

Northern B Health and Disability Ethics Committee

Annual Report
2019

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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 00008715) 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 my privilege to present this report of the work of Northern B HDEC over the last year. In the year ending June 2019, the committee reviewed a total of 192 applications. 114 of these were intervention studies and 78 were observational research. 117 applications were reviewed at full committee meetings, while 75 came through the expedited (low risk) pathway. Together with an increase in numbers of applications, the complexity of research in New Zealand continues to grow. As a result, the ethical complexity also increases , and I am tremendously grateful to the members of NTB both for their continued dedication to the demanding task of ensuring that research meets the recognised ethical standards, and their responsiveness to the challenges presented by new types of research. I confirm that Northern B has functioned effectively over the reporting period, and in accordance with the HRCEC’s expectations for proper process and membership, the Guidelines for the Approval of Ethics Committees, and HDECs Standard Operating Procedures. My thanks also go to all staff of HDEC Secretariat for ensuring that the committee functions as well as possible.

Membership has been steady: we fare-welled Ms. Maliaga Erick after many years of service to NTB, and welcomed Ms. Susan Sherrard as a lay member. The formal processes for appointments and renewals are slow. As a result, a number of us are serving after our previous terms have expired (in cases, more than one year post the expiration date). I am especially grateful for those members who have indicated that they do not wish to have their appointment renewed for a further term, but who continue to serve the committee in the meantime so as to avoid disruption. Some researchers have queried the validity of decisions in light of the fact that memberships have expired, and have been reassured as per the Operating Procedures that every member of HDEC shall continue in office until their successor is appointed. The members’ fees structures have not been reviewed for a number of years, and although the HDEC Chairs have raised this with successive Ministers of Health and been reassured that a review is warranted, the timeframe for this is unclear.

Fortunately, there is now a full contingent of Advisors in the Secretariat who, together with the Administrative team, are managing the work-load very ably under Rob McHawk’s careful leadership. Having a fully staffed Secretariat is critical, especially as the HDECs system will face a number of significant challenges in the coming months. The new NEAC Ethical Standards, expected in late 2019, will necessarily require an update to the software in both the applicants and members’ on-line portals, and there will be a new set of Operating Procedures. These are significant pieces of work requiring dedicated resources and expertise on top of those required to keep the applications flowing through the committees according to the expected standards of timeliness. There is likely to be a grace period required as the system transitions to the updated Ethical Standards, and as both members, health researchers and sponsors are trained to apply them.

We are all eagerly anticipating the updated Standards as they are expected to resolve gaps in the 2012 versions, provide detailed guidance with respect to a number of emerging research areas and designs, and address the ethical issues arising from research with diverse participants, including the most vulnerable. Of particular relevance will be the guidance and Standards in relation to managing health data, especially in the dynamic context of data-intensive research using machine learning in the health care system, ‘big-data’ and linking, algorithms, the internet-of-things, and software as a medical device. The ethical issues related to this type of research are emerging and very complex, and it is for these reasons I support the growing call to have an additional HDEC dedicated to ‘data research’ and to provide leadership in this important area. For all health researchers, the new Standards will require detailed plans for managing data safely in their protocols, and this presents an opportunity for localities as responsible research hosts -including universities - to embed policies that ensure safe data throughout their organisations. At present, I believe there is too much inconsistency in this area.

There are other areas of health research which continue to present ethical challenges. In particular, and while medical devices remain unregulated in advance of the new Therapeutic Products legislation, assessing the ethics of these studies, for example first-in-human, permanent and active implantables, it is difficult to know where the balance of benefit over harm lies, especially where there is no official body (such as Medsafe for medicines) currently mandating reports of adverse events. We are seeing an increase in the numbers of such studies. Once enacted in a couple of years, the TP legislation should resolve many of these issues, although I note the sector’s concerns around the potential for an overly burdensome bureaucracy. The issues around research with adults who lack capacity to consent remain as we await a response from the HDC Commissioner in respect of his consultation of Right 7(4). In the meantime, researchers in emergency and critical-care more regularly present protocols that satisfy the Best Interest test. It is more difficult to meet the test when researching conditions such as dementia, and it is of concern that important and otherwise ethical research is disincentivised by what some consider may be an overly high threshold.

I wish to take this opportunity to acknowledge the work of researchers and their teams who present a very high quality of applications to Northern B HDEC, and who work collaboratively with both the committee and the Secretariat to ensure that the studies not only protect the rights and interests of participants but also exhibits the kind of research excellence that is necessary to achieve the vision of having a world leading health system.

Ms Kate O’Connor

Chairperson

Northern B Health and Disability Ethics Committee

# Membership and attendance

Mrs Helen Walker and Patries Herst (CEN) co-opted from Central HDEC in order to meet quorum due to apologies.

## Membership

### List of EC members within the reporting period

**Mrs Kate O'Connor**

Membership category: Ethics and moral reasoning

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

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

**Mrs Stephanie Pollard**

Membership category: The design and conduct of intervention studies

Date of appointment: 1st July 2015

Current term expires: 1st July 2018

Mrs Stephanie Pollard is currently employed as an independent Clinical Research Consultant. She obtained a Master’s degree in Healthcare Ethics and Law in 2005.

**Ms Tangihaere Macfarlan\***

Membership category: Consumer/community perspectives

Date of appointment: 20th May 2017

Current term expires: 20th May 2020

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. Miss Macfarlane has completed a Bachelor of Health Science and a Diploma in Māori Business, among other studies.

**Dr Nora Lynch**

Membership category: The provision of health and disability services

Date of appointment: 19th March 2017

Current term expires: 19th March 2022

Dr Nora Lynch is a specialist rheumatologist.

She was part of the Ministry of Health Working Party that worked on the National Research Ethics Guidelines Update (2017) and is an International Fellow of the Royal Australasian College of Physicians

**Mrs Leesa Russell**

Membership category: The design and conduct of intervention studies/ observation studies

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Mrs Leesa Russell is a Clinical Audit Manager at St John. She has a Masters and a Bachelors degree in Sociology from the University of Auckland.

**Mr John Hancock**

Membership category: Law

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

John is currently a Senior Legal Adviser at the Human Rights Commission. Prior to that, he was Principal Adviser (Legal) at the Office of the Children’s Commission. He also has extensive experience in civil society advocacy and law reform work, international human rights reporting and has served on Ministerial committees and the boards of non-government organisations.

**Mrs Jane Wylie**

Membership category: The design and conduct of intervention studies

Date of appointment: 20th May 2017

Current term expires: 20th May 2020

Jane currently serves on the Auckland Health Research Ethics Committee (AHREC) under the Auckland Academic Health Alliance and is a member of several health professional organisations. She been a Research Project Manager at the University of Auckland of studies investigating molecular profiling in blood cancers. She holds a MHSc(Hons) with post-graduate studies in medical ethics, health law, research design and cancer therapies.

**Ms Susan Sherrard**

Membership category: Consumer/community perspectives

Date of appointment: 19th March 2019

Current term expires: 19th March 2022

Susan Sherrard has a lived experience of disability and is currently a Project Lead for the disability based projects being implemented by Te Pou o te Whakaaro Nui. She holds a Master of Arts in Nursing, and a Diploma in Psychotherapy.

