

Northern A Health and Disability Ethics Committee

Annual Report
2020

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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 Health and Disability Ethics Committee 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 Health and Disability Ethics Committee 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

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 2020, the committee reviewed a total of 121 applications. 71 of these were intervention studies and 50 were observational research. