

Northern A Health and Disability Ethics Committee

Annual Report  
2017

Citation: New Zealand Health and Disability Ethics Committee. 2018. *Northern A Health and Disability Ethics Committee: Annual Report 2016.* Wellington: Ministry of Health.

Published in September 2018 by the Ministry of Health  
PO Box 5013, Wellington 6140, New Zealand

ISBN 978-1-98-856808-9 (online)  
HP 6954

This document is available on the New Zealand Health and Disability Ethics Committee website: www.ethics.health.govt.nz

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# About the committee

The Northern A 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 A 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 A HDEC is registered (number IRB00008714) 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

Dr Brian Fergus was re-appointed as chairperson of Northern A in December 2015. Northern A as performed consistently well with no significant issues. A number of memebrs have resigned or retired from Northern A in the past 12 months creating opportunities for new members. 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 into meetings.

Dr Fergus contributed to 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

**Dr Brian Fergus (Chair)**

Membership category: Community Representative

Date of appointment: 11th November 2015

Current term expires: 11th November 2018

His career included management positions in industry, and management consulting before founding and running his own computer services company (1997-2008). Dr Fergus completed a Diploma of Business Administration at the University of Auckland, a PhD in Chemistry at McGill University, Montreal, Canada, a Master of Science and a Bachelor of Science at the University of Auckland. He is a former member of the Auckland District Health Board (2007-2010) and a previous member of the Baradene College Board of Trustees. Brian is a member of ECART (Ethics Committee for Assisted Reproductive Technology). Brian was the chair of the Northern X HDEC.

**Ms Susan Buckland**

Membership category: Community Representative

Date of appointment: 11th November 2015

Current term expires: 11th November 2016

Ms Buckland is a freelance journalist and editor, specialising in the arts and travel writing. She previously managed public relations for Air New Zealand (1979 – 1992) and was an independent public relations consultant from 1992 - 2005. Ms Buckland is an elected member of Auckland District Health Board (2007 – present), a Starship Foundation Trustee (2007 – present) and is a Professional Conduct Committee member of the Medical Council of New Zealand. She has previously been Chair of New Zealand Travel Communicators (1992 – 2000) and a Trustee for World Wildlife Fund New Zealand (1997 – 1998). She completed a Bachelor of Arts at Auckland University (1996) and a Diploma of Italian Language at Perugia University (1967).

**Ms Christine Crooks\***

Membership category: Interventional Studies

Date of appointment: 11th November 2015

Current term expires: 11th November 2018

Christine Crooks is a clinical trial coordinator and project manager at Cancer and Blood Services, Auckland City Hospital. She manages all aspects of several oncology clinical trials including collaborative group and pharmaceutical sponsored trials. Christine’s background in health research has involved managing intervention studies while completing PhD (students, athletes and older adults) and conducting an observational research project as a postdoctoral research fellow (infants and young children). She is a member of the New Zealand Association for Clinical Research, Australia New Zealand Breast Cancer Trials Group and Australia New Zealand Gynaecological Oncology Group. Christine has a PhD and MSc (Nutritional Science) from Massey University and a Science degree from Waikato University.

**Dr Karen Bartholomew**

Membership category: Interventional Studies

Date of appointment: 13th May 2016

Current term expires: 13th May 209

Dr Karen Bartholomew is currently at the Clinical Director of the Health Gain Team in Planning and Funding at Auckland and Waitemata DHBs working in women’s health and Māori health, and is involved in a number of research projects. Karen graduated with a Microbiology degree from Massey University in 1998. She worked from a consumer perspective in a Women’s Health Collective and Rape Crisis while in Palmerston North and then moved to Auckland graduating with her medical qualification (2004) and Masters of Public Health with honours (2011) from the University of Auckland. She has undertaken a range of clinical work, with a focus on women’s health. She holds a specialist qualification in Public Health Medicine, and has an interest in women’s health, maternity, screening and public health genomics. She is also has a strong interest in the ethics of public health, screening and research.

**Dr Kate Parker**

Membership category: Interventional Studies

Date of appointment: 13th May 2016

Current term expires: 13th May 209

Kate works at the University of Auckland as Programme Manager of the NETwork! Project, a NZ-wide multidisciplinary project investigating the incidence, treatment and genomic basis of neuroendocrine cancer. Previously, Kate was Director of Business Operations, for Proacta, a biotechnology start-up company developed new treatments for oncology in partnership with the Auckland Cancer Society Research Centre. Kate has also worked with Auckland UniServices, focusing on commercializing technologies invented at the University of Auckland.

Before moving to New Zealand, Kate worked at GlaxoSmithkline in the UK as a Manager in the Business Projects Team, advising the R&D business on strategic and operational issues. She also spent 5 years at ISO Healthcare consulting (now part of the Monitor Group) and 6 years at CMR International, a not-for-profit research organization that advises the pharmaceutical industry on issues in international drug development.

She has PhD in drug development from the University of Wales (Cardiff) and an MSc in Clinical Pharmacology from the University of Aberdeen.

**Ms Rochelle Style**

Membership category: Ethical and Moral Reasoning

Date of appointment: 15th June 2017

Current term expires: 14th June 2020

Rochelle Style currently works as an independent researcher. She holds an Honours degree in Law from the University of Canterbury (1986) and was a litigation partner in a major New Zealand law firm, Bell Gully, from 1995-1999. During that time, she acted as Pharmac’s principal legal counsel and defended it against proceedings brought by the pharmaceutical industry, including a successful appeal to the Privy Council. She also acted on behalf of major pharmaceutical companies defending their intellectual property rights.

After resigning her partnership to start a family Rochelle undertook part-time consultancy work at Bell Gully from 2000 – 2005 in addition to providing pro-bono advice to the health and education sectors from 2004-2010. From 2011-2016 Rochelle was a member of the Capital and Coast DHB’s Clinical Ethics Advisory Committee from 2011 – 2016 dealing with difficult ethical dilemmas in a hospital context. In 2016 Rochelle completed a Masters of Bioethics and Health Law (MBHL) (with distinction) through the University of Otago. Her Masters dissertation focused on the use of Big-Data for pharmaco-epidemiological research in New Zealand and considered the legal and ethical implications of transparency, trust and consent.

In addition to being a current member of the Northern A Health and Disability Ethics Committee, Rochelle is a member of a Ministry of Health Working Group tasked with re-drafting the ethical guidelines for health research in New Zealand.

**Dr Catherine Jackson**

Membership category: Health Practitioner Service provision

Date of appointment: 11th November 2016

Current term expires: 11th November 2019

Dr Catherine Jackson is a public health medical practitioner. She has extensive research experience in public health research and ethics experience and in population health outcomes research, informed consent processes for children, and specialises in epidemiology. She is employed by Waitemata DHB as a public health physician and is a registered Medical Officer.

