

Northern A Health and Disability Ethics Committee

Annual Report
2021

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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 IRB00008712) 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

As the Committee’s Acting Chair, I am pleased to present this Annual Report of the work of Northern A HDEC (NTA) over the last year. In the year ending June 2021, the committee reviewed a total of 98 applications. 75 of these were intervention studies and 43 were observational research. 96 applications were reviewed at full committee meetings, while 2 were reviewed through the expedited (low risk) pathway.

I would like to express the committee’s sadness at the passing of Dr Mānuka Hēnare, the committee’s previous Chair, in January 2021.

I confirm that Northern A 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. With the year-on-year increase in volume and complexity of applications, it is apparent that HDECs are now stretched to the limits of their capacity, and the strategic refresh forthcoming through the Modernisation project is welcome. Additionally, a review of the fees framework that apply to HDECs would be appreciated.

NTA has admirably faced the challenge of the last year, frequently with full-to-capacity meetings and many complex studies. NTA members have vigorously applied the ethical standards provided in the NEAC Standards (2019), with particular attention to studies containing higher risk factors, such as those involving children, or the  future and unspecified use of tissue and data, studies involving medical devices  and first-in-human clinical trials, studies located in emergency settings where participants are too unwell to provide consent, and studies that require a waiver of consent from HDECs. NTA also has stringently focused on the responsible management of personal information across the research life-cycle, particularly where commercial overseas sponsors are involved.  This concentration of effort ensures that the  detailed reviews supplied to investigators support greatly improved re-submissions. I anticipate that the roll-out of the new application form within the new ERM platform, alongside within-form guidance that links to the relevant sections of the NEAC Standards and other Regulations, will  further assist researchers to submit applications to the required standards.

My sincere thanks go to all Members and staff of the HDEC Secretariat for their support of me in my Acting Chair capacity,  and for ensuring that the committee functions smoothly. Particular thanks are due to Catherine Garvey for undertaking the expedited review of low ethical risk applications and amendments, along with  Dr Peter Gallagher seconded from another HDEC. I am also grateful to Helen Walker who has stepped in to Chair NTA on occasions, and to Dr Kate Parker and Ms Garvey who serve on the emergency COVID-19 HDEC. Otherwise membership has been steady, and I warmly congratulate Catherine Garvey on her appointment to the Chair’s role from September 2021.

It has been a great pleasure to work with Northern A as its Acting Chair for 18 months. With a new Chair in place, I am confident that the committee will continue its responsible work of ensuring that the ethical standards that aim to protect participants in health  and disability research are met.

Kate O’Connor

Acting Chair for the reporting period – Northern A HDEC

# Membership and attendance

## Membership

### List of EC members within the reporting period

### Mrs Kate O’Connor (Chair)

Membership category: Ethical and Moral Reasoning

Date of appointment: 29th January 2020

Current term expires: 29th January 2021

Kate O'Connor was formerly the Executive Secretary of the AUT Ethics Committee. Prior to this she worked as a research Contracts Manager for Uniservices Ltd in the University of Auckland's School of Population Health, was Secretary for the University of Auckland's Human Participants Ethics Committee, and the Biological Safety Committee. She has Master of Arts in philosophy and a Post Graduate Diploma in business. She was on the Working Party of the NEAC National Ethical Standards, and Royal Society Te Apārangi's Code of Professional Standards and Ethics. She is a member of the Data Ethics Advisory Group (NZ Stats).

**Dr Karen Bartholomew**

Membership category: Intervention Studies

Date of appointment: 18th July 2016

Current term expires: 18th July 2019

Dr Karen Bartholomew is currently employed at Planning and Funding in Auckland Waitemata DHBs working in Child, Maternal and Youth 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 Master 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 having a strong interest in public health and research ethics, and is a member of the Massey University Human Ethics Committee (Northern) and the Health and Disability Ethics Committee Northern A.

**Dr Kate Parker**

Membership category: Observational Studies

Date of appointment: 11th February 2017

Current term expires: 11th February 2020

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.

**Ms Rochelle Style**

Membership category: Ethical/Moral Reasoning

Date of appointment: 14th June 2017

Current term expires: 14th June 2020

Rochelle Style holds an Honours Degree in Law (University of Canterbury, 1985) and a Masters of Bioethics & Health Law (Distinction) (University of Otago, 2017).

She was a partner in one of New Zealand’s leading law firms, Bell Gully, and acted as Litigation Counsel on behalf of PHARMAC. She is a current Ministerial appointee on the Northern A Health and Disability Ethics Committee and was a member of an expert Working Party appointed by the Ministry of Health to update the National Ethical Health Research guidelines (September 2017–March 2018). She also has valuable clinical ethics experience gained through her appointment, over 5 years, as a member of the Capital & Coast DHB’s Clinical Ethics Advisory Group.

Rochelle is also an independent researcher and has published on the governance of health data research in New Zealand and delivered lectures and presentations on data ethics, including at the University of Otago and Victoria University of Wellington.

**Dr Michael Meyer**

Membership category: Health and Disability Service Provision

Date of appointment: 11th February 2020

Current term expires: 11th February 2023

Neonatal Paediatrician, Neonatal Unit, Middlemore Hospital, Auckland.

Honorary Associate Professor, Department of Paediatrics, University of Auckland, Auckland.

**Dr Sotera Catapang**

Membership category: Observation Studies

Date of appointment: 11th February 2020

Current term expires: 11th February 2023

Sotera studied Doctor of Medicine at the Cebu Institute of Medicine (CIM), Cebu City, Philippines and was granted license in 1976; worked with a private firm as general practitioner before joining a residency training program (Macy Foundation grant) on Primary Care Pediatrics with Cebu Velez General Hospital, the medical training center of CIM; thereafter, she joined its faculty. She acquired a Master of Science in Public Health – Major in Biostatistics at the University of the Philippines (2000), under a study grant from CIM sponsored by the Philippine Council for Health Research and Development. She was awarded the Assistant Professor position by CIM for the Department of Anatomy-Section of Histology and Neuroanatomy, and concurrent Biostatistician for the Clinical Epidemiology Unit. In early 2000, she studied nursing and she became a Registered Nurse in 2004. She stayed with the academy, focused on research as professor and coordinator of medical and paramedical research for a couple of medical schools and a national university; hence, had the opportunity to pursue a PhD in Education - Majoring in Research and Evaluation at the Cebu Normal University, completing only its academic requirements.

**Ms Catherine Garvey**

Membership category: Law

Date of appointment: 19th March 2019

Current term expires: 19th March 2022

Catherine qualified from the university of Auckland with a BA/LLB. Catherine is a barrister at Quay Chambers in central Auckland. She has practised law with a particular interest in medico-legal issues, since 2000.

Catherine is currently the Deputy Chairperson of the Social Workers Complaints and Disciplinary Tribunal, and a member of the Massey University Human Ethics Committee.

**Mrs Helen Walker**

Membership category: Consumer Community Perspectives (Co-Opted)

Date of appointment: 22nd May 2020

Current term expires: 22nd May 2023

Helen is currently the Chair of the Central HDEC, a Member of the Medical Sciences Council, a Trustee of the Cranford Hospice Trust, Chairman of the New Zealand Singing School, and the owner of the Kilgaren Farming Partnership. She completed a Bachelor of Science at Massey University, a Certificate in Company Direction through the New Zealand Institute of Directors and is a Chartered member of the Institute. Helen was previously a Director and Chair of Health Hawkes Bay, Guardian/Kaitiaki of the Turnbull Library, Director of Unison Networks Ltd and Hawke’s Bay District Health Board. Helen is also Chair of the Central Hawke’s Bay Consumers Power Trust, Past President of the Waipawa Musical and Dramatic Club, and a member of the Waipawa Municipal Theatre Refurbishment Trust. Finance Audit and Risk has been a major part all these roles with the position of FAR Chair in most.

##

## 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*** | **9 Jul 2020** | **13 Aug 2020** | **10 Sep 2020** | **08 Oct 2020** | **12 Nov 2020** | **10 Dec 2020** | **11 Feb 2021** | **10 Mar 2021** | **14 Apr 2021** | **12 May 2021** | **9 Jun 2021** | **Total**  |
| Dr Karen Bartholomew  | NL | **Y** | **Y** | **Y** | **Y** | A | **Y** | A | A | **Y** | **Y** | **Y** | 8/11 |
| Mrs Kate O'Connor  | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | A | **Y** | 9/11 |
| Dr Kate Parker  | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Ms Rochelle Style  | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Ms Catherine Garvey  | L | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Dr Sotera Catapang  | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Dr Michael Meyer  | NL | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | A | A | A | 7/11 |
| Mrs Helen WalkerCo-opted | L | / | / | / | / | / | / | / | / | **Y** | **Y** | / | 2/11 |
| **Total no. of members present**  |  | **7** | **7** | **5** | **7** | **6** | **7** | **5** | **6** | **6** | **6** | **6** |  |
| **No. of applications considered**  |  | **9** | **9** | **8** | **9** | **9** | **12** | **8** | **8** | **9** | **8** | **8** |  |

## Training and conferences

### Specify the training undergone by new members

There were no new members appointed during this reporting period.

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

Training was held on the new ethics IT system. An update on ethics and review training is provided in the cover letter.

**If no training was undertaken, provide reasons below**

This reporting round did not include any new members or formal training days. Training was scheduled numerous times in anticipation of new members being appointed. Appointments were continually delayed, resulting in NEAC writing to the Minister. Their letter is attached, and once appointments were made in August 2021 training for all members was subsequently provided. An agenda is provided that covers the training topics.

# Applications reviewed

### Summary of applications received by full EC

The Secretariat notes that HDEC cannot defer, however they can provisionally approve. We have answered as if defer is a provisional approval.

|  |  |
| --- | --- |
| No. of applications approved | 0 |
| No. of applications approved subject to conditions  | 6 |
| No. of applications deferred and subsequently approved | 49 |
| No. of applications deferred as at time of report | 12 |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | 2 |
| 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) | 23 |
| No. of applications which do not require ethics committee approval (applications submitted to Committee that were either incomplete or out of scope) | 35 |
| No. of studies withdrawn by researcher | 4 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC  | 0 |
| **Total number of applications received by full EC**  | **131** |