**Mrs Helen Walker (Co-opted)**

Membership category: Consumer/community perspectives

Date of appointment: 1st July 2015

Current term expires: 1st July 2018

Mrs Helen Walker is currently the Chairman of the Central HDEC, Chairman of the Medical Sciences Council, Chairman of Audit for Health Hawkes Bay Ltd, a Kaitiaki/Guardian of the Turnbull Library and the owner and financial controller of Kilgaren Farming Partnership. Mrs Walker is a previous Director of Unison Networks Ltd (2004-2010), the Hawke’s Bay District Health Board (2001-2007) and Chairman of the Central Hawke’s Bay Consumers Power Trust (1993-2003).

**Dr Patries Herst (Co-opted)**

Membership category: Intervention studies

Date of appointment: 27th October 2015

Current term expires: 27th October 2018

Dr Patries Herst is a senior lecturere at the Department of Radiation Therapy at University of Otago (Wellington) as well as a visitng scientist at Victoria University and the Malaghan Insittute. She completed a PhD in cancer cell biology at Malaghan Institute of Medical Research. Dr Herst conducts cell based medical research at the Malaghan institute.

##

## 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)*** | **3 Jul 2018** | **7 Aug 2018** | **4 Sep 2018** | **2 Oct 2018** | **6 Nov 2018** | **4 Dec 2018** | **5 Feb 2019** | **5 Mar 2019** | **2 Apr 2019** | **7 May 2019** | **4 Jun 2019** | **Total** |
| Mrs Kate O'Connor | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
|  Mrs Stephanie Pollard | NL | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Ms Tangihaere Macfarlane | L | **Y** | **Y** | A | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 9/11 |
|  Dr Nora Lynch | NL | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
|  Mrs Leesa Russell | NL | **Y** | **Y** | **Y** | **Y** | A | A | **Y** | **Y** | **Y** | **Y** | **Y** | 8/11 |
|  Mr John Hancock | L | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | A | 9/11 |
|  Mrs Jane Wylie | NL | A | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | 8/11 |
| Ms Susan Sherrard | L | / | / | / | / | / | / | / | / | / | / | **Y** | 1/1 |
| Mrs Maliaga Erick | L | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | / | 9/10 |
| Mrs Helen Walker (Co-opted) | L | /  | / | / | / | **Y** | / | / | / | / | / | / | 1 |
| Dr Patries Herst (Co-opted) | NL | / | Y | / | / | **Y** | / | / | / | / | / | / | 2 |
| **Total no. of members present** |  | **7** | **7** | **7** | **7** | **6** | **7** | **8** | **8** | **8** | **7** | **7** |  |
| **No. of applications considered** |  | **5** | **11** | **9** | **8** | **10** | **12** | **12** | **11** | **7** | **8** | **5** | **98** |

## Training and conferences

### Specify the training undergone by new members

Orientation training for new member.

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

|  |  |  |
| --- | --- | --- |
| **Date** | **Details of on-going training for EC members** (This includes seminars and conferences that EC members attend.) | **No. of attendees** |
| 15 June 2018 | Cancer Genomics Variant Calling Workshop, Tamaki Yacht Club, Auckland. | 1 |
| Aug 2018 | NZ Association of Clinical Research Conference Auckland, Fisher & Paykell. | 1 |
| 20 Aug 2018 | Cellular Therapies, Prof Cath Bollard, Baylor College, School of Biological Sciences University of Auckland. | 1 |
| 23 Aug 2018 | GENO Symposium Liggins Institute. | 1 |
| 3 Sept. 2018 | NEAC Guidelines revision meeting, University of Auckland. | 1 |
| 6 Sept 2018 | Growing up in NZ seminar,School of Population Health. | 1 |
| 21 Sept 2018 | Cancer Genomics research seminar University of Auckland. | 1 |
| 24 Oct 2018 | Cancer Genomics research seminar, University of Auckland | 1 |
| 26 Oct 2018 | Training on ethics and SOP Revision by Auckland Health Research Ethics Committee, University of Auckland. | 1 |
| 13 Nov 2018 | Genomic Profiling in Cancer seminar. University of Auckland. | 1 |
| 19 Nov 2018 | CMHSE Ethics Seminar, Philippa Malpas, University of Auckland. | 1 |
| 3 Dec 2018 | Cancer Trials NZ Annual Scientific Meeting 2018, Domain Lodge Grafton | 1 |
| 2018 | Completed and passed **Level 1,2 and 3 Short Courses in Te Reo** at Unitec, Auckland | 1 |
| 2018 | Completed and passed Stage 3 paper in the history department at University of Auckland: **327: Waitangi: Treaty to Tribunal.** | 1 |
| 2019 | Currently enrolled in Stage 3 paper in the Maori Studies department at University of Auckland: **396: Tikanga Maori-Ancestral Ways in Modern Times** | 1 |
| 19 Mar 2019 | Therapeutics Products draft (medical devices). | 1 |
| 22 Mar 2019 | The New Zealanders for Health Research seminar. | 1 |

# Applications reviewed

### Summary of applications received by full EC

|  |  |
| --- | --- |
| No. of applications approved  | 1 |
| No. of applications approved subject to conditions / pending | 9 |
| No. of applications deferred and subsequently approved | 75 |
| No. of applications deferred as at time of report | 8 |
| No. of applications deferred and subsequently declined | 0 |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | 3 |
| 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.) | 3 |
| No. of applications which do not require ethics committee approval (out of HDEC scope of review across all 4 HDECs)\* | 473 |
| No. of studies withdrawn by researcher | 0 |
| No. of studies terminated by sponsor | 1 |
| No. of studies transferred to another EC  | 0 |

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

|  |  |
| --- | --- |
| No. of applications approved | 58 |
| No. of invalid applications  | 9 |
| No. of applications provisionally approved at time of report | 4 |
| No. of applications referred for full committee review | N/A |
| No. of applications declined | 4 |
| **Total number of applications received under expedited/low risk review** | **75** |

|  |  |
| --- | --- |
| Total number of applications received: | **192** |

#

# Complaints and overdue application summary

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

## Complaints received

N/A – No complaints received

## 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. Researchers have up to 90 days to respond.

Average review time was 33 days for expedited applications. Target timeframe for expedited applications is 15 calendar days.