**Ms Toni Miller QSM JP**

Membership category: Consumer/Community perspectives

Date of appointment: 11th November 2016

Current term expires: 11th November 2019

Toni Miller holds a number of board roles and directorships and is a JP. She serves as a lay member on the following boards and trusts:

* Centre for Social Impact – Director ( 2015 – present)
* Altera Body Corporate # 481478 – Chair (2015-present)
* Foundation North [previously ASB Community Trust] - Trustee (2011 - present)
* Auckland Central Community Response Forum [ MSD] – Deputy Chair (2010 - present)
* Social Workers Registration Board – Board Member (2011 – present)- Chair of Finance and Risk

## 

## 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 6** | **Dec 15** | **Feb** | **Mar** | **Apr** | **May** | **Jun** | **Total** |
| Dr Brian Fergus | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | 11 |
| Ms Susan Buckland | L | **Y** | **Y** | A | X | X | X | X | X | X | X | X | X | 2 |
| Ms Shamim Shagani | NL | **Y** | **Y** | A | X | X | X | X | X | X | X | X | X | 2 |
| Dr Charis Brown | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | X | X | X | 9 |
| Ms Christine Crooks | NL | **Y** | **Y** | A | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | 10 |
| Dr Karen Bartholomew | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | 11 |
| Ms Rosemary Abbott | L | **Y** | A | **Y** | **Y** | **Y** | A | A | A | **Y** | **Y** | A | X | 6 |
| Dr Kate Parker | NL | A | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | 10 |
| Ms Rochelle Style | L | X | X | X | X | X | X | X | X | X | X | X | A | 0 |
| Mr John Hancock | L | X | **Y** | **Y** | X | X | X | X | X | X | X | X | X | 2 |
| Ms Phyllis Huitema | L | X | X | **Y** | X | X | X | X | X | X | X | X | X | 1 |
| Mrs Leesa Russel | NL | X | X | **Y** | X | X | Y | X | X | X | X | X | X | 2 |
| Ms Tangihaere MacFarlane | L | X | X | X | **Y** | X | X | X | X | X | X | X | X | 1 |
| Dr Catherine Jackson | NL | X | X | X | X | A | **Y** | X | A | **Y** | **Y** | **Y** | **Y** | 5 |
| Ms Toni Millar | L | X | X | X | X | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | 7 |
| Dr Angela Ballantyne | L | X | X | X | X | X | **Y** | X | X | X | X | X | X | 1 |
| Dr Patries Herst | NL | X | X | X | X | X | X | **Y** | X | X | X | X | X | 1 |
| Ms Raewyn Idoine | L | X | X | X | X | X | X | **Y** | X | X | X | X | X | 1 |
| Dr Nicola Swain | NL | X | X | X | X | X | X | **Y** | X | X | X | X | X | 1 |
| Dr Nora Lynch | NL | X | X | X | X | X | X | **Y** | X | X | X | X | X | 1 |
| Dr Cordeilia Thomas | L | X | X | X | X | X | X | **Y** | Y | X | X | X | Y | 1 |
| Dr Peter Gallagher | NL | X | X | X | X | X | X | **Y** | X | X | X | X | X | 1 |
| Mrs Helen Walker | L | X | X | X | X | X | X | X | X | X | **Y** | X | X | 1 |
| **Total no. of members present** |  | **7** | **8** | **7** | **7** | **7** | **8** | **8** | **7** | **8** | **7** | **6** | **7** |  |
| **No. of applications considered** |  | **10** | **12** | **12** | **12** | **11** | **12** | **12** | **11** | **12** | **12** | **11** | **12** |  |

## Training and conferences

### Specify the training undergone by new members

New member training for 3 members.

GCP training for two members.

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

Training was conducted before a number of meetings throughout the year by staff and speakers, one in good clinical pracrice as well as bio banking training May 2017, GCP training June 2017, and platform trials with Colin McArthur.

# Applications reviewed

### Summary of applications received by full EC

|  |  |
| --- | --- |
| No. of applications approved | 108 |
| No. of applications approved subject to conditions / pending | 1 |
| No. of applications deferred and subsequently approved | N/A |
| No. of applications deferred as at time of report | N/A |
| 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) | 18 |
| No. of applications which do not require ethics committee approval | 23 |
| No. of studies withdrawn by researcher | 3 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC | N/A |
| **Total number of applications received by full EC** | **153** |

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

|  |  |
| --- | --- |
| No. of applications approved | 63 |
| No. of applications approved subject to conditions / pending | 0 |
| No. of applications which do not require ethics committee approval | 20 |
| No. of applications referred for full committee review | 0 |
| **Total number of applications received under expedited/low risk review** | **83** |

|  |  |
| --- | --- |
| Total number of applications received (combine the total number of applications in 8.1 and 8.2) | **236** |

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# Complaints and overdue application summary

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

## Complaints received

SPICE study: a complaint was made by Dr Ram in November 2016 about recruitment practices for a study at Wellington Hospital and the failure to discuss the non-consensual study with family members and that a family member was enrolled in the study without adequate family involvement. Information was not supplied until some days after recruitment occurred due to shortages of research nurse staff. The complaint was heard by the committee, with submissions from the researchers and family both made to the committee. Recruitment into the study was halted while all 174 participants’ consent processes were reviewed. The family received an apology at the committee hearing and processes were fully reviewed and documented. The study recommenced after this. Dr Ram noted it was an important study.