**Summary of applications received under expedited / low risk review**

|  |  |
| --- | --- |
| No. of applications approved | 0 |
| No. of applications approved subject to conditions  | 0 |
| No. of applications deferred and subsequently approved | 0 |
| No. of applications deferred as at time of report | 1 |
| No. of applications which do not require ethics committee approval (applications submitted to Committee that were incomplete or out of scope) | 1 |
| No. of applications referred for full committee review | 0 |
| No. of applications declined | 0 |
| No. of studies withdrawn by researcher | 0 |
| **Total number of applications received under expedited / low risk review** | **2** |

|  |  |
| --- | --- |
| **Total number of applications received:** | **133** |

#

# Complaints and overdue application summary

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

## Complaints received

**Complaint One**

**Study Reference**: 20/NTA/75

**Type of Complaint:** A complaint to HDEC regarding study conduct

**Review Date:** Ongoing

**Complaint Received**: 28/06/2021

**Nature of Complaint:**

The complaint is about a participant who unfortunately passed away during the study. Concerns have been raised by the participant’s daughter. She was particularly concerned about the study’s informed consent process.

**Actions Taken:**

* Complaint sent to Manager
* Manager acknowledged the complaint.
* Chair of NTB HDEC informed and requested information from the CI.
* Chair and Manager, with advisory staff, met with the research team.
* Chair of NTB HDEC requested the CI attend a full HDEC meeting to discuss the complaint and the amendment to re-start the study.
* NTB HDEC requested an audit of consent processes and requested a process and plan to respond to the complainant, and provide the committee with information on compensation to the family.
* CMO of ADHB requested that the DHB take the complaint and be responsible for the audit.
* CMO updated HDEC noting a response to the complaint has been sent to the complainant. ADHB have yet to hear back
* The design for the audit of consent processes in interventional radiology research has been completed and we are recruiting a second auditor to assist. ADHB expect that at least 20 hours will be required to complete the actual audit. ADHB will advise once that work is finished

**Outcome:**

This complaint is ongoing. The HDEC Manager is in regular contact with the ADHB CMO. The study amendment that aims to re-start the study is provisionally approved.

## 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 25 days for expedited applications. Target timeframe for expedited applications is 15 calendar days. The Average time has been skewed by an outlier with significant numbers on the clock due to submission issues from the researcher or technical issues faced by the secretariat as well as statutory holidays (with the clock running during break periods).

(Standard Operating Procedures for Health and Disability Ethics Committees, para 9-102).

Average review time was 27 days for full applications. Target timeframe for full applications is 35 days. (Standard Operating Procedures for Health and Disability Ethics Committees, para 54-59).