Average review time was 56 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

| **Study reference** | **Short title** | **CI Name** | **Clock Start** | **Outcome of first review[If date = provisional]** | **Study status** | **Date of final decision** | **CI Organisation[locality not captured]** | **Main sponsor type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 18/NTB/116 | Gonorrhoea resistance to Azithromycin in Auckland | Dr Rose Forster | 7/07/2018 | 9/08/2018 | Approve | 31/10/2018 |  | no sponsor |
| 18/NTB/117 | Inflammation In Coronary Artery Disease | Ms Georgina Bird | 13/07/2018 | 2/08/2018 | Approve | 29/10/2018 | Victoria University of Wellington | no sponsor |
| 18/NTB/118 | Efficacy and safety of intravenous neridronic acid in CRPS | Dr Barney Montgomery | 26/07/2018 | 19/08/2018 | Approve | 20/09/2018 | Optimal Clinical Trials | pharmaceutical company |
| 18/NTB/120 | The CRYSTAL Study | Dr Jim Stewart | 26/07/2018 |  | Approve | 13/08/2018 | Auckland District Health Board | medical device company |
| 18/NTB/124 | NHFO2: 6 Minute Walk Study | Dr James Harper | 26/07/2018 |  | Approve | 19/08/2018 | Medical Research Institute of New Zealand | medical device company |
| 18/NTB/126 | Tuberculosis infection in Māori | Prof. Philip Hill | 26/07/2018 |  | Decline | 13/08/2018 | University of Otago | no sponsor |
| 18/NTB/127 | Peripartum depression, olfaction, and eating behaviour | Dr Mei Peng | 26/07/2018 | 13/08/2018 | Approve | 12/09/2018 | University of Otago | academic institution |
| 18/NTB/128 | Peri-operative management of dabigatran in patients with neck of femur fractures | Dr Reinhold Gregor |  |  | Invalid Application | 8/08/2018 |  | no sponsor |
| 18/NTB/129 | Eye disease in Obstructive Sleep Apnoea | Dr Rasha Al-Taie | 26/07/2018 | 13/08/2018 | Approve | 1/10/2018 | University of Auckland | no sponsor |
| 18/NTB/130 | Otoacoustic emissions as a potential hearing screen for preschool children. | Dr Pat Tuohy | 26/07/2018 | 19/08/2018 | Approve | 5/09/2018 | Ministry of Health | other government agency |
| 18/NTB/131 | MEWS Study | Dr Matthew Drake |  |  | Invalid Application | 24/07/2018 | Auckland District Health Board | no sponsor |
| 18/NTB/132 | Predictors of mortality before and after aortic valve surgery | Dr Tom Kai Ming Wang |  |  | Invalid Application | 4/10/2018 | Auckland City Hospital | no sponsor |
| 18/NTB/133 | BTI-201: Study of plasma gelsolin (rhu-pGSN) added to standard of care in people hospitalised with acute community acquired pneumonia (CAP) | Dr Catherina Chang | 26/07/2018 | 19/08/2018 | Approve | 12/09/2018 | Waikato Hospital | pharmaceutical company |
| 18/NTB/134 | Continue data gathering from previous selenium study. | Dr. Nishi Karunasinghe | 26/07/2018 | 19/08/2018 | Approve | 30/11/2018 | University of Auckland | no sponsor |
| 18/NTB/135 | Elderly Acute General Surgery PN Audit | Mrs Lauren Porten |  |  | Invalid Application | 25/07/2018 | Auckland District Health Board | no sponsor |
| 18/NTB/136 | Study of KPL-301 for treatment of Giant Cell Arteritis compared with placebo. | Dr Nigel Gilchrist | 26/07/2018 | 19/08/2018 | Approve | 4/10/2018 | CGM Research Trust | pharmaceutical company |
| 18/NTB/137 | A Multicenter, Double-Masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of Conbercept Intravitreal Injection in Subjects with Neovascular Age-related Macular Degeneration | Dr Alison Pereira | 26/07/2018 | 19/08/2018 | Approve | 24/09/2018 | Auckland Eye Ltd | pharmaceutical company |
| 18/NTB/138 | Building bridges of understanding in rongoa Maori healing and medical health treatment collaboration | Mr Jonathan Koea | 2/08/2018 | 31/08/2018 | Approve | 4/10/2018 | Waitemata District Health Board | no sponsor |
| 18/NTB/139 | Antiretroviral drug resistance 2012 to 2018. | Dr Simon Briggs | 9/08/2018 | 30/08/2018 | Approve | 21/09/2018 | Auckland City Hospital | no sponsor |
| 18/NTB/140 | ATB200/AT2221 Pompe | A/Prof Richard Roxburgh | 23/08/2018 | 18/09/2018 | Approve | 29/11/2018 | Auckland City Hospital | pharmaceutical company |
| 18/NTB/141 | Posterior tibial slope | Dr Timothy Roberts | 9/08/2018 | 30/08/2018 | Approve | 21/09/2018 |  | no sponsor |
| 18/NTB/142 | Evaluating the impact of prehospital care on mortality following major trauma | Associate Professor Bridget Kool | 21/08/2018 |  | Approve | 12/09/2018 | University of Auckland | academic institution |
| 18/NTB/143 | Outcomes of clinical trial participation | Dr Michelle Wilson | 21/08/2018 | 12/09/2018 | Approve | 30/10/2018 | Auckland District Health Board | district health board (DHB) |
| 18/NTB/144 | Low-Fat Versus Ketogenic Diet In Alzheimer’s Disease | Dr Matthew Phillips | 23/08/2018 | 18/09/2018 | Approve | 2/11/2018 | Neurology Dept, Waikato Hospital | no sponsor |
| 18/NTB/145 | Acceptability of caring contacts by text messages. | Miss Olivia High | 23/08/2018 | 18/09/2018 | Approve | 24/10/2018 | Massey University | no sponsor |
| 18/NTB/146 | Kakano:Pilot study evaluation of an app to enhance parenting capacity and child wellbeing. | Dr Stephanie Moor | 23/08/2018 | 18/09/2018 | Approve | 30/10/2018 |  | no sponsor |
| 18/NTB/147 | M16-066 | Professor Richard Gearry | 23/08/2018 | 19/09/2018 | Approve | 14/12/2018 | Canterbury District Health Board | pharmaceutical company |
| 18/NTB/148 | M16-067 | Professor Richard Gearry | 23/08/2018 | 20/09/2018 | Approve | 14/12/2018 | Canterbury District Health Board | pharmaceutical company |
| 18/NTB/149 | Study of VIR-2218 in Healthy Volunteers and Patients with Chronic Hepatitis B | Prof Edward Gane | 23/08/2018 | 25/09/2018 | Approve | 25/09/2018 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 18/NTB/150 | Cimetidine for Reducing Oxaliplatin Neurotoxicity (CITRON) | Professor Mark McKeage | 23/08/2018 |  | Approve | 21/09/2018 | The University of Auckland | academic institution |
| 18/NTB/151 | Staying Upright | Prof Ngaire Kerse | 23/08/2018 | 20/09/2018 | Approve | 31/10/2018 | University of Auckland | other government agency |
| 18/NTB/152 | The clinical manifestations and disease course of Juvenile Dermatomyositis (JDM) in a New Zealand cohort. | Dr Anthony Concannon |  |  | Invalid Application | 25/09/2018 |  | no sponsor |