## 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/NTA/101 | Laser Therapy for Lymphedema: Feasibility Trial | Professor David Baxter | 14/07/2016 | 28/07/2016 | Provisionally Approve | Approve | 2/09/2016 | University of Otago | academic institution | Locality |
| 16/NTA/102 | Outcomes following silicone metacarpophalangeal joint implant arthroplasty treated in a dynamic splint | Ms Julie Collis | 14/07/2016 | 27/07/2016 | Provisionally Approve | Approve | 4/08/2016 | Counties | no sponsor | Locality |
| 16/NTA/104 | Comparison of Cough Strength in Patients with dysphagia and healthy participants | Miss Emma Wallace | 21/07/2016 |  |  | Approve | 5/08/2016 | University of Canterbury | no sponsor | Locality |
| 16/NTA/105 | Voluntary tremor suppression in Parkinson's disease | Dr Rebekah Blakemore | 21/07/2016 | 2/08/2016 | Provisionally Approve | Approve | 22/08/2016 | University of Otago, Christchurch | no sponsor | Locality |
| 16/NTA/106 | An RCT of mindfulness for colorectal cancer. | Dr Andrew McCombie | 20/07/2016 | 1/08/2016 |  | Approve | 10/08/2016 | University of Otago, Christchurch | no sponsor | Locality |
| 16/NTA/107 | PIPEF - Propofol Pain Study | Ass Prof Dr R Ross Kennedy | 21/07/2016 |  |  | Approve | 5/08/2016 | CDHB | no sponsor | Locality |
| 16/NTA/108 | PROSPER | Dr Michelle Wilson | 26/07/2016 | 23/08/2016 |  | Approve | 6/09/2016 |  | academic institution | Locality |
| 16/NTA/109 | FAST Feasibility Study | Dr. Seif El-Jack | 26/07/2016 | 23/08/2016 | Provisionally Approve | Approve | 26/09/2016 | Waitemata District Health Board | medical device company | Locality |
| 16/NTA/110 | Evaluation of the Safety of N1539 Following Major Surgery | Dr John Currie | 26/07/2016 | 23/08/2016 |  | Approve | 8/09/2016 | Clinical Trials New Zealand | pharmaceutical company | Locality |
| 16/NTA/111 | The REACTOR trial. Randomised Evaluation of Active Control of Temperature versus Ordinary temperature management. | Dr Paul Young | 26/07/2016 |  |  | Approve | 23/08/2016 |  | collaborative research | Locality |
| 16/NTA/112 | The NZ PrEP study: A demonstration project | Dr Sunita Azariah | 28/07/2016 | 23/08/2016 | Provisionally Approve | Approve | 15/09/2016 | Auckland District Health board | collaborative research | Locality |
| 16/NTA/113 | Treatment of mild-moderate Impetigo | Dr Alison Leversha | 28/07/2016 | 23/08/2016 | Provisionally Approve | Approve | 26/10/2016 | Starship Children's Health | no sponsor | Locality |
| 16/NTA/115 | Vaginal prostaglandins for IOL with term PROM | Dr Mei Ling Pearson | 27/07/2016 | 10/08/2016 |  | Approve | 24/08/2016 |  | no sponsor | Locality |
| 16/NTA/116 | MS1819-SD phase IIa clinical trial for EPI caused by CP and/or distal pancreatectomy. | Dr Richard Stubbs | 28/07/2016 | 23/08/2016 | Provisionally Approve | Approve | 27/09/2016 | P3 Research Ltd | pharmaceutical company | Locality |
| 16/NTA/118 | He Kura: Asthma in Schools PHASE 2 (Asthma Trial) | Mrs Bernadette Jones | 28/07/2016 | 23/08/2016 |  | Approve | 17/11/2016 | University of Otago- Wellington | no sponsor | Locality |
| 16/NTA/120 | Prediction of a response to treatment during first episode psychosis | Associate Professor Bruce Russell | 29/07/2016 | 23/08/2016 | Provisionally Approve | Approve | 28/11/2016 | University of Auckland | academic institution | Locality |
| 16/NTA/121 | Margins Project | A/Prof Ian Campbell | 29/07/2016 |  |  | Approve | 23/08/2016 | Waikato District Health Board | no sponsor | Locality |
| 16/NTA/123 | Prucalopride in postoperative ileus | Associate Professor Ian Bissett | 29/07/2016 |  |  | Approve | 23/08/2016 | University of Auckland | academic institution | Locality |
| 16/NTA/124 | DARTS Study | Mr. Parma Nand | 29/07/2016 |  |  | Decline | 23/08/2016 | Auckland District Health Board | medical device company | Locality |
| 16/NTA/127 | Multinodular goitre study | Dr Marianne Elston | 1/08/2016 |  |  | Approve | 19/08/2016 |  | no sponsor | Locality |
| 16/NTA/128 | Defining “normal”: A prospective analysis of synovial fluid from non-septic knees | Dr Rushi chandar Penumarthy | 3/08/2016 | 24/08/2016 | Provisionally Approve | Approve | 6/09/2016 |  | no sponsor | Locality |
| 16/NTA/130 | Riboflavin prior to cystoscopy | Associate Professor Michael Stitely | 25/08/2016 | 7/09/2016 | Provisionally Approve | Approve | 19/09/2016 | University of Otago, Dunedin School of Medicine | no sponsor | Locality |
| 16/NTA/131 | Riociguat rEplacing PDE-5i therapy evaLuated Against Continued PDE-5i thErapy | Prof Lutz Beckert | 1/09/2016 | 21/09/2016 | Provisionally Approve | Approve | 14/12/2016 | University of Otago | pharmaceutical company | Locality |
| 16/NTA/132 | Acerta 309 | Dr Peter Ganly | 1/09/2016 | 21/09/2016 | Provisionally Approve | Approve | 2/12/2016 | CDHB | pharmaceutical company | Locality |
| 16/NTA/133 | Whare Aroha transition study | Associate Professor Stephen Neville | 1/09/2016 | 21/09/2016 | Provisionally Approve | Approve | 27/10/2016 | AUT University | no sponsor | Locality |
| 16/NTA/134 | KEYNOTE-355 for Triple Negative Breast Cancer | Dr David Porter | 1/09/2016 | 21/09/2016 | Provisionally Approve | Approve | 13/12/2016 | Auckland City Hospital | pharmaceutical company | Locality |
| 16/NTA/136 | Blood test handling and stability study (for i-STAT cardiac troponin I) | Dr MARTIN THAN | 28/08/2016 | 15/09/2016 | Provisionally Approve | Approve | 17/10/2016 |  | pharmaceutical company | Locality |
| 16/NTA/139 | Consolidation of Breast Cancer Registers | Ms Reena Ramsaroop | 1/09/2016 |  |  | Approve | 21/09/2016 | NZ Breast Cancer Foundation | non-governmental organisation (NGO) | Locality |
| 16/NTA/140 | Effects of milk oligosaccharides on the gut-brain axis | Dr Caroline Thum | 1/09/2016 |  |  | Decline | 21/09/2016 | AgResearch Limited | other government agency | Locality |
| 16/NTA/141 | ICON 2 Validation | Ms Hansinie Laing | 1/09/2016 | 21/09/2016 | Provisionally Approve | Approve | 2/11/2016 | Fisher & Paykel Healthcare | medical device company | Locality |
| 16/NTA/142 | Keratin4VLU; A randomised trial | Dr Andrew Jull | 1/09/2016 |  |  | Approve | 21/09/2016 | University of Auckland | no sponsor | Locality |
| 16/NTA/144 | Dyspnoea during exercise | Dr Kevin Ellyett | 1/09/2016 | 21/09/2016 | Provisionally Approve | Approve | 19/10/2016 | Auckland District Health Board | no sponsor | Locality |
| 16/NTA/146 | PREDICT KT Study | Dr Stuart Dalziel | 1/09/2016 |  |  | Approve | 21/09/2016 | Starship Children's Health, Auckland District Health Board | no sponsor | Locality |
| 16/NTA/148 | The SPACE Trial | Dr Natalie Walker | 1/09/2016 |  |  | Approve | 21/09/2016 | University of Auckland | academic institution | Locality |
| 16/NTA/149 | A study of the Relative Oral Bioavailability of AL-3778 Capsules and Tablets and Drug Interaction in healthy subjects | Dr Christian Schwabe | 1/09/2016 | 22/09/2016 | Provisionally Approve | Approve | 7/10/2016 | Auckland Clinical Studies Ltd | pharmaceutical company | Locality |