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

## Applications reviewed by full committee

| **Study reference** | **Short Title** | **CI Name** | **Outcome of first review (if date = provisional/Invalid)** | **Study Status** | **Date of final decision** | **CI Organisation (locality not captured)** | **Main sponsor type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 20/NTA/103 | Healthy Messages for Healthy Kids | Dr Victoria Egli |  | Invalid Application | 6/07/2020 |  | academic institution |
| 20/NTA/104 | Herpes zoster Vaccine effectiveness | Mr James Mbinta |  | Out Of Scope | 3/05/2021 | School of Health, Wellington Faculty of Health, Victoria University of Wellington | no sponsor |
| 20/NTA/105 | TOPUPS | Professor Cathy Stinear |  | Invalid Application | 6/07/2020 | University of Auckland | no sponsor |
| 20/NTA/111 | CloSure Study | Mr Andrew Hill |  | Decline | 12/08/2020 | Auckland District Health Board | medical device company |
| 20/NTA/112 | TOPUPS | Professor Cathy Stinear | 12/08/2020 | Approve | 20/08/2020 | University of Auckland | no sponsor |
| 20/NTA/113 | CBP-201-WW001 | Dr Joanna Joseph | 12/08/2020 | Approve | 22/09/2020 | P3 Research | pharmaceutical company |
| 20/NTA/114 | Healthy Messages for Healthy Kids | Dr Victoria Egli | 12/08/2020 | Withdrawn by Researcher | 29/03/2021 |  | academic institution |
| 20/NTA/116 | Phase 2b Study of Cotadutide for CKD and T2DM | Dr John Baker | 12/08/2020 | Approve | 9/10/2020 | Middlemore Clinical Trials | pharmaceutical company |
| 20/NTA/117 | Re-imagining parenting for parents with a learning disability | Dr Brigit Mirfin-Veitch | 12/08/2020 | Approve | 25/08/2020 | Donald Beasley Institute | no sponsor |
| 20/NTA/118 | Analysis of Laboratory Results Patterns (Revision 2) | Mr Samuel Wong | 27/07/2020 | Approve | 25/08/2020 | Vensa Health | other |
| 20/NTA/122 | ARM Trial | Doctor Meghan Hill | 31/08/2020 | Approve | 1/10/2020 | University of Auckland | academic institution |
| 20/NTA/126 | ESPRESSo: Enhancing Spontaneous Recovery after Stroke study | Prof Winston Byblow | 31/08/2020 | Approve | 23/09/2020 | University of Auckland | no sponsor |
| 20/NTA/127 | OPTIMISE Study | Dr Sara Boucher | 31/08/2020 | Approve | 1/10/2020 | University of Otago | academic institution |
| 20/NTA/128 | Understanding the blood level of a new coagulant factor VIIa in participants with congenital Haemophilia A | Dr Dean Quinn |  | Approve | 31/08/2020 | P3 Research Ltd | pharmaceutical company |
| 20/NTA/129 | NTLA-2001 in Patients with Hereditary Transthyretin Amyloidosis with Polyneuropathy (ATTRv-PN) | Prof Edward John Gane | 31/08/2020 | Approve | 19/10/2020 | New Zealand Liver Transplant Unit | pharmaceutical company |
| 20/NTA/130 | Study Investigating the Effectiveness and Safety of medicines in adolescents with autism | Dr Rebecca Griffith | 31/08/2020 | Approve | 14/10/2020 | Optimal Clinical Trials Ltd | pharmaceutical company |
| 20/NTA/131 | Improving the Respiratory Health of Maori and Pacific children in New Zealand | Mrs Jacinta Faalili-Fidow | 31/08/2020 | Approve | 23/09/2020 | Moana Research | non-governmental organisation (NGO) |
| 20/NTA/132 | Teaching Alternative Communication Systems to Children with Autism and Developmental Disabilities. | Dr. Amarie Carnett | 31/08/2020 | Approve | 9/10/2020 | Victoria University of Wellington | no sponsor |
| 20/NTA/133 | Erythropoietin in Trauma (EPO – TRAUMA) | Dr Colin McArthur | 31/08/2020 | Approve | 10/11/2020 | Auckland District Health Board | collaborative research |
| 20/NTA/134 | Change in Ejection Fraction Study | Ms Cathrine Patten |  | Invalid Application | 13/08/2020 | Auckland District Health Board | no sponsor |
| 20/NTA/135 | CANVAS | Dr Guy Stanley |  | Invalid Application | 13/08/2020 | Cairns Hospital & Hinterland Health Service | no sponsor |
| 20/NTA/137 | COVID-19 cases with prolonged symptoms: a New Zealand Case Series | Dr Susan Jack |  | Invalid Application | 25/08/2020 | Southern District Health Board | no sponsor |
| 20/NTA/138 | Tru-MK7 brand joint health supplement: Qualitative and quantitative investigation | Dr Saeid Baroutian |  | Decline | 30/09/2020 | University of Auckland | no sponsor |
| 20/NTA/139 | Comparison of Tretinoin capsules under fed conditions. | Dr Noelyn Hung |  | Approve | 30/09/2020 | Zenith Technology Corporation Limited | pharmaceutical company |
| 20/NTA/140 | A study to test different doses of BI 730357 in people with active psoriatic arthritis | Dr Sunil Kumar | 30/09/2020 | Approve | 18/11/2020 | Counties Manukau District Health Board | pharmaceutical company |
| 20/NTA/141 | CAST | Dr Clinton Lewis | 30/09/2020 | Approve | 27/01/2021 | Auckland District Health Board | collaborative research |