| 18/NTB/153 | Journey II BCS Total Knee System: Patient Reported Outcome Measures | Mr Peter Ruthven MacGregor Black | 20/08/2018 | 21/09/2018 | Approve | 30/10/2018 | Southern Cross Hospital | medical device company |
| 18/NTB/154 | Cochlear implants and cognitive decline | Dr Julia Sarant |  |  | Invalid Application | 13/09/2018 | The University of Melbourne | academic institution |
| 18/NTB/155 | Quantification of intranasal topical gadolinium distribution | Miss Joey Siu | 31/08/2018 | 2/10/2018 | Approve | 4/10/2018 |  | academic institution |
| 18/NTB/156 | Kidney transplantation from DCD donors | Dr Michael Collins | 7/09/2018 | 21/09/2018 | Approve | 31/10/2018 | Auckland District Health Board | no sponsor |
| 18/NTB/157 | Albinism - visual impact, ocular findings, and potential visual aids | Dr Shuan H Dai | 13/09/2018 | 23/10/2018 | Approve | 12/03/2019 | University of Auckland | no sponsor |
| 18/NTB/159 | DYNAMIC-III | Dr Mark Jeffery | 13/09/2018 | 4/02/2019 | Approve | 4/02/2019 | Canterbury Dustrict Health Board | collaborative research |
| 18/NTB/160 | ZEST 2 | Professor Peter Gilling | 20/09/2018 | 23/10/2018 | Approve | 3/09/2019 | Tauranga Urology Research Limited | medical device company |
| 18/NTB/161 | Ketone monoester supplementation in individuals with prediabetes | A/Professor Max Petrov | 20/09/2018 | 23/10/2018 | Approve | 5/12/2018 | The University of Auckland | academic institution |
| 18/NTB/162 | Postnatal depression in mothers of babies born by Caesarean section | Dr Richard Carpenter | 20/09/2018 | 23/10/2018 | Approve | 12/12/2018 | Waitemata District Health Board | no sponsor |
| 18/NTB/163 | SUBCUTANEOUS TIBIAL NERVE STIMULATION FOR URGENCY URINARY INCONTINENCE: A FOLLOW-ON STUDY | Dr. Sharon English | 20/09/2018 |  | Decline | 23/10/2018 | Urology Associates | medical device company |
| 18/NTB/164 | A randomised double blind placebo control trial of the efficacy of oral N-acetyl Cysteine in mild traumatic brain injury patients presenting to a regional Emergency Department | Dr Tom Jerram | 20/09/2018 | 23/10/2018 | Approve | 14/02/2019 | NMDHB | no sponsor |
| 18/NTB/165 | Intertester reliability study | Mr Darragh Kenny | 14/09/2018 | 4/10/2018 | Approve | 14/02/2019 | TBI Health Group | other |
| 18/NTB/166 | Antimicrobial prescribing in New Zealand: comparison between different prescriber groups | Ms Betty Poot |  |  | Invalid Application | 24/09/2018 | Victoria University of Wellington | no sponsor |
| 18/NTB/167 | Ethnic Differences in the Incidence of Phyllodes Tumours in the wider Auckland Region | Dr Megan Grinlinton | 17/09/2018 | 4/10/2018 | Approve | 20/11/2018 | Auckland District Health Board | no sponsor |
| 18/NTB/169 | Evaluating current Cerebral Palsy diagnostic practice | Dr Sian Williams | 19/09/2018 |  | Approve | 4/10/2018 | University of Auckland | academic institution |
| 18/NTB/170 | Collection and use of peripheral cells from healthy volunteers | Dr Nuala Helsby | 21/09/2018 |  | Approve | 4/10/2018 | University of Auckland | academic institution |
| 18/NTB/171 | RIOT | Dept Anaesthesia Research Office |  |  | Invalid Application | 3/10/2018 |  | no sponsor |
| 18/NTB/172 | Opioid prescribing from surgical wards at Waikato hospital | dr Michael Foss | 1/10/2018 | 12/10/2018 | Approve | 2/11/2018 |  | district health board (DHB) |
| 18/NTB/173 | Prelude BTK | Associate Professor Andrew Holden | 25/10/2018 |  | Approve | 21/11/2018 | Auckland District Health Board | medical device company |
| 18/NTB/174 | Evaluation of novel biomarkers in endometriosis | Miss Teagan Hoskin | 2/10/2018 |  | Approve | 12/10/2018 | University of Otago | academic institution |
| 18/NTB/175 | Emotion and suicide | Mr Steven Davey | 2/10/2018 | 12/10/2018 | Approve | 25/10/2018 | University of Otago Wellington | academic institution |
| 18/NTB/177 | ATLAS Injury: Pilot Study | Dr Samuel Moon | 10/10/2018 | 14/10/2018 | Provisionally approve |  | Counties Manukau DHB | no sponsor |
| 18/NTB/178 | Robots for independence | Prof Ngaire Kerse |  |  | Invalid Application | 12/10/2018 | Auckland University | other government agency |
| 18/NTB/179 | A Study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn’s Disease Study to evaluate the safety and effectiveness of guselkumab in people with moderate | Dr Michael Schultz | 18/10/2018 | 25/02/2019 | Approve | 25/02/2019 | Dunedin Hospital | pharmaceutical company |
| 18/NTB/180 | A study into the effectiveness and safety of R131 vaginal ointment in women with cellular changes to the cervix | Dr Amanda Tristram | 18/10/2018 | 22/11/2018 | Approve | 13/12/2018 | CCDHB | pharmaceutical company |
| 18/NTB/181 | Assessment of the trial drug CBL-514 in healthy adults. | Dr Chris Wynne | 18/10/2018 | 22/11/2018 | Provisionally approve |  | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 18/NTB/182 | HWEN at Korowai Manaaki: A Process Evaluation | Dr Clare-Ann Fortune | 18/10/2018 | 22/11/2018 | Approve | 7/02/2019 | Victoria University of Wellington | academic institution, district health board (DHB), other government agency |
| 18/NTB/183 | Neonatal Ear Study | Ms Gayl Humphrey | 18/10/2018 | 5/12/2018 | Approve | 13/03/2019 | University of Auckland | no sponsor |
| 18/NTB/184 | Effortful decision making after stroke | Dr Kelly Jones | 18/10/2018 |  | Approve | 22/11/2018 | AUT University | academic institution |
| 18/NTB/186 | CSP-EMR | Dr Ravinder Ogra |  |  | Invalid Application | 12/10/2018 | Counties Manukau DHB | no sponsor |
| 18/NTB/188 | Glyceryl trinitrate use during HIDA scans for sphincter of Oddi dysfunction | Dr Bonnie Leung | 17/10/2018 |  | Approve | 6/12/2018 | Auckland City Hospital | no sponsor |
| 18/NTB/189 | Understanding Skin Conditions and Developing New Treatments | Dr Hilary Sheppard |  |  | Invalid Application | 17/10/2018 | Universtiy of Auckland | academic institution |
| 18/NTB/190 | Novel passive stoma bypass device ('stoma-link') | A/Prof Gregory O'Grady | 18/10/2018 | 5/12/2018 | Approve | 7/02/2019 | Univeristy of Auckland | academic institution |