| 16/NTA/151 | Achieving healthy weight gain in pregnancy. | Dr Kirsten Coppell | 7/09/2016 |  |  | Approve | 21/09/2016 | University of Otago | no sponsor | Locality |
| 16/NTA/152 | Gram-negative Extreme Resistance at Middlemore 1 - Pilot Study (GERMS-1) | Dr Chris Hopkins | 8/09/2016 | 22/09/2016 | Provisionally Approve | Approve | 21/10/2016 | Counties Manukau District Health Board | district health board (DHB) | Locality |
| 16/NTA/153 | Acute mountain sickness and the kidneys | Dr Mickey Fan | 9/09/2016 | 23/09/2016 | Provisionally Approve | Approve | 17/10/2016 | University of Otago | no sponsor | Locality |
| 16/NTA/154 | Weaning foods, gut bacteria and health | Dr Shanthi Parkar | 9/09/2016 | 23/09/2016 | Provisionally Approve | Approve | 7/10/2016 | Plant & Food Research (PFR) | other government agency, other | Locality |
| 16/NTA/156 | The EMBLEM UNTOUCHED Study | Dr Margaret Hood | 29/09/2016 |  |  | Approve | 19/10/2016 |  | medical device company | Locality |
| 16/NTA/157 | ITACS | Dr Shay McGuinness | 29/09/2016 | 19/10/2016 | Provisionally Approve | Approve | 31/01/2017 | Auckland District Health Board | no sponsor | Locality |
| 16/NTA/158 | The feasibility of assessing changes in muscle strength in children with Cerebral Palsy following Chiropractic care. | Mrs Jenna Salmons | 29/09/2016 | 19/10/2016 | Provisionally Approve | Approve | 16/11/2016 | Auckland University of Technology | academic institution | Locality |
| 16/NTA/159 | The ACT-F Trial: Does active follow-up of invitation lead to higher participation in bowel screening by Māori, Pacific and Asians? | Dr Peter Sandiford | 29/09/2016 |  |  | Approve | 19/10/2016 | Waitemata District Health Board | district health board (DHB) | Locality |
| 16/NTA/160 | 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 | 29/09/2016 |  |  | Decline | 19/10/2016 | Serco/AUT | no sponsor | Locality |
| 16/NTA/162 | Long term outcomes following Traumatic Brain Injury (TBI) in Childhood | Dr Kelly Jones | 29/09/2016 | 19/10/2016 | Provisionally Approve | Approve | 24/11/2016 | AUT University | academic institution | Locality |
| 16/NTA/163 | Levels of cognitive dysfunction in service users of community mental health teams at Counties Manukau Health | Dr Melodie Barr | 29/09/2016 | 19/10/2016 | Provisionally Approve | Approve | 9/11/2016 | Counties Manukau District Health Board | no sponsor | Locality |
| 16/NTA/164 | Prelude Study | Associate Professor Andrew Holden | 29/09/2016 |  |  | Approve | 19/10/2016 | Auckland District Health Board | medical device company | Locality |
| 16/NTA/165 | The Benzathine Penicillin G Formulation Preferences Study | Dr Dianne Sika-Paotonu | 29/09/2016 | 19/10/2016 | Provisionally Approve | Approve | 14/12/2016 | Victoria University of Wellington | academic institution | Locality |
| 16/NTA/166 | Community water supplies: ensuring microbial safety for disease prevention | Dr Liping Pang | 29/09/2016 |  |  | Approve | 19/10/2016 | Institute of Environmental Science and Research | other government agency | Locality |
| 16/NTA/167 | A study of RO7020531 in healthy subjects and patients with chronic hepatitis B | Professor Ed Gane | 29/09/2016 | 19/10/2016 | Provisionally Approve | Approve | 9/11/2016 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 16/NTA/169 | Pain Free TRUS B | Mr Nicholas Buchan | 29/09/2016 | 19/10/2016 | Provisionally Approve | Approve | 1/12/2016 | Canterbury Urology Research Trust | district health board (DHB) | Locality |
| 16/NTA/172 | Gut Microbiome Transfer for Severe Adolescent Obesity | Professor Wayne Cutfield | 6/10/2016 | 20/10/2016 | Provisionally Approve | Approve | 8/11/2016 | University of Auckland | academic institution | Locality |
| 16/NTA/173 | Developing Diagnostic & Prognostic Tests for Prostate Cancer Using Multiple RNA Biomarker Amplicon Sequencing (RBAS) | Dr Gen Johnston | 19/10/2016 | 1/11/2016 |  | Approve | 8/11/2016 | Caldera Health | other | Locality |
| 16/NTA/174 | TVT outcomes in obesity | Dr Nicola Boyd | 21/10/2016 | 8/11/2016 | Provisionally Approve | Approve | 27/01/2017 | CMDHB | no sponsor | Locality |
| 16/NTA/175 | The effect of different preparation information on side effects following intravenous iron infusion | Professor Keith Petrie | 25/10/2016 | 8/11/2016 | Provisionally Approve | Approve | 21/11/2016 | University of Auckland | no sponsor | Locality |
| 16/NTA/177 | ICU-ROX TRIPS | Ms Diane Mackle | 3/11/2016 | 28/11/2016 |  | Approve | 8/12/2016 | Medical Research Institute of NZ | other | Locality |
| 16/NTA/178 | Comparison of the blood levels of two forms of lorazepam 2.5 mg in healthy volunteers under fasting conditions | Dr Noelyn Hung | 3/11/2016 |  |  | Approve | 29/11/2016 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 16/NTA/179 | Study of safety, tolerability, pharmacokinetics and efficacy of LMB763 in patients with non-alcoholic steatohepatitis (NASH) | Dr Dean Quinn | 3/11/2016 | 28/11/2016 | Provisionally Approve | Approve | 31/01/2017 |  | pharmaceutical company | Locality |
| 16/NTA/180 | Blood biomarkers for detection of disease burden in patients with melanoma | Prof. Cristin G Print | 3/11/2016 |  |  | Approve | 28/11/2016 | The University of Auckland | academic institution | Locality |
| 16/NTA/181 | NIVORAD | Mr Louis Lao | 3/11/2016 | 29/11/2016 | Provisionally Approve | Approve | 16/03/2017 | Auckland District Health Board | academic institution | Locality |
| 16/NTA/183 | Arthroresis screw in tibialis posterior reconstruction | Dr David Kieser | 3/11/2016 | 29/11/2016 | Provisionally Approve | Approve | 27/01/2017 | CDHB | no sponsor | Locality |
| 16/NTA/184 | Are k-wires better to be buried or unburied | Dr David Kieser | 3/11/2016 |  |  | Decline | 29/11/2016 | CDHB | no sponsor | Locality |
| 16/NTA/188 | A study of RO7062931 in healthy subjects and patients chronically infected with hepatitis B virus infection | Professor Ed Gane | 3/11/2016 | 28/11/2016 | Provisionally Approve | Approve | 19/12/2016 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 16/NTA/189 | YOD - Waikato | Dr Lochanie Fonseka | 2/11/2016 |  |  | Approve | 17/11/2016 | Waikato DHB | no sponsor | Locality |
| 16/NTA/190 | Child and Famly Unit patient and whanau feedback. | 3/11/2016 | 28/11/2016 | Provisionally Approve | Approve | 31/01/2017 |  | no sponsor | Locality |  |
| 16/NTA/192 | Comparison of the blood levels of two forms of phentermine 40 mg in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | 3/11/2016 | 29/11/2016 | Provisionally Approve | Approve | 31/01/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 16/NTA/194 | GALACTIC-HF | Professor Russell Scott | 3/11/2016 | 28/11/2016 | Provisionally Approve | Approve | 31/01/2017 | CDHB | pharmaceutical company | Locality |