| 20/NTA/142 | ALG-000184-201: A Phase 1 study of ALG-000184 in Healthy Volunteers and patients with Chronic Hepatitis B | Prof Edward Gane | 30/09/2020 | Approve | 16/10/2020 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 20/NTA/143 | B7801001: Assessment of single doses of PF-06755347, in healthy male participants. | Dr Chris Wynne | 30/09/2020 | Approve | 18/11/2020 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/NTA/145 | Voice hearing in dissociative identity disorder | Prof Martin Dorahy |  | Invalid Application | 7/09/2020 | University of Canterbury | no sponsor |
| 20/NTA/146 | Effects of cardiorespiratory fitness and obesity on immunity, body compositions, and aerobic capacity | Dr Dorota Starzak |  | Decline | 30/09/2020 | UCOL | academic institution |
| 20/NTA/147 | Chiropractic Management of Football(Scoccer) Research | Dr Haresh Patel |  | Invalid Application | 3/09/2020 | Nil | no sponsor |
| 20/NTA/148 | Improving outcome in paediatric kidney transplant patients | Dr Chanel Prestidge |  | Withdrawn by Researcher | 7/09/2020 |  | no sponsor |
| 20/NTA/149 | (duplicate) TORPIDO 30/60 | Dr Liza Edmonds |  | Decline | 30/09/2020 | Dunedin Hospital | district health board (DHB) |
| 20/NTA/153 | BEAT-Calci | Dr Janak de Zoysa | 2/11/2020 | Approve | 12/01/2021 | Waitemata DHB | academic institution |
| 20/NTA/154 | NIHP | Dr Amul Sibal | 2/11/2020 | Approve | 10/02/2021 | ADHB | medical device company, academic institution |
| 20/NTA/155 | Overcoming dental anxiety with needle-free tooth anaesthesia | Prof. Paul Brunton |  | Decline | 2/11/2020 |  | academic institution |
| 20/NTA/156 | SACAT Study | Ms Marnie Carter |  | Decline | 2/11/2020 | Allen + Clarke | other government agency |
| 20/NTA/159 | (duplicate) None | Professor Paul Hofman |  | Decline | 2/11/2020 | Liggins Institute | pharmaceutical company |
| 20/NTA/161 | NUTRIENT | Mrs Eileen Gilder | 2/11/2020 | Approve | 27/01/2021 | Auckland District Health Board | no sponsor |
| 20/NTA/162 | Surfing related spinal cord injuries | Dr john mitchell |  | Out Of Scope | 7/10/2020 |  | no sponsor |
| 20/NTA/163 | A randomised controlled pilot study of ketamine-assisted therapy | Dr. Nicholas Hoeh | 2/11/2020 | Approve | 29/03/2021 | University of Auckland School of Medicine | academic institution |
| 20/NTA/164 | Fetal CCHD study | Dr Zoe Vetten | 2/11/2020 | Approve | 9/02/2021 | Starship Child Health | no sponsor |
| 20/NTA/165 | (duplicate) Evaluation of a CBT-sensory modulation intervention for children with anxiety. | Mr Tafadzwa MAVHUNGA | 2/11/2020 | Approve | 15/12/2020 | AUT University | academic institution |
| 20/NTA/166 | HD loss-of-interruption study | Dr Richard Roxburgh | 26/11/2020 | Approve | 20/04/2021 | University of Auckland | collaborative research |
| 20/NTA/167 | How accurate are our hospital records in relation to your ethnic group(s)? | Dr Hayley Bennett |  | Invalid Application | 5/11/2020 | Bay of Plenty District Health Board | no sponsor |
| 20/NTA/168 | Modelling the impact of volunteers in GoodSAM | Dr Caroline Jagtenberg |  | Invalid Application | 5/11/2020 | Vrije Universiteit Amsterdam | no sponsor |
| 20/NTA/169 | (duplicate) Tru-MK7 brand joint health supplement: Qualitative and quantitative investigation | Dr Baroutian Saeid |  | Decline | 26/11/2020 | University of Auckland | pharmaceutical company |
| 20/NTA/170 | Low-intensity therapy and parent coaching for young children with ASD: An RCT. | Dr Hannah Waddington | 26/11/2020 | Approve | 11/01/2021 |  | no sponsor |
| 20/NTA/171 | (duplicate) (duplicate) Gastrointestinal Dysfunction in Critical Illness - (GIFT study : Part II) | Ms Varsha Asrani |  | Decline | 26/11/2020 | ADHB / University of Auckland | academic institution, collaborative research , district health board (DHB) |
| 20/NTA/173 | The REVIVE study | Dr Jennifer Taylor | 26/11/2020 | Approve | 12/02/2021 | Capital and Coast District Health Board | pharmaceutical company |
| 20/NTA/174 | EXPAND TAVR I | Dr Sanjeevan Pasupati | 26/11/2020 | Approve | 28/01/2021 | Waikato District Health Board | medical device company |
| 20/NTA/175 | Daily Oral LUM-201 in Naïve-to-Treatment, Prepubertal Children with Growth Hormone Deficiency | Professor Esko Wiltshire | 26/11/2020 | Approve | 1/02/2021 | Capital and Coast District Health Board | pharmaceutical company |
| 20/NTA/176 | LANDMARK Trial | Dr Mark Webster | 26/11/2020 | Approve | 25/03/2021 | Auckland District Health Board | medical device company |
| 20/NTA/177 | Hydrolysed meat in residential aged-care | Miss Xiaojing Wu |  | Decline | 26/11/2020 | The University of Auckland | academic institution |
| 20/NTA/179 | Brain Injury Incidence and Service Access New Zealand in the Community (BIONIC2) | Dr Kelly Jones |  | Decline | 22/12/2020 | Auckland University of Technology | academic institution |
| 20/NTA/181 | “Exploring a novel brain stimulation protocol for treatment of tinnitus.” | Ms Sophia Smeele | 22/12/2020 | Approve | 17/02/2021 | University of Otago | academic institution |