| 18/NTB/191 | The use of the RACER-PAP during exercise in normal healthy adults | DR Julie Reeve | 18/10/2018 | 5/12/2018 | Approve | 18/03/2019 | AUT University | no sponsor |
| 18/NTB/193 | The relevance of maternal clinical background in Oranga Tamariki referrals of MMH patients | Dr Elena Bratu | 17/10/2018 |  | Decline | 31/10/2018 | Auckland District Health Board | no sponsor |
| 18/NTB/194 | TRCA-303 Study | DR Kannaiyan Rabindranath | 18/10/2018 | 23/11/2018 | Approve | 14/02/2019 | Waikato Ditrict Health Board | pharmaceutical company |
| 18/NTB/195 | TAVI and BMI | Mr David J McCormack |  |  | Invalid Application | 19/10/2018 | The Waikato Hospital | no sponsor |
| 18/NTB/199 | Assessment of operating time, incidence of return to theatre events, incidence of secondary reconstruction and financial feasibility of utilising intraoperative imaging with and without rapid prototyp | Dr Liam Moore |  |  | Invalid Application | 30/10/2018 | Christchurch Hospital | no sponsor |
| 18/NTB/200 | Review of functional outcomes following Intramedullary nail fixation of forearm fracture. | Dr Rushi Chandar Penumarthy | 24/10/2018 | 3/11/2018 | Provisionally approve |  |  | no sponsor |
| 18/NTB/201 | ASD Prescribing Practices | Dr Hiran Thabrew |  |  | Invalid Application | 29/10/2018 | University of Auckland | no sponsor |
| 18/NTB/204 | Floating Shoulder Injury: Outcomes following Operative vs Non operative management | Dr Viknesh Kamalanathan |  |  | Invalid Application | 29/10/2018 | Wellington Hospital | no sponsor |
| 18/NTB/207 | Ethnicity accuracy in Waikato | Dr Jade Tamatea |  |  | Invalid Application | 30/10/2018 |  | no sponsor |
| 18/NTB/208 | Hapunga Auahi Kore TVC Pilot | Doctor Marewa Glover |  |  | Invalid Application | 30/10/2018 | COREISS Ltd | no sponsor |
| 18/NTB/209 | Whakangā: Living with bronchiectasis | Mr silas thielmann |  |  | Invalid Application | 12/11/2018 | Otago University | no sponsor |
| 18/NTB/210 | AVess FIH Study | Associate Professor Andrew Holden | 22/11/2018 |  | Approve | 17/12/2018 | Auckland District Health Board | medical device company |
| 18/NTB/211 | PRISM-UDR | Dr Colin McArthur | 22/11/2018 | 17/12/2018 | Approve | 28/03/2019 | Auckland District Health Board | pharmaceutical company |
| 18/NTB/213 | Oranga Rongoā | Ms Leanne Te Karu | 12/11/2018 | 12/12/2018 | Approve | 14/02/2019 |  | academic institution |
| 18/NTB/214 | Service Users and their whanau experience of continuity of care for substance use | Mr Andre McLachlan |  |  | Invalid Application | 14/11/2018 | Waikato Institute of Technology (WINTEC) | academic institution |
| 18/NTB/215 | Contraception Survey | Dr Sue Tutty | 12/11/2018 | 18/02/2019 | Approve | 13/03/2019 | Counties Manukau DHB | district health board (DHB) |
| 18/NTB/216 | Study of ARO-ANG3 in Adult Healthy Volunteers and Dyslipidemic Patients | Dr Christian Schwabe | 22/11/2018 | 17/12/2018 | Approve | 29/01/2019 | Auckland Clinical Studies Ltd | pharmaceutical company |
| 18/NTB/217 | REVIRAL 1 | Dr. Thorsten Stanley | 22/11/2018 |  | Approve | 17/12/2018 | CCDHB | pharmaceutical company |
| 18/NTB/218 | vitamin C in community acquired pneumonia | Prof Stephen Chambers | 22/11/2018 | 17/12/2018 | Approve | 13/03/2019 | University of Otago, Christchurch | no sponsor |
| 18/NTB/219 | A study to see if a new chronic sinusitis treatment is useful and safe in the treatment of adult participants | Dr Thomas Kuruvilla | 22/11/2018 | 17/12/2018 | Approve | 25/02/2019 | Southern Clinical Trials Ltd | pharmaceutical company |
| 18/NTB/220 | KEYNOTE-756 Amendment 01 | Dr Sarah Barton | 22/11/2018 | 17/12/2018 | Approve | 11/02/2019 | Capital and Coast District Hospital | pharmaceutical company |
| 18/NTB/221 | 304 (AIDA) | Dr Benjamin Griffiths | 22/11/2018 | 17/12/2018 | Approve | 14/02/2019 | Wellington Hospital | pharmaceutical company |
| 18/NTB/222 | FIGARO UC 303 | Dr Benjamin Griffiths | 22/11/2018 | 17/12/2018 | Approve | 14/02/2019 | Wellington Hospital | pharmaceutical company |
| 18/NTB/223 | Phase 3 Study of Lenvatinib (E7080/MK-7902) plus Pembrolizumab (MK- 3475) for First-line Therapy of Advanced Hepatocellular Carcinoma | Professor Edward Gane | 22/11/2018 | 17/12/2018 | Approve | 11/04/2019 | Auckland District Health Board | pharmaceutical company |
| 18/NTB/224 | MK-3475-859:Pembrolizumab/placebo plus chemotherapy as first-line therapy in participants with HER2 negative advanced gastric or GEJ adenocarcinoma | Dr Dragan Damianovich | 22/11/2018 | 17/12/2018 | Approve | 14/02/2019 | Auckland District Health Board | pharmaceutical company |
| 18/NTB/225 | FIGARO UC 302 | Dr Benjamin Griffiths | 22/11/2018 | 17/12/2018 | Approve | 15/02/2019 | Wellington Hospital | pharmaceutical company |
| 18/NTB/226 | The New Zealand Childhood Meningitis and Encephalitis Study | Dr Natalie Martin | 16/11/2018 |  | Approve | 12/12/2018 |  | no sponsor |
| 18/NTB/229 | Treatment outcomes of enterococcal endocarditis. | Dr Simon Briggs | 15/11/2018 |  | Approve | 7/12/2018 | Auckland City Hospital | no sponsor |
| 18/NTB/231 | Cutting Carbs for Diabetes Control (CCDC) | Dr Lily Fraser | 26/11/2018 | 21/12/2018 | Approve | 15/02/2019 | Turuki Health Care, Mangere | other |
| 18/NTB/232 | Safety of repeated administrations of Methoxyflurane | Dr Kelly Byrne | 28/11/2018 | 16/01/2019 | Approve | 17/02/2019 |  | pharmaceutical company |
| 18/NTB/234 | Effect of chewing on glycaemic response - Noodle study | Dr Esther Kim | 17/12/2018 |  | Approve | 18/01/2019 | The New Zealand Institute for Plant and Food Research Limited | other government agency |
| 18/NTB/236 | Reduced carbohydrate diets in gestational diabetes | Dr Rosemary Hall | 18/12/2018 | 19/02/2019 | Approve | 16/05/2019 |  | no sponsor |
| 18/NTB/237 | Taurite Tū- Development of Falls Prevention exercise programme for Māori | Ms Katrina Bryant | 12/12/2018 |  | Approve | 22/01/2019 | Te Rūnanga ō Ōtākou/University of Otago School of Physiotherapy | other |
| 18/NTB/238 | Social Rhythm and Light Therapy for Bipolar Disorder | Dr Katie Douglas | 8/12/2018 | 22/01/2019 | Approve | 17/02/2019 |  | no sponsor |