| 16/NTA/197 | Ketamine and Cognitive Behavioural Therapy for Treatment Resistant Depression | Ms Ella Kroch | 24/11/2016 | 13/12/2016 | Provisionally Approve | Approve | 3/02/2017 | Massey University | academic institution, other | Locality |
| 16/NTA/199 | Beta-blocker adherence in LQTS | Dr Kathryn Waddell-Smith | 24/11/2016 |  |  | Decline | 13/12/2016 |  | other | Locality |
| 16/NTA/200 | Whānau Pakari on Orimupiko marae | Dr Yvonne Anderson | 24/11/2016 | 13/12/2016 | Provisionally Approve | Withdrawn by Researcher | 26/04/2017 | Taranaki District Health Board/Liggins Institute | academic institution | Locality |
| 16/NTA/202 | GSK ASCEND-D 200807 | Dr Kannaiyan Rabindranath | 24/11/2016 | 13/12/2016 | Provisionally Approve | Approve | 13/03/2017 | Waikato Hospital | pharmaceutical company | Locality |
| 16/NTA/203 | GSK ASCEND-ND 200808 | Dr Kannaiyan Rabindranath | 24/11/2016 | 13/12/2016 | Provisionally Approve | Approve | 13/03/2017 | Waikato Hospital | pharmaceutical company | Locality |
| 16/NTA/204 | The Attain Study | Dr Kate Gardner | 24/11/2016 | 13/12/2016 | Provisionally Approve | Approve | 3/02/2017 | Canterbury District Health Board | pharmaceutical company | Locality |
| 16/NTA/205 | (duplicate) Antibiotic Timing and Culture Yields in Paediatric Musculoskeletal Infection | Mr Matthew Boyle | 24/11/2016 |  |  | Approve | 13/12/2016 | Auckland City Hospital | no sponsor | Locality |
| 16/NTA/206 | Omega-3 fatty acids and mild traumatic brain injury | Ms Brylee Cresswell | 18/11/2016 | 5/12/2016 |  | Approve | 19/12/2016 |  | academic institution, other | Locality |
| 16/NTA/208 | The CREEDS Study | Assoc. Prof Jeremy Krebs | 24/11/2016 | 13/12/2016 | Provisionally Approve | Approve | 20/02/2017 | University of Otago and Capital and Coast DHB | no sponsor | Locality |
| 16/NTA/209 | NIMO-Prem | Dr Maria Saito Benz | 24/11/2016 | 13/12/2016 | Provisionally Approve | Approve | 29/03/2017 |  | district health board (DHB) | Locality |
| 16/NTA/211 | Experiences of prescription and over-the-counter opioid dependence | Ms Carina Walters | 24/11/2016 | 13/12/2016 | Provisionally Approve | Approve | 30/03/2017 | University of Auckland, Faculty of Medical & Health Sciences | academic institution | Locality |
| 16/NTA/214 | 30-day Mortality of Patients Admitted to Intensive Care Unit with Acute Upper Gastrointestinal-Bleed (AUGIB) | Dr Junaid Beig | 18/11/2016 | 30/11/2016 |  | Approve | 14/12/2016 |  | no sponsor | Locality |
| 16/NTA/215 | Emergency treatment of anterior shoulder dislocations | Dr. Mark Sagarin | 24/11/2016 |  |  | Decline | 13/12/2016 | Taranaki DHB | no sponsor | Locality |
| 16/NTA/217 | CROSSFIRE | Dr Ilia Elkinson | 22/11/2016 | 30/11/2016 | Provisionally Approve | Approve | 9/03/2017 | Wellington Hospital | no sponsor | Locality |
| 16/NTA/220 | The effect of different preparation information on side effects following colonoscopy | Professor Keith Petrie | 23/11/2016 | 7/12/2016 |  | Approve | 19/12/2016 | University of Auckland | no sponsor | Locality |
| 16/NTA/225 | Linking days alive and out of hospital with surgical site infection: the ‘LASSI’ feasibility study | Professor Alan Merry | 25/11/2016 | 8/12/2016 |  | Approve | 14/12/2016 | University of Auckland | academic institution | Locality |
| 16/NTA/226 | High Dose Rate (HDR) brachytherapy as a salvage treatment for locally recurrent prostate cancer | Mr Dean Paterson | 29/11/2016 | 9/12/2016 | Provisionally Approve | Approve | 18/01/2017 | Capital and Coast DHB | district health board (DHB) | Locality |
| 16/NTA/227 | Nasal high flow in acute respiratory failure in AECOPD – A feasibility study | Dr James Fingleton | 1/12/2016 | 22/12/2016 | Provisionally Approve | Approve | 9/02/2017 | Medical Research Institute of New Zealand | other | Locality |
| 16/NTA/228 | A Treatment Study of ACH-0144471 in Patients with Paroxysmal Nocturnal Hemoglobinuria | Dr Peter Browett | 1/12/2016 | 22/12/2016 | Provisionally Approve | Approve | 16/01/2017 | Auckland Clinical Studies | pharmaceutical company | Locality |
| 16/NTA/229 | A study comparing Filgotinib and placebo in Subjects with Moderately to Severely Active Crohn’s Disease | Dr Ben Griffiths | 1/12/2016 | 22/12/2016 | Provisionally Approve | Approve | 9/02/2017 | Capital and Coast District Health Board Wellington | pharmaceutical company | Locality |
| 16/NTA/230 | A Long-Term Extension Study to Evaluate Filgotinib in Subjects with Crohn’s Disease | Dr Ben Griffiths | 1/12/2016 | 22/12/2016 | Provisionally Approve | Approve | 9/02/2017 | Capital and Coast District Health Board Wellington | pharmaceutical company | Locality |
| 16/NTA/231 | REDUCCTION | Dr David Semple | 1/12/2016 |  |  | Decline | 22/12/2016 | Auckland City Hospital | academic institution | Locality |
| 16/NTA/232 | M16-126: A Study of Glecaprevir/Pibrentasvir in Adults with Chronic Hepatitis C Virus Genotype 5 or 6 | Prof Edward Gane | 1/12/2016 |  |  | Approve | 22/12/2016 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 16/NTA/233 | Comparison of the blood levels of four forms of isotretinoin 10mg and 25mg capsules in healthy male volunteers under fasting conditions | Dr Noelyn Hung | 1/12/2016 |  |  | Approve | 22/12/2016 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 16/NTA/234 | Can a new blood test predict dementia | Dr Joanna Williams | 1/12/2016 |  |  | Approve | 22/12/2016 |  | no sponsor | Locality |
| 16/NTA/235 | EFC14335\_ICARIA MM | Dr Hilary Blacklock | 1/12/2016 | 22/12/2016 | Provisionally Approve | Approve | 14/02/2017 | Middlemore Clinical Trials | pharmaceutical company | Locality |
| 16/NTA/236 | An exploratory Safety Study of 480 Biomedical Mometasone Furoate Sinus Drug Depot (MFSDD) in Adult Subjects with Chronic Sinusitis | A/Prof Richard Douglas | 1/12/2016 | 22/12/2016 | Provisionally Approve | Approve | 31/01/2017 | University of Auckland | medical device company | Locality |
| 16/NTA/237 | Endoform Dental Membrane - Clinical Feedback Study | Dr. Warwick Duncan | 1/12/2016 | 22/12/2016 | Provisionally Approve | Withdrawn by Researcher | 21/03/2017 | London Street Specialists | medical device company | Locality |
| 16/NTA/238 | Vitamin C for Severe Sepsis | Dr Anitra Carr | 1/12/2016 | 22/12/2016 | Provisionally Approve | Approve | 2/05/2017 | University of Otago, Christchurch | no sponsor | Locality |
| 16/NTA/239 | Assessment of productive bioactivation of cyclophosphamide | Dr Nuala Helsby | 6/12/2016 |  |  | Approve | 19/12/2016 | The University of Auckland | academic institution | Locality |
| 16/NTA/240 | Myocardial Perfusion Scan (MPS) in CKD 5 | Dr Margaret Fisher | 6/12/2016 |  |  | Approve | 19/12/2016 |  | no sponsor | Locality |
| 16/NTA/241 | URINARY BIOMARKERS FOR INFLAMMATORY BOWEL DISEASE | Dr Sundaram (Sunny) Veerappan | 14/12/2016 |  |  | Approve | 22/12/2016 | Tauranga Hospital | collaborative research | Locality |
| 16/NTA/243 | Walking to better health after stroke | Dr Lynne Clay | 16/01/2017 | 26/01/2017 | Provisionally Approve | Approve | 15/02/2017 | University of Otago | academic institution | Locality |