| 20/NTA/182 | Evolution and characterisation of dysphagia after stroke from admission to 6 months | Mrs Marion VALLET |  | Decline | 22/12/2020 | University of Canterbury - Rose Centre for Stroke Recovery and Research | academic institution |
| 20/NTA/183 | 73763989PAHPB2006: The PENGUIN Study to Assess Efficacy, Safety, Tolerability, and PK of JNJ-73763989, JNJ-56136379, NUCs, and PegIFN Alpha-2a in CHB patients | Prof Edward Gane |  | Decline | 22/12/2020 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 20/NTA/184 | Dual-task attention and swallowing performance after traumatic brain injury | Dr Karen Ng |  | Decline | 22/12/2020 | Laura Fergusson Brain Injury Trust | no sponsor |
| 20/NTA/185 | NAVIGATE Study - Oral TRK Inhibitor larotrectinib in Participants with NTRK Fusion-Positive Tumors. Study 20289 | Dr Richard North | 22/12/2020 | Withdrawn by Researcher | 17/02/2021 | Bay of Plenty District Health Board | pharmaceutical company |
| 20/NTA/186 | Overcoming dental anxiety with needle-free tooth anaesthesia | Prof. Paul Brunton | 22/12/2020 | Approve | 10/02/2021 |  | academic institution |
| 20/NTA/187 | The ARTERIAL US Study | Dr Robyn May | 22/12/2020 | Approve | 1/02/2021 | University of Auckland | academic institution |
| 20/NTA/188 | Metacognitive Training (MCT) Group for adults with psychosis | Mr Wade Stent |  | Decline | 22/12/2020 | Christchurch District Health Board | no sponsor |
| 20/NTA/189 | A clinical trial to assess the safety and efficacy of seladelpar in patients with primary biliary cholangitis (PBC) and an inadequate response to or intolerance to ursodeoxycholic acid (UDCA). | Dr Jing Hieng (Jeffrey) Ngu |  | Decline | 22/12/2020 | Canterbury District Health Board | pharmaceutical company |
| 20/NTA/190 | COVID-19: Children & Youth with Brain Injury | Dr Kelly Jones | 22/12/2020 | Approve | 25/03/2021 | Auckland University of Technology | academic institution |
| 20/NTA/191 | KAMA Study | Dr Marinus Stowers | 22/12/2020 | Approve | 25/03/2021 |  | district health board (DHB) |
| 20/NTA/192 | Review of the Women's Health Pain Service Nurse Led Clinic | Dr Douglas Campbell |  | Invalid Application | 11/12/2020 | Aucklan District Health Board | no sponsor |
| 21/NTA/101 | (duplicate) The CRITICAL-ACS Study | Dr Philip Adamson | 28/06/2021 | Provisionally approve |  | University of Otago | academic institution |
| 21/NTA/102 | ITL-2002-CL-001: A Study to Evaluate NTLA-2002 in Patients with Hereditary Angioedema (HAE) | Dr. Hilary Longhurst |  | Decline | 28/06/2021 | New Zealand Clinical Research | pharmaceutical company |
| 21/NTA/104 | Neural Correlates of Love: An Electroencephalography (EEG)-based Hyperscanning Study | Professor Dirk De Ridder |  | Out Of Scope | 11/06/2021 |  | academic institution |
| 21/NTA/11 | Paediatric difficult airway audit | Dr Lisa Barneto |  | Invalid Application | 20/01/2021 | Addenbrooke's hospital, Cambridge University Trust | no sponsor |
| 21/NTA/12 | MOR208C310. Tafasitamab plus lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-intermediate and high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBC | Directors April Josephsen & Jennifer Larsen |  | Invalid Application | 20/01/2021 |  | pharmaceutical company |
| 21/NTA/19 | 73763989PAHPB2006: The PENGUIN Study to Assess Efficacy, Safety, Tolerability, and PK of JNJ-73763989, JNJ-56136379, NUCs, and PegIFN Alpha-2a in CHB patients | Professor Edward Gane |  | Approve | 26/02/2021 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 21/NTA/21 | A study to test efficacy of different doses of BI 456906 in people with non-alcoholic steatohepatitis (NASH) and liver fibrosis. | Prof Ed Gane | 26/02/2021 | Approve | 8/04/2021 | Auckland Clinical Studies Ltd. | pharmaceutical company |
| 21/NTA/23 | UPLIFT | Dr Rebecca Slykerman | 25/02/2021 | Approve | 25/03/2021 | University of Auckland | no sponsor |
| 21/NTA/24 | BGB-11417 Phase 1b/2 AML and MDS | Dr Travis Perera | 25/02/2021 | Approve | 30/04/2021 | Capital and Coast District Health Board | pharmaceutical company |
| 21/NTA/26 | Efgartigimod PH20 SC for the treatment of Primary Immune Thrombocytopenia in Adults. | Dr Rajeev Rajagopal | 25/02/2021 | Approve | 9/04/2021 |  | pharmaceutical company |
| 21/NTA/27 | A clinical trial to assess the safety and efficacy of seladelpar in patients with primary biliary cholangitis (PBC) and an inadequate response to or intolerance to ursodeoxycholic acid (UDCA) (2021 re | Dr Jing Hieng (Jeffrey) Ngu | 25/02/2021 | Approve | 18/05/2021 | Canterbury District Health Board | pharmaceutical company |
| 21/NTA/3 | A retrospective audit of three methods of Positive Airway Pressure initiation for patients with Obstructive Sleep apnoea at Middlemore Hospital during the Covid era | Dr Josephine McCabe |  | Invalid Application | 11/01/2021 |  | no sponsor |