| 18/NTB/239 | SALTS (Sodium ALTernatives Study) | Dr Helen Eyles | 18/12/2018 | 18/01/2019 | Approve | 17/02/2019 | The University of Auckland | academic institution |
| 18/NTB/240 | Management of Thumb Osteoarthritis feasibility study | Ms Miranda Buhler | 20/12/2018 | 19/02/2019 | Approve | 14/03/2019 | University of Otago | academic institution |
| 18/NTB/241 | (duplicate) IDI Health Research Study | Dr Hiran Thabrew | 20/12/2018 |  | Approve | 21/12/2018 | University of Auckland | no sponsor |
| 18/NTB/242 | Pilot study of Advantan® fatty ointment applied to the skin of healthy male and female volunteers | Dr Noelyn Hung | 20/12/2018 |  | Approve | 15/01/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/NTB/1 | Vibration therapy for toddlers with cerebral palsy | Mrs Alena Adaikina | 24/01/2019 | 22/02/2019 | Approve | 16/04/2019 | University of Auckland | no sponsor |
| 19/NTB/10 | Incidence of invasive skin cancer in renal transplant recipients in Christchurch, New Zealand | Dr Harmony Thompson | 24/01/2019 | 22/02/2019 | Provisionally approve |  | Canterbury District Health Board | no sponsor |
| 19/NTB/100 | 0170 - Phase 3 Clinical Effect Durability of TD-9855 for Treating snOH in Subjects with Primary Autonomic Failure | Prof Tim Anderson | 20/06/2019 | 22/07/2019 | Provisionally approve |  | New Zealand Brain Research | pharmaceutical company |
| 19/NTB/101 | ACHIEVE | Dr Janak de Zoysa | 20/06/2019 | 22/07/2019 | Approve | 27/08/2019 | Waitemata DHB | academic institution |
| 19/NTB/102 | Instylla Hydrogel Embolic System First In Human Study | Associate Professor Andrew Holden | 20/06/2019 | 22/07/2019 | Approve | 5/09/2019 | Auckland District Health Board | medical device company |
| 19/NTB/103 | CHRYSALIS | Associate Professor Andrew Holden | 20/06/2019 | 22/07/2019 | Approve | 9/08/2019 | Auckland District Health Board | medical device company |
| 19/NTB/104 | Neurovascular coupling in healthy humans | Dr James Fisher | 21/06/2019 | 3/07/2019 | Approve | 17/07/2019 | University of Auckland | academic institution |
| 19/NTB/105 | UltraD3: Ultrasonic Dental Diagnostic Device | Prof Warwick Duncan | 21/06/2019 | 3/07/2019 | Provisionally approve |  | University of Otago | academic institution |
| 19/NTB/106 | A pharmacist-led medicines review intervention in community-dwelling Māori older adults– a feasibility study | Ms Joanna Hikaka | 22/06/2019 | 3/07/2019 | Approve | 18/07/2019 | University of Auckland | academic institution |
| 19/NTB/11 | Tuberculosis infection in Māori - Prison | Prof. Philip Hill | 24/01/2019 | 22/02/2019 | Approve | 25/03/2019 | University of Otago | no sponsor |
| 19/NTB/12 | Review of cases of Scedosporium or Lomentospora mould infections. | Dr Arthur Morris | 24/01/2019 |  | Approve | 22/02/2019 | Auckland City Hospital | no sponsor |
| 19/NTB/13 | Oral Zoledronate Dose-Finding Study | Prof Ian Reid | 24/01/2019 | 22/02/2019 | Approve | 27/03/2019 | University of Auckland | no sponsor |
| 19/NTB/15 | Housing in New Zealand - My Experiences, My Rights | Dr Brigit Mirfin-Veitch | 21/02/2019 | 20/03/2019 | Approve | 16/04/2019 | Donald Beasley Institute | other |
| 19/NTB/16 | Perseveration in Post-Stroke Aphasia | Miss Jessica Tranter | 21/02/2019 | 21/03/2019 | Approve | 2/07/2019 | The University of Queensland | no sponsor |
| 19/NTB/17 | M18-891, Moderate to Severe Atopic Dermatitis: Evaluation of Upadacitinib in Adolescent and Adult Subjects | Dr Steven Lamb | 21/02/2019 | 19/03/2019 | Approve | 16/04/2019 | Greenlane Clinical Centre | pharmaceutical company |
| 19/NTB/18 | Human tissue bank for MH | Professor Kathryn Stowell | 21/02/2019 | 21/03/2019 | Approve | 4/07/2019 | Massey University | district health board (DHB) |
| 19/NTB/19 | Safety of hysterosalpingography using Lipiodol in women and offspring | Professor Paul Hofman | 21/02/2019 |  | Decline | 21/03/2019 | Liggins Institute, University of Auckland | academic institution |
| 19/NTB/2 | Vibration therapy for children with cerebral palsy | Mrs Alena Adaikina | 31/01/2019 | 22/02/2019 | Approve | 16/04/2019 | University of Auckland | no sponsor |
| 19/NTB/20 | Patient recorded outcome measures of anterior versus posterior approach for Total Hip Joint Replacements. | Dr Alexandria Gibson | 12/02/2019 |  | Decline | 27/02/2019 | Middlemore Hospital | no sponsor |
| 19/NTB/21 | Adolescent Bariatric Surgery study | Dr Brandon Orr-Walker | 14/02/2019 | 13/03/2019 | Approve | 26/03/2019 | CMDHB | other |
| 19/NTB/22 | Deeper OUS | Associate Professor Andrew Holden | 21/02/2019 | 21/03/2019 | Approve | 10/04/2019 | Auckland District Health Board | medical device company |
| 19/NTB/24 | CS1003 in Subjects with solid tumours | Dr Matthew Strother | 21/02/2019 | 21/03/2019 | Approve | 21/05/2019 | Christchurch Hospital | pharmaceutical company |
| 19/NTB/25 | Glaucoma Diagnosis using Machine learning algorithms | Dr Anmar Abdul-Rahman |  |  | Invalid Application | 22/02/2019 |  | no sponsor |
| 19/NTB/26 | Bordetella Pertussis infections and carrier status in individuals post DPT immunisation | Dr Ezra Mabidikama |  |  | Invalid Application | 26/02/2019 |  | no sponsor |
| 19/NTB/27 | PREP2 VIP | Professor Cathy Stinear | 21/02/2019 | 21/03/2019 | Approve | 16/04/2019 |  | academic institution |
| 19/NTB/28 | MelEpiResponse | Professor Michael Eccles | 21/02/2019 | 21/03/2019 | Approve | 17/05/2019 | University of Otago, Dunedin School of Medicine | no sponsor |
| 19/NTB/29 | The mechanism of Continuous Positive Airway Pressure (CPAP) on hearing function in Obstructive Sleep Apnea (OSA) patients | Mrs Irene Cheung | 21/02/2019 | 6/03/2019 | Approve | 15/03/2019 | University of Auckland | academic institution |
| 19/NTB/3 | CARMEN CD 307 | Dr Benjamin Griffiths | 24/01/2019 | 21/02/2019 | Approve | 25/03/2019 | Capital and Coast District Health Board - Wellington Hospital | pharmaceutical company |
| 19/NTB/30 | Women's experiences of using Virtual Reality in labour | Ms Lorna Massov | 21/02/2019 | 21/03/2019 | Approve | 4/04/2019 | Victoria University of Wellington | academic institution |