| 17/NTA/1 | The Injury Profile Related to the Opening of Trampoline Arenas | Dr Lloyd Roffe | 16/01/2017 | 27/01/2017 |  | Approve | 3/02/2017 | Canterbury District Health Board | no sponsor | Locality |
| 17/NTA/10 | Return to work following mild traumatic brain injury. | Dr David Lapenga Oyaka | 2/02/2017 | 10/02/2017 |  | Approve | 16/02/2017 | ABI Rehabilitation Ltd | no sponsor | Locality |
| 17/NTA/101 | The benefits of participating in a dementia-friendly book club at the residential aged care facility: A proposal for a randomised controlled pilot study plus qualitative evaluation. | Dr Dalice Audrey Sim | 8/06/2017 |  |  | Decline | 27/06/2017 | University of Otago | other | Locality |
| 17/NTA/103 | Distal radius fracture functional outcomes in the elderly patient | Dr Hrvoje Vidakovic | 6/06/2017 | 19/06/2017 |  | Approve | 28/06/2017 | Southern DHB | no sponsor | Locality |
| 17/NTA/104 | Green Lane surgical data back-fill (1958-88) | Dr TOM GENTLES | 8/06/2017 |  |  | Decline | 27/06/2017 | ADHB | no sponsor | Locality |
| 17/NTA/105 | A study comparing ABT-494 to placebo and adalimumab in subjects with active psoriatic arthritis (SELECT PsA1) | Dr Doug White | 8/06/2017 | 27/06/2017 | Provisionally Approve | Approve | 28/09/2017 |  | pharmaceutical company | Locality |
| 17/NTA/106 | A study comparing ABT-494 to placebo in patients with psoriatic arthritis. SELECT-PsA 2 | Dr Doug White | 8/06/2017 | 27/06/2017 | Provisionally Approve | Approve | 28/09/2017 |  | pharmaceutical company | Locality |
| 17/NTA/108 | Severe anemia outcomes in Jehovah's Witnesses | Professor Colleen Bergin | 5/06/2017 | 14/06/2017 | Provisionally Approve | Withdrawn by HDEC | 16/10/2017 | Auckland City Hospital | no sponsor | Locality |
| 17/NTA/109 | SMART-C | Professor Ed Gane | 8/06/2017 | 27/06/2017 | Provisionally Approve | Approve | 31/08/2017 | Auckland Clinical Studies Ltd and Auckland City Hospital | academic institution | Locality |
| 17/NTA/11 | CT analysis of pelvic and lumbar spine parameters | Mr Peter Robertson | 2/02/2017 | 14/02/2017 | Provisionally Approve | Approve | 13/04/2017 | Auckland District Health Board | no sponsor | Locality |
| 17/NTA/111 | Paediatic ctDNA | Prof Parry Guilford | 8/06/2017 |  |  | Decline | 27/06/2017 | University of Otago | no sponsor | Locality |
| 17/NTA/112 | Clinical Application of pharyngeal high resolution manometry. | Dr Kristin Gozdzikowska | 8/06/2017 |  |  | Decline | 27/06/2017 | University of Canterbury | collaborative research | Locality |
| 17/NTA/113 | Gestational Age | Dr Anusha Ganeshalingham | 8/06/2017 | 19/06/2017 | Provisionally Approve | Approve | 12/07/2017 |  | no sponsor | Locality |
| 17/NTA/115 | Non-Alcoholic Fatty Liver Disease (NAFLD): the feasibility of two different weight loss dietary approaches | Dr Kirsten Coppell | 9/06/2017 | 30/06/2017 | Provisionally Approve | Approve | 18/07/2017 | University of Otago | no sponsor | Locality |
| 17/NTA/116 | MK-3682-021: Study of Efficacy and Safety of MK-3682B in Subjects with HCV Direct-Acting Antiviral Failures | Prof Edward Gane | 8/06/2017 | 27/06/2017 | Provisionally Approve | Approve | 10/08/2017 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 17/NTA/117 | MK-3682B-037: MK-3682B in Hepatitis C Virus Genotype 3 participants | Prof Edward Gane | 8/06/2017 | 27/06/2017 | Provisionally Approve | Approve | 15/08/2017 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 17/NTA/119 | Outcome Measures in Surgical Patients | Mr. Harry Alexander | 9/06/2017 |  |  | Approve | 23/06/2017 | University of Auckland | no sponsor | Locality |
| 17/NTA/12 | REMAP-CAP | Dr Colin McArthur | 9/02/2017 | 2/03/2017 | Provisionally Approve | Approve | 25/05/2017 | Auckland District Health Board | collaborative research | Locality |
| 17/NTA/120 | Kids THRIVE | Dr Anusha Ganeshalingham | 8/06/2017 | 27/06/2017 |  | Provisionally approve |  | no sponsor | Locality | 17/NTA/120 |
| 17/NTA/122 | The Genetics of Discoid Lupus Eythematosus in Māori and Pacific People | Dr Paul Jarrett | 3/08/2017 |  |  | Decline | 28/08/2017 | Counties Manukau District Health Board. The University of Auckland. | no sponsor | Locality |
| 17/NTA/124 | Sensory Modulation for Anxiety in Primary Care | Dr Daniel Sutton | 23/06/2017 | 10/07/2017 |  | Approve | 26/07/2017 |  | no sponsor | Locality |
| 17/NTA/125 | Auckland Asian Preschool Children Health Survey | Dr Sharon Wong | 23/06/2017 | 18/07/2017 |  | Approve | 8/09/2017 | The University of Auckland | no sponsor | Locality |
| 17/NTA/126 | The Blood-brain barrier in motor neuron disease | Dr Deidre Jansson | 28/06/2017 | 14/07/2017 | Provisionally Approve | Approve | 28/09/2017 | The University of Auckland | academic institution | Locality |
| 17/NTA/127 | Resubmission of CK-101-101: A Study of the Safety and Efficacy of CK-101 in Patients with Advanced Solid Tumours | Dr Dean Harris | 6/07/2017 | 1/08/2017 |  | Approve | 17/08/2017 | Christchurch Hospital | pharmaceutical company | Locality |
| 17/NTA/128 | Validation of a new pulse wave velocity monitor against Doppler Ultrasound (Study I) | Dr Ekta Singh Dahiya | 30/06/2017 | 14/07/2017 |  | Approve | 21/07/2017 | Auckland University of Technology (AUT) | academic institution | Locality |
| 17/NTA/129 | AURORA | Dr David Orr | 6/07/2017 | 1/08/2017 | Provisionally Approve | Approve | 13/10/2017 | Auckland City Hospital | pharmaceutical company | Locality |
| 17/NTA/13 | M15-889 HDEC | Dr David Simpson | 9/02/2017 | 2/03/2017 | Provisionally Approve | Approve | 28/04/2017 | Waitemata District Health Board | pharmaceutical company | Locality |
| 17/NTA/15 | Measuring haemoglobin concentration in obstetric patients | Dr Jack Hill | 7/02/2017 | 16/02/2017 | Provisionally Approve | Approve | 12/04/2017 | Auckland District Health Board | no sponsor | Locality |
| 17/NTA/19 | Comparison of the blood levels of two forms of phentermine 40 mg in healthy male and female volunteers under fasting conditions | Dr Noelyn Hung | 9/02/2017 |  |  | Approve | 3/03/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/2 | Making information about gout and its treatment more understandable to patients with gout | Ms Alina Krasnoryadtseva | 16/01/2017 | 27/01/2017 | Provisionally Approve | Approve | 2/05/2017 | The University of Auckland | academic institution | Locality |
