr Marinus Stowers | 25/05/2017 |  |  | Decline | 20/06/2017 |  | district health board (DHB) | Locality |
| 17/NTB/93 | Intravenous and Intraperitoneal lignocaine | Professor Andrew Hill | 25/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 24/07/2017 |  | academic institution | Locality |
| 17/NTB/94 | He Korowai Manaaki | Associate Professor Beverley Lawton | 25/05/2017 |  |  | Decline | 20/06/2017 | Women's Health Research Centre | academic institution | Locality |
| 17/NTB/96 | M16-043 | Dr Rajeev Rajagopal | 25/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 19/09/2017 | Middlemore Clinical Trials | pharmaceutical company | Locality |
| 17/NTB/97 | IN.PACT AV Access Study | Associate Professor Andrew Holden | 25/05/2017 | 20/06/2017 |  | Approve | 29/06/2017 | Auckland District Health Board | medical device company | Locality |
| 17/NTB/98 | Steroids To Reduce the Impact on Delirium Study (STRIDE) | Dr Michal Kluger | 25/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 7/07/2017 | Waitemata DHB | no sponsor | Locality |
| 17/NTB/99 | HIP ATTACK | Dr Julian Dimech | 25/05/2017 | 20/06/2017 | Provisionally Approve | Approve | 21/09/2017 | Counties Manukau District Health Board | academic institution | Locality |

# Declaration by Head of Organisation with Primary Responsibility for the EC

## Declaration by EC Chairperson

**Name of EC: Northern B Health and Disability Ethics Committee**

**I declare for the above named EC:**

* that the information supplied on this form and any attachment(s) is true and correct; and
* that, for the period to which this form relates, the EC has operated in accordance with relevant Guidelines and Legislation.

**Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature: Date:**

## Declaration by Head of Organisation with Primary Responsibility for the EC

**Name of EC: Northern B Health and Disability Ethics Committee**

**Name of organisation:**

**On behalf of the above named organisation, and in relation to the above named EC,
I declare that:**

* I am duly authorised to sign this declaration;
* the information supplied on this form and any attachment(s) is true and correct;
* the EC is adequately resourced and maintained;
* for the period to which this form relates, the organisation ensured that the EC’s Terms of Reference included information on the:
	+ scope of its responsibilities,
	+ relationship to non-affiliated researchers,
	+ accountability,
	+ mechanisms of reporting, and
	+ remuneration (if any) for members;
* the organisation accepts legal responsibility for decisions and advice received from the EC; and
* EC members are indemnified.

**Name:** Ms Kate O’Connor

 Title First Name Last Name

**Position :** Chairperson

**E-mail :** hdecs@moh.govt.nz



**Signature: Date:** 26 October 2017

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