| 19/NTB/31 | A study assessing the similarity of different formulations of E0302 | Dr Christian Schwabe | 21/02/2019 |  | Approve | 21/03/2019 | Auckland Clinical Studies Limited | pharmaceutical company |
| 19/NTB/32 | Adaptable Wrist Splint versus Cast for Distal Radius Fractures | Mr Michael Boland | 5/03/2019 |  | Decline | 15/03/2019 |  | medical device company |
| 19/NTB/35 | Hyperbaric Oxygen Therapy for the treatment of acute sensorineural hearing loss | Dr Ben Thomson | 14/03/2019 |  | Decline | 12/04/2019 |  | no sponsor |
| 19/NTB/36 | STONES | Professor Peter Gilling | 21/03/2019 | 15/04/2019 | Approve | 30/07/2019 | Tauranga Urology Research Limited | medical device company |
| 19/NTB/37 | CA045-002 | Dr Nicola Lawrence | 21/03/2019 | 12/04/2019 | Approve | 13/06/2019 | Auckland City Hospital | pharmaceutical company |
| 19/NTB/38 | (duplicate) N-finity REFUNCTION Study | Dr Stephen Merrilees | 21/03/2019 |  | Approve | 15/04/2019 | Auckland District Health Board | medical device company |
| 19/NTB/39 | Effect of animal and plant proteins on glycaemic response to staple carbohydrates | Dr John Monro | 16/03/2019 | 28/03/2019 | Approve | 17/04/2019 | New Zealand Institute for Plant and Food Research | no sponsor |
| 19/NTB/4 | CARMEN CD 306 | Dr Benjamin Griffiths | 24/01/2019 | 21/02/2019 | Approve | 25/03/2019 | Capital and Coast District Health Board - Wellington Hospital | pharmaceutical company |
| 19/NTB/40 | The effect of MitoQ on the recovery of muscle function following eccentric exercise | Dr Troy Merry | 19/03/2019 | 28/03/2019 | Approve | 21/05/2019 | University of Auckland FMHS | academic institution |
| 19/NTB/41 | Evaluation of a Peer Led Wheelchair Skills Group for Children. | Ms Debbie Wilson | 21/03/2019 | 15/04/2019 | Approve | 17/05/2019 | Seating To Go | no sponsor |
| 19/NTB/42 | IMPACT-Type 1 | Professor Paul Hofman | 21/03/2019 | 15/04/2019 | Approve | 30/05/2019 | Liggins Institute, University of Auckland | academic institution |
| 19/NTB/43 | Patient recorded outcome measures of Total Hip Replacements using an anterior approach at Middlemore Hospital | Dr Alexandria Gibson |  |  | Invalid Application | 20/03/2019 | Middlemore Hospital | no sponsor |
| 19/NTB/44 | Improving road safety and health: Understanding kava’s impact on driver fitness | Dr Apo Aporosa | 20/03/2019 | 29/03/2019 | Approve | 15/05/2019 | The University of Waikato | no sponsor |
| 19/NTB/45 | AB-729-001:Safety, Tolerability, and Pharmacokinetics of AB-729 in Healthy Subjects and Subjects with Chronic HBV Infection | Prof Edward Gane | 21/03/2019 | 15/04/2019 | Approve | 6/05/2019 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 19/NTB/48 | Improving mood and sleep in teenage males using relaxation music played on crystal singing bowls | Mr Alexander Matthews | 21/03/2019 |  | Approve | 4/04/2019 | N/A | no sponsor |
| 19/NTB/49 | NZ PLASTIC SURGERY EXPERIENCE WITH PREGNANCY AND PARENTHOOD | Dr Stephanie Savage |  |  | Invalid Application | 21/03/2019 | Christchurch Plastic Surgery Department | no sponsor |
| 19/NTB/5 | NP30179 - Phase I Dose Escalation Trial of RO7082859 in patients with R/R NHL | Professor Peter Browett | 24/01/2019 | 22/02/2019 | Approve | 25/03/2019 | The University of Auckland | pharmaceutical company |
| 19/NTB/50 | Cognitive-Reablement (Cog-Reablement) for people with Cognitive Decline | Dr Kathryn Peri | 22/03/2019 | 4/04/2019 | Approve | 15/05/2019 |  | non-governmental organisation (NGO) |
| 19/NTB/51 | RAPID Paediatric Program | Dr Ross Drake | 28/03/2019 |  | Approve | 17/04/2019 | Auckland District Health Board | no sponsor |
| 19/NTB/52 | Safety of hysterosalpingography using Lipiodol in women and offspring | Prof Paul Hofman | 1/04/2019 | 18/04/2019 | Approve | 22/05/2019 | Liggins Institute, University of Auckland | academic institution |
| 19/NTB/53 | Experiences of Maori with TBI in the Waikato | Dr Tai Kake | 4/04/2019 | 23/04/2019 | Approve | 20/06/2019 | University of Auckland | academic institution |
| 19/NTB/54 | Enhancing Long-Term Recovery in Mood Disorders | Dr Katie Douglas | 9/04/2019 | 8/05/2019 | Approve | 16/05/2019 |  | no sponsor |
| 19/NTB/55 | Cognitive Stimulation Therapy for Māori and Pasifika people with dementia. | Dr Gary Cheung | 25/04/2019 |  | Decline | 20/05/2019 | University of Auckland | academic institution |
| 19/NTB/56 | Balloon Angioplasty versus Shockwave Intravascular Lithotripsy for calcified coronary stenoses | Dr Seif El-Jack | 25/04/2019 |  | Decline | 21/05/2019 | Waitemata District Health Board | no sponsor |
| 19/NTB/57 | A study of GS-9674 in Non-Cirrhotic Primary Sclerosing Cholangitis patients | Dr Dominic Ray-Chaudhuri | 25/04/2019 | 10/06/2019 | Approve | 23/07/2019 | Auckland City Hospital | pharmaceutical company |
| 19/NTB/58 | FRAMBOISE | Professor Cathy Stinear | 25/04/2019 | 21/05/2019 | Approve | 5/06/2019 |  | no sponsor |
| 19/NTB/59 | A histopathological study of hysterectomy specimens in patients with refractory heavy menstrual bleeding | Dr Phillippa Walker | 24/04/2019 | 13/05/2019 | Approve | 11/07/2019 |  | no sponsor |
| 19/NTB/6 | Tank water versus municipal water supply: does it affect rates of surgical site infection in patients receiving skin cancer surgery? | Dr Young Lee | 17/01/2019 |  | Decline | 18/02/2019 | Waikato District Health Board | no sponsor |
| 19/NTB/60 | Shockwave TAVL FIM IV Study | Dr Mark Webster | 25/04/2019 | 20/05/2019 | Approve | 16/07/2019 | Auckland District Health Board | medical device company |
| 19/NTB/61 | MRI in Lung Cancer | Dr Louis Lao | 13/04/2019 |  | Approve | 15/05/2019 |  | district health board (DHB) |
| 19/NTB/62 | The prevalence of cancer in primary care | Prof Ross Lawrenson | 13/04/2019 | 15/05/2019 | Approve | 21/05/2019 | University of Waikato | academic institution |
| 19/NTB/63 | Vibration exercise in peripheral artery disease | Assoc Prof Darryl Cochrane | 17/04/2019 | 15/05/2019 | Approve | 5/06/2019 | Massey University | no sponsor |
| 19/NTB/64 | Dermatomyositis in the Waikato- A Retrospective Review | Ms Islay Dickie Islay Dickie | 17/04/2019 | 15/05/2019 | Approve | 1/07/2019 |  | no sponsor |