| 17/NTA/20 | Comparison of the blood levels of two forms of phentermine 40 mg in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | 9/02/2017 |  |  | Approve | 3/03/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/21 | Comparison of the blood levels of two forms of phentermine 15 mg in healthy male and female volunteers under fasting conditions | Dr Noelyn Hung | 9/02/2017 |  |  | Approve | 3/03/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/22 | Comparison of the blood levels of two forms of phentermine 40 mg in healthy male and female volunteers under fasting conditions and at steady state. | Dr Noelyn Hung | 9/02/2017 |  |  | Approve | 2/03/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/23 | GS-US-384-3914: A Clinical Study of Regimens in Subjects with Nonalcoholic Steatohepatitis (NASH) | Prof Edward Gane | 9/02/2017 | 2/03/2017 |  | Approve | 31/03/2017 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 17/NTA/24 | PIP in Primary Care Study - what predicts regression from prediabetes to normoglycaemia? | Dr Kirsten Coppell | 10/02/2017 | 22/02/2017 |  | Approve | 2/03/2017 | University of Otago | no sponsor | Locality |
| 17/NTA/25 | PARTNER 3 - Low Risk | Dr Mark Webster | 9/02/2017 |  |  | Approve | 2/03/2017 | Auckland District Health Board | medical device company | Locality |
| 17/NTA/26 | Assessment of the JUUL 5% Nicotine Salt Based ENDS Product, When Used by Current Smokers. | Dr Chris Wynne | 9/02/2017 |  |  | Approve | 2/03/2017 | Christchurch Clinical Studies Trust | other | Locality |
| 17/NTA/27 | Infinite-ous | Mr Andrew Hill | 9/02/2017 | 2/03/2017 | Provisionally Approve | Approve | 6/04/2017 | Auckland District Health Board | medical device company | Locality |
| 17/NTA/28 | New Zealand Motor Neurone Disease Registry | Dr Richard Roxburgh | 21/02/2017 | 3/03/2017 | Provisionally Approve | Approve | 18/04/2017 | Auckland District Health Board | non-governmental organisation (NGO) | Locality |
| 17/NTA/29 | FAME 1 EYE | Dr Fiona Wu | 9/03/2017 | 3/04/2017 | Provisionally Approve | Approve | 15/05/2017 | Auckland District Helath Board | academic institution | Locality |
| 17/NTA/30 | Intraarticular tranexamic acid for knee arthroscopy | Dr David Kieser | 9/03/2017 |  |  | Decline | 4/04/2017 | CDHB | no sponsor | Locality |
| 17/NTA/32 | CLEAR | Dr. Dean Corbett | 9/03/2017 |  |  | Approve | 3/04/2017 | Auckland Eye | medical device company | Locality |
| 17/NTA/33 | Pentoxifylline to PROTECT the preterm brain | Dr Max Berry | 9/03/2017 | 3/04/2017 | Provisionally Approve | Approve | 9/05/2017 | University of Otago | district health board (DHB) | Locality |
| 17/NTA/35 | DV3-MEL-01: SD-101 in Combination With Pembrolizumab in advanced Melanoma or HNSCC | Dr Matthew Strother | 9/03/2017 | 19/05/2017 |  | Approve | 26/05/2017 | Christchurch Hospital | pharmaceutical company | Locality |
| 17/NTA/36 | Avacopan treatment for ANCA associated vasculitis. | Professor Robert Walker | 9/03/2017 | 3/04/2017 | Provisionally Approve | Approve | 22/05/2017 |  | pharmaceutical company | Locality |
| 17/NTA/37 | Australasian Colorectal Cancer Family Study - Follow-up Study | Dr Susan Parry | 6/03/2017 |  |  | Approve | 17/03/2017 | Auckland District Health Board | collaborative research | Locality |
| 17/NTA/38 | What predicts user engagement with popular gout apps? | Dr Anna Serlachius | 6/03/2017 | 16/03/2017 | Provisionally Approve | Approve | 6/04/2017 | University of Auckland | academic institution | Locality |
| 17/NTA/40 | The Medeon Study | Dr Mark Webster | 9/03/2017 |  |  | Approve | 4/04/2017 | Auckland District Health Board | medical device company | Locality |
| 17/NTA/41 | Comparison of the blood levels of two forms of imatinib tablets in healthy male volunteers under fed conditions | Dr Noelyn Hung | 9/03/2017 |  |  | Withdrawn by Researcher | 5/04/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/42 | Comparison of the blood levels of three forms of imatinib tablets in healthy male volunteers under fed conditions | Dr Noelyn Hung | 9/03/2017 | 4/04/2017 | Provisionally Approve | Decline | 30/05/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/43 | CA209-915 | Dr Richard North | 9/03/2017 | 4/04/2017 | Provisionally Approve | Approve | 12/05/2017 | Bay of Plenty District Health Board | pharmaceutical company | Locality |
| 17/NTA/44 | KISS study: Kinase Inhibition with Sprycel Start up | Professor Peter John Browett | 9/03/2017 |  |  | Approve | 4/04/2017 | The University of Auckland, School of Medical Sciences | academic institution | Locality |
| 17/NTA/46 | Anti-Carbohydrate Antibody Responses in Multiple Sclerosis | Professor Anne Camille La Flamme | 21/03/2017 | 28/03/2017 | Provisionally Approve | Approve | 11/04/2017 |  | academic institution | Locality |
| 17/NTA/47 | Repeated Exercise in Chronic Fatigue Syndrome | Dr Lynette Hodges | 23/03/2017 | 30/03/2017 | Provisionally Approve | Approve | 5/05/2017 |  | academic institution | Locality |
| 17/NTA/48 | Community onset sepsis in infants | Dr Sarah Primhak | 23/03/2017 |  |  | Approve | 4/04/2017 | Paediatric infectious diseases | no sponsor | Locality |
| 17/NTA/5 | Evaluation of novel biomarkers in respiratory disease | Miss Teagan Hoskin | 1/02/2017 | 13/02/2017 | Provisionally Approve | Approve | 2/03/2017 | University of Otago, Christchurch | academic institution | Locality |
| 17/NTA/50 | PERFECT STUDY | Dr. Laura Bannister | 3/04/2017 |  |  | Approve | 11/04/2017 |  | no sponsor | Locality |
| 17/NTA/51 | rTMS for Treatment-Resistant Depression | Dr Suresh Mathukumaraswarmy | 6/04/2017 | 26/04/2017 | Provisionally Approve | Approve | 17/05/2017 | University of Auckland | academic institution | Locality |
| 17/NTA/52 | (duplicate) M15-942 HCV (MAGELLAN-3) | A/Prof Dr Michael G. Schultz | 6/04/2017 | 26/04/2017 | Provisionally Approve | Approve | 12/06/2017 | Southern District Health Board | pharmaceutical company | Locality |
| 17/NTA/53 | The effect of Arts Therapy Interventions on the negative symptoms of schizophrenia in adult offenders. | Miss Supreet Chadha | 6/04/2017 |  |  | Decline | 26/04/2017 | Mason Clinic Regional Forensic Psychiatry Services | no sponsor | Locality |
| 17/NTA/55 | Risk assessment for emergency laparotomy | Dr Ahmed Barazanchi | 6/04/2017 |  |  | Decline | 26/04/2017 | The Univeristy of Auckland | academic institution | Locality |
| 17/NTA/56 | Reducing confusion after surgery in older people | Dr Amy Gaskell | 6/04/2017 | 26/04/2017 | Provisionally Approve | Approve | 1/06/2017 | Waikato DHB | academic institution, collaborative research , district health board (DHB) | Locality |
| 17/NTA/58 | Children with autism, chiropractic and sensory integration | Dr Kelly Jones | 6/04/2017 | 27/04/2017 | Provisionally Approve | Approve | 28/07/2017 | AUT University | academic institution | Locality |
| 17/NTA/61 | What are the healthcare experiences of the Emergency Department among adult Māori patients in Tauranga Hospital, New Zealand? | Miss Sneha Abraham | 12/04/2017 | 24/04/2017 | Provisionally Approve | Approve | 5/05/2017 | University of Birmingham Medical School | no sponsor | Locality |
| 17/NTA/62 | The BEST Fluids study: Better Evidence for Selecting Transplant Fluids | Dr Michael Collins | 6/04/2017 | 26/04/2017 | Provisionally Approve | Approve | 22/06/2017 | Auckland District Health Board | academic institution, collaborative research | Locality |