| 21/NTA/30 | Novel intraoral application of knotless sutures in third-molar surgery | Mr Nigel Tan | 25/02/2021 | Approve | 10/05/2021 |  | no sponsor |
| 21/NTA/31 | The PASSIVATE Study | Dr Phil Adamson | 25/02/2021 | Approve | 30/04/2021 | University of Otago, Christchurch | academic institution |
| 21/NTA/32 | MK-4305-088 - Impact of Suvorexant-Mediated Sleep on Cerebrospinal Fluid Biomarkers in Participants With Insomnia and Early Alzheimer’s Disease | Dr Nigel Gilchrist |  | Withdrawn by Researcher | 11/02/2021 | CGM Research Trust | pharmaceutical company |
| 21/NTA/33 | Hydrolysed meat in residential aged-care | Miss Xiaojing Wu | 6/04/2021 | Approve | 11/05/2021 |  | academic institution |
| 21/NTA/34 | The Feasibility and Acceptability of Match Emoji. | Mr Russell Pine | 6/04/2021 | Approve | 28/05/2021 | Victoria University of Wellington | no sponsor |
| 21/NTA/35 | Parapneumonic effusion and empyema: aetiology and clinical outcome evaluation in Canterbury. | Dr Margot (J.M.) de Koning Gans | 6/04/2021 | Approve | 28/06/2021 | University of Otago Christchurch | academic institution |
| 21/NTA/36 | TRAIL: A Biorepository for the Pathology Department, Dunedin School of Medicine. | Professor Michael Eccles |  | Decline | 6/04/2021 | University of Otago, Dunedin School of Medicine | academic institution |
| 21/NTA/37 | Comparison of dimethyl fumarate capsules under fasting conditions. | Dr Noelyn Hung |  | Approve | 6/04/2021 | Zenith Technology Corporation Limited | pharmaceutical company |
| 21/NTA/38 | Comparison of dimethyl fumarate capsules under fed conditions | Dr Noelyn Hung |  | Approve | 6/04/2021 | Zenith Technology Corporation Limited | pharmaceutical company |
| 21/NTA/39 | AMH levels in New Zealand women | Dr Michael Pankhurst |  | Invalid Application | 4/03/2021 | University of Otago | academic institution |
| 21/NTA/40 | ChildPlayWorks data analysis project | Ms. Judi Jacobsen |  | Decline | 6/04/2021 | ChildPlayWorks Charitable Trust | no sponsor |
| 21/NTA/41 | ONL-1204-GA-001: A study on the treatment of ONL1204 in patients with geographic atrophy (GA) associated with age-related macular degeneration (AMD) associated with AMD | Dr James Howard Borthwick | 6/04/2021 | Approve | 18/05/2021 | Southern Eye Specialists | pharmaceutical company |
| 21/NTA/46 | A pilot study of traditional acupuncture as an adjunct treatment for IBS-diarrhoea | Dr Li Feng | 4/05/2021 | Approve | 12/07/2021 | New Zealand College of Chinese Medicine | academic institution |
| 21/NTA/49 | New Zealand Emergency Department COVID-19 Preparedness Survey | Dr. Michael Howard |  | Invalid Application | 6/04/2021 | Northland DHB | no sponsor |
| 21/NTA/51 | MAGIC Trial | DR Benjamin Gladwin | 4/05/2021 | Approve | 23/07/2021 | Capital and Coast District Health Board | no sponsor |
| 21/NTA/52 | A Phase 3, Open-label Extension Study of Viltolarsen in Ambulant Boys with Duchenne Muscular Dystrophy (DMD) | Dr Gina O'Grady | 4/05/2021 | Approve | 18/06/2021 | Auckland Clinical Studies Ltd and Starship Hospital | pharmaceutical company |
| 21/NTA/53 | Markov Chains in Cancer Screening | Mrs Erandi Nanayakkara |  | Invalid Application | 8/04/2021 |  | no sponsor |
| 21/NTA/54 | GS-US-465-4439: A Phase 2a Study to Evaluate the Safety and Efficacy of Selgantolimod-Containing Combination Therapies in Patients with Chronic Hepatitis B | Prof Edward Gane | 4/05/2021 | Approve | 11/06/2021 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 21/NTA/55 | The SODa-BIC RCT | Dr Paul Young | 4/05/2021 | Approve | 28/05/2021 | Capital Coast District Health Board | no sponsor |
| 21/NTA/56 | Examining the influence of BMI on CRM involvement in patients with rectal cancer. | Dr Mathew Morreau |  | Invalid Application | 8/04/2021 |  | no sponsor |
| 21/NTA/57 | The Bone Zone Trial | Dr Paul Young | 4/05/2021 | Approve | 15/06/2021 | Capital Coast District Health Board | no sponsor |
| 21/NTA/58 | Open-label long-term trial of efgartigimod PH20 SC for the treatment of Primary Immune Thrombocytopenia in adults. | Dr Rajeev Rajagopal |  | Decline | 4/05/2021 | Middlemore Clinical Trials | pharmaceutical company |
| 21/NTA/60 | GDM and school age outcomes (GiST) | Dr Jane Alsweiler |  | Decline | 4/05/2021 |  | academic institution |
| 21/NTA/61 | The CRITICAL-ACS Study | Dr Philip Adamson |  | Decline | 4/05/2021 | University of Otago | academic institution |
| 21/NTA/63 | Fractures in survivors of critical illness – A New Zealand data linkage study | dr paul young |  | Invalid Application | 15/04/2021 |  | no sponsor |
| 21/NTA/64 | Sensory neuropathy, ultrasound and RFC1 testing | Dr Richard Roxburgh |  | Invalid Application | 15/04/2021 | ADHB | no sponsor |
| 21/NTA/65 | LIBerate-HeFH | Professor Russell Scott | 4/06/2021 | Provisionally approve |  | Clinical & Pharmaceutical Research Trust | pharmaceutical company |