| 19/NTB/66 | FAM49B in bacteraemia | Dr Alan Davidson | 5/06/2019 | 11/06/2019 | Approve | 29/07/2019 | The University of Auckland | academic institution |
| 19/NTB/67 | Poziotinib for Patient \_\_\_ | Dr Ian Kennedy | 25/04/2019 |  | Invalid Application | 9/05/2019 |  | no sponsor |
| 19/NTB/68 | Vitamin C status in patients with chronic wounds | Professor Margreet Vissers | 23/04/2019 |  | Approve | 22/05/2019 | UNIVERSITY OF OTAGO, CHRISTCHURCH | no sponsor |
| 19/NTB/69 | Prevalence of germline mutations by exome wide sequencing in primary hyperparathyroidism | Dr Richard Carroll | 24/04/2019 | 11/06/2019 | Approve | 4/09/2019 |  | no sponsor |
| 19/NTB/7 | (duplicate) SUBCUTANEOUS TIBIAL NERVE STIMULATION FOR URGENCY URINARY INCONTINENCE: A FOLLOW-ON STUDY | Dr. Sharon English | 24/01/2019 | 22/02/2019 | Approve | 25/03/2019 | Urology Associates | medical device company |
| 19/NTB/70 | Scrotal and Core Temperature | Dr Marilyn Wong |  |  | Invalid Application | 26/04/2019 | Waikato Hospital | no sponsor |
| 19/NTB/71 | Nivolumab for prevention of recurrent Hepatocellular Carcinoma after Resection or Ablation. | Professor Edward Gane | 25/04/2019 | 20/05/2019 | Approve | 12/07/2019 | Auckland District Health Board | pharmaceutical company |
| 19/NTB/72 | A Phase 1 Trial of Interleukin 12 Gene Therapy for Advanced Cancer | Dr Chris Wynne | 25/04/2019 | 21/05/2019 | Approve | 31/07/2019 | Christchurch Clinical Studies Trust Limited | pharmaceutical company |
| 19/NTB/73 | Ophthalmology specialty training among medical graduates in New Zealand. Interest in Ophthalmology specialty training among medical graduates in New Zealand. | Dr Simone Freundlich |  |  | Invalid Application | 26/04/2019 |  | no sponsor |
| 19/NTB/74 | Retrospective review of outcomes following ablation of renal cancer with radiofrequency or microwave ablation | Doctor Malcolm Gill | 10/05/2019 |  | Approve | 16/05/2019 |  | no sponsor |
| 19/NTB/75 | Kākano: a parenting app to improve parenting sense of competence | Dr Lucy D'Aeth | 10/05/2019 | 17/05/2019 | Approve | 20/06/2019 | Canterbury District Health Board | no sponsor |
| 19/NTB/76 | Establishing Digital Biomarkers for Evaluating Postoperative Recovery From Major Abdominal Surgery | A/Prof. Greg O'Grady |  |  | Invalid Application | 24/05/2019 | University of Auckland/Auckland City Hospital | academic institution |
| 19/NTB/79 | Dynamic Rectal | Dr Dean Harris | 23/05/2019 | 24/06/2019 | Approve | 31/07/2019 | Christchurch Hospital | collaborative research |
| 19/NTB/8 | MRI for neuroinflammation | Dr Joanne Lin | 24/01/2019 | 22/02/2019 | Approve | 6/03/2019 | University of Auckland | academic institution |
| 19/NTB/80 | GS-US-320-1092 A Randomized, Double-Blind Study of Tenofovir Alafenamide (TAF) in Children and Adolescent Subjects with Chronic Hepatitis B Virus | Dr Helen Evans | 16/05/2019 | 24/06/2019 | Approve | 30/08/2019 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 19/NTB/81 | Long-term opioid use following trauma in the Bay of Plenty | Dr. Scott McLaughlin | 23/05/2019 | 29/05/2019 | Provisionally approve |  | Bay of Plenty District Health Board | no sponsor |
| 19/NTB/82 | Supporting peers after TBI | Associate Professor Nicola M Kayes | 23/05/2019 | 24/06/2019 | Approve | 22/08/2019 | AUT University | academic institution |
| 19/NTB/83 | Rescue Cumulative Dose Study | Prof Richard Beasley | 23/05/2019 | 24/06/2019 | Approve | 9/07/2019 | Medical Research Institute of New Zealand | other |
| 19/NTB/84 | Influence of a Pneumatic Compression Device on Recovery in Wheelchair Basketball Athletes | Ms ALISON Oliver | 23/05/2019 | 10/06/2019 | Approve | 25/06/2019 | University of Waikato | academic institution |
| 19/NTB/85 | Pembrolizumab after resection or ablation in patients with Hepatocellular Carcinoma | Professor Edward Gane | 23/05/2019 | 24/06/2019 | Approve | 2/08/2019 | Auckland District Health Board | pharmaceutical company |
| 19/NTB/86 | Orienting men with Prostate Cancer | Dr Heather Heron-Speirs | 24/05/2019 | 29/05/2019 | Approve | 7/08/2019 | Heron-Speirs Psychology | no sponsor |
| 19/NTB/9 | Robotic vaginal mesh removal | Dr Eva Fong | 24/01/2019 | 22/02/2019 | Approve | 18/03/2019 | Urology institute | no sponsor |
| 19/NTB/95 | ACE inhibitor cessation in the setting of well-functioning Fontan hearts. | Prof Yves d'Udekem | 20/06/2019 | 22/07/2019 | Provisionally approve |  |  | no sponsor |
| 19/NTB/96 | ARRAY-818-201 | Dr Catherine Barrow | 20/06/2019 | 22/07/2019 | Provisionally approve |  | Capital and Coast District Health Board | pharmaceutical company |
| 19/NTB/97 | 0169 - Phase 3 Clinical Effect of TD-9855 for Treating snOH in Subjects with Primary Autonomic Failure | Prof Tim Anderson | 20/06/2019 | 22/07/2019 | Provisionally approve |  | New Zealand Brain Research | pharmaceutical company |
| 19/NTB/98 | Investigation of improved nasal high flow to enhance carbon dioxide clearance and maintain oxygen saturation during shared airway surgery and A supplementary study to investigate the utility of Opt | Mr Matthew Payton | 20/06/2019 | 22/07/2019 | Provisionally approve |  | Fisher & Paykel Healthcare | medical device company |
| 19/NTB/99 | Evaluation of Upadacitinib in Adult Subjects with Moderate to Severe Atopic Dermatitis | Dr Penelope Montgomery | 20/06/2019 | 22/07/2019 | Provisionally approve |  | Optimal Clinical Trials | pharmaceutical company |

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

## Declaration by EC Chairperson

**Name of EC: Northern A Health and Disbility 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:** Kate O’Connor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_



**Signature: Date: 30** September 2019

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

**Name of EC: Northern A Health and Disbility Ethics Committee**

**Name of organisation:** Ministry of Health

**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:** Mr Rob McHawk

 Title First Name Last Name

**Position :** Manager – Ethics

**E-mail :** Rob.McHawk@health.govt.nz



**Signature: Date:** 30 September 2019

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)