| 17/NTA/63 | Study of Ibrutinib and Rituximab in Treatment Naïve Follicular Lymphoma | Dr Garry Forgeson | 6/04/2017 | 26/04/2017 | Provisionally Approve | Approve | 28/06/2017 | Palmerston North Hospital | pharmaceutical company | Locality |
| 17/NTA/64 | Next Generation Sequencing of HLA Genes | Mr Jonathan Downing | 6/04/2017 |  |  | Approve | 12/04/2017 | NZ Blood | no sponsor | Locality |
| 17/NTA/66 | Comparison of the blood levels of two forms of a combination tablet containing paracetamol/codeine/doxylamine in healthy volunteers under fasting conditions | Dr Noelyn Hung | 6/04/2017 |  |  | Approve | 26/04/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/67 | A study comparing how fast the trial drug inclisiran is processed and cleared by the body, in healthy adults and in adults with reduced kidney function. | Dr Richard Robson | 6/04/2017 |  |  | Approve | 26/04/2017 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company | Locality |
| 17/NTA/68 | Comparison of the blood levels of two forms of mesalazine tablets in healthy volunteers under fasting conditions | Dr Noelyn Hung | 6/04/2017 |  |  | Approve | 26/04/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/7 | Low Anterior Resection Syndrome: Incidence and Risk Factors | Professor Ian Bissett | 1/02/2017 | 14/02/2017 |  | Approve | 20/02/2017 | The University of Auckland | academic institution | Locality |
| 17/NTA/70 | CK-101-101: A Study of the Safety and Efficacy of CK-101 in Patients with Advanced Solid Tumours | Dr Dean HARRIS | 6/04/2017 |  |  | Decline | 26/04/2017 | Canterbury Regional Cancer and Heamatology Service | pharmaceutical company | Locality |
| 17/NTA/72 | Patient Reported Outcomes in Implanted Cardiac Devices | Miss Justine Paddison | 12/04/2017 | 24/04/2017 | Provisionally Approve | Approve | 2/05/2017 |  | no sponsor | Locality |
| 17/NTA/73 | (duplicate) Body Composition Monitor v clinical fluid assessment | Dr Sarah Gleeson | 19/04/2017 | 5/05/2017 | Provisionally Approve | Approve | 24/05/2017 |  | no sponsor | Locality |
| 17/NTA/74 | Acute asthma management in children | Dr Jocelyn Neutze | 19/04/2017 |  |  | Approve | 5/05/2017 | Counties Manukau District Health Board (Counties Manukau Health) | no sponsor | Locality |
| 17/NTA/75 | Women's experience and decision-making related to first birth. | Ms Suzanne Miller | 20/04/2017 | 5/05/2017 |  | Approve | 12/05/2017 |  | no sponsor | Locality |
| 17/NTA/78 | Lung response to pressure oscillations | Prof. Ahmed Al-Jumaily | 4/05/2017 |  |  | Decline | 26/05/2017 | Institute of Biomedical Technologies | academic institution | Locality |
| 17/NTA/8 | The BALANCE Study | Dr Shay McGuinness | 9/02/2017 | 2/03/2017 | Provisionally Approve | Approve | 5/05/2017 | Auckland District Health Board | no sponsor | Locality |
| 17/NTA/80 | Ribose-cysteine supplementation to improve cardiovascular health | Professor Sally McCormick | 4/05/2017 | 26/05/2017 | Provisionally Approve | Approve | 30/08/2017 | University of Otago | no sponsor | Locality |
| 17/NTA/81 | RATIONAL:Role of Antibiotic Therapy or IVIg on Infections in Haematology | Dr. Robert Weinkove | 4/05/2017 | 26/05/2017 | Provisionally Approve | Approve | 19/07/2017 | Capital & Coast District Health Board | academic institution, district health board (DHB) | Locality |
| 17/NTA/83 | EMBO-FIH | Associate Professor Andrew Holden | 4/05/2017 |  |  | Approve | 26/05/2017 | Auckland District Health Board | medical device company | Locality |
| 17/NTA/84 | Study of the Safety And Efficacy of Sofosbuvir/Velpatasvir/Voxilaprevir for 12 Weeks in Subjects who Participated in a Prior Gilead-Sponsored HCV Treatment Study | Prof Edward Gane | 4/05/2017 |  |  | Approve | 26/05/2017 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company | Locality |
| 17/NTA/85 | Comparison of the blood levels of two forms of dofetilide 0.5 mg capsules in healthy volunteers under fasting conditions | Dr Noelyn Hung | 4/05/2017 |  |  | Approve | 26/05/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/86 | Comparison of the blood levels of two forms of dofetilide 0.5 mg capsules in healthy volunteers under fed conditions | Dr Noelyn Hung | 4/05/2017 |  |  | Approve | 26/05/2017 | Zenith Technology Corporation Limited | pharmaceutical company | Locality |
| 17/NTA/87 | ES-SCLC KEYNOTE- 604 | Dr Dean HARRIS | 4/05/2017 | 26/05/2017 | Provisionally Approve | Approve | 8/08/2017 | Canterbury Regional Cancer and Heamatology Service | pharmaceutical company | Locality |
| 17/NTA/88 | Ranger II SFA | Associate Professor Andrew Holden | 4/05/2017 |  |  | Approve | 26/05/2017 | Auckland District Health Board | medical device company | Locality |
| 17/NTA/89 | TOBA II - BTK | Associate Professor Andrew Holden | 4/05/2017 |  |  | Approve | 26/05/2017 | Auckland District Health Board | medical device company | Locality |
| 17/NTA/9 | Drink juice and be on the move | Dr Jocelyn Eason | 2/02/2017 | 13/02/2017 |  | Approve | 22/02/2017 | The New Zealand Institute of Plant and Food Research Ltd. | other government agency | Locality |
| 17/NTA/90 | End of life choice preferences of people with terminal illness | Ms Jessica Young | 5/05/2017 | 17/05/2017 |  | Approve | 25/05/2017 | University of Otago | no sponsor | Locality |
| 17/NTA/93 | Efficacy and safety of long-term treatment with ACH0144471 in PNH patients | Dr Peter Browett | 4/05/2017 |  |  | Approve | 26/05/2017 | Auckland Clinical Studies | pharmaceutical company | Locality |
| 17/NTA/94 | Assessment of the cause of the acute transient vestibular syndrome. | Dr Duncan Smyth | 16/05/2017 |  |  | Approve | 31/05/2017 | Capital and Coast District Health Board | no sponsor | Locality |
| 17/NTA/97 | CHESTY (CHEST infection prevalence after surgerY); a multi-centre observational trial. | Dr Julie Reeve | 30/05/2017 |  |  | Approve | 13/06/2017 | AUT University | no sponsor | Locality |
| 17/NTA/98 | MVT-601-3201 | Prof Peter Gilling | 8/06/2017 | 27/06/2017 | Provisionally Approve | Approve | 30/08/2017 | Urology BOP Ltd | pharmaceutical company | Locality |
| 17/NTA/99 | Assessment of JUUL 5% Nicotine Salt Based ENDS Products, When Used by Healthy Adult Smokers. | Dr Chris Wynne | 8/06/2017 |  |  | Approve | 27/06/2017 | Christchurch Clinical Studies Trust | other | Locality |

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

## Declaration by EC Chairperson

**Name of EC: Northern A 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:** Brian Fergus\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature: Date:**

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

**Name of EC: Northern A Health and Disability 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:** Dr Brian Fergus

Title First Name Last Name

**Position :** Chairperson

**E-mail :** hdecs@moh.govt.nz

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**Signature: Date:** 27 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)