| 21/NTA/66 | MedCan Feasibilty | Dr Karen Oldfield |  | Out Of Scope | 3/05/2021 | Medical Research Institute of New Zealand | other |
| 21/NTA/67 | EQ121-010: A Phase 1 Study to Evaluate the Safety and Pharmacokinetics of EQ121 in Healthy Adults and Patients with Rheumatoid Arthritis. | Dr. Chris Wynne |  | Approve | 4/06/2021 | New Zealand Clinical Research | pharmaceutical company |
| 21/NTA/68 | UNITE Project | Dr Katie Douglas | 4/06/2021 | Provisionally approve |  | University of Otago | no sponsor |
| 21/NTA/69 | LIBerate-CVD | Dr Jane Kerr | 4/06/2021 | Provisionally approve |  | Clinical & Pharmaceutical Research Trust | pharmaceutical company |
| 21/NTA/70 | LIBerate-HR | Dr Jane Kerr | 4/06/2021 | Provisionally approve |  | Clinical & Pharmaceutical Research Trust | pharmaceutical company |
| 21/NTA/71 | Sensory neuropathy, ultrasound and RFC1 testing | Dr Richard Roxburgh | 4/06/2021 | Provisionally approve |  | ADHB | no sponsor |
| 21/NTA/72 | Building a strong, sustainable and diverse education workforce to ensure that all tamariki/children and ākonga/students are engaged, thrive and able to succeed. | Dr Adam Swanson |  | Out Of Scope | 4/05/2021 | Ministry of Education | other government agency |
| 21/NTA/73 | A Study for Participants with Moderate to Severe Chronic Obstructive Pulmonary Disease and Chronic Bronchitis (FRONTIER 4) | Dr Dean Quinn | 4/06/2021 | Approve | 5/07/2021 | P3 Research Ltd | pharmaceutical company |
| 21/NTA/74 | Factors involved with re-admission in mental health | Dr. Jerry Hendriks |  | Out Of Scope | 6/05/2021 | Auckland DHB | no sponsor |
| 21/NTA/75 | International Cryptococcus Audit | Professor Monica Slavin |  | Invalid Application | 6/05/2021 | Melbourne Health- The Royal Melbourne Hospital | no sponsor |
| 21/NTA/76 | A Latent Class Trajectory Analysis of Family Violence Perpetration in New Zealand | Mr Daniel Jones |  | Out Of Scope | 6/05/2021 | University of Canterbury | no sponsor |
| 21/NTA/77 | The Healthy New Zealand Foods Pilot Study | Professor Jeremy Krebs |  | Decline | 4/06/2021 | Capital and Coast DHB | no sponsor |
| 21/NTA/80 | Functional Brain Networks of Memory in People with Schizophrenia | Mr Khan Buchwald |  | Out Of Scope | 13/05/2021 |  | no sponsor |
| 21/NTA/81 | Impact of time of surgery on postoperative outcomes. | Miss Phoebe O'Connor |  | Invalid Application | 13/05/2021 | University of Auckland | no sponsor |
| 21/NTA/82 | Dipeptidyl peptidase-4 inhibitor-associated Bullous pemphigoid in Auckland region, New Zealand | Dr Cheng Huang |  | Out Of Scope | 13/05/2021 |  | no sponsor |
| 21/NTA/83 | The Nitric Follow-up Study | Dr John Beca | 28/06/2021 | Provisionally approve |  | Auckland District Health Board | no sponsor |
| 21/NTA/86 | The effects of MitoQ supplementation on trained athletes | Mr Paul Cadman |  | Out Of Scope | 28/05/2021 | Elevate Coaching | pharmaceutical company |
| 21/NTA/87 | Drug survival of dermatology patients at Waikato district health board | Dr Geetika Seth |  | Out Of Scope | 31/05/2021 | Waikato district health board | no sponsor |
| 21/NTA/88 | Symptom monitoring in dialysis | Dr Suetonia Palmer |  | Out Of Scope | 31/05/2021 |  | no sponsor |
| 21/NTA/89 | Cocoa flavanols and brain function during hypoxia | Mr Peter Bloomfield |  | Out Of Scope | 4/06/2021 | The University of Auckland | academic institution |
| 21/NTA/90 | CHOLENZ Study | Associate Professor Christopher Harmston |  | Out Of Scope | 31/05/2021 | Whangarei Hospital | collaborative research , district health board (DHB) |
| 21/NTA/91 | First-in-Human Study of XMT-1536 in Cancers Likely to Express NaPi2b | Dr. Peter Chee Choong Fong | 28/06/2021 | Provisionally approve |  | Auckland City Hospital | pharmaceutical company |
| 21/NTA/93 | (duplicate) GWAS of asthma in Niue Islanders | Dr. William Abbott | 28/06/2021 | Approve | 12/07/2021 |  | no sponsor |
| 21/NTA/94 | Auckland Sleep Surgery Study | Mr Sumit Samant |  | Decline | 28/06/2021 | Auckland District Health Board | no sponsor |
| 21/NTA/95 | Non-Invasive Ventilation Mask Assessment | Dr Robert Martynoga |  | Decline | 28/06/2021 | Waikato DHB | medical device company |
| 21/NTA/96 | Patient responses to oxygen therapy (PROT) | Dr Tony Williams | 28/06/2021 | Approve | 23/07/2021 | Middlemore Hospital | medical device company |
| 21/NTA/97 | OVER-IT | Dr Rosalind Crombie |  | Out Of Scope | 4/06/2021 | Canterbury District Health Board | no sponsor |

# 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:** Kate O’Connor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_



**Signature: Date: 24 September 2021**

## 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:** Mr Nic Aagaard

 Title First Name Last Name

**Position :** Manager - Ethics

**E-mail :** hdecs@moh.govt.nz nz



**Signature: Date:** 24 September 2021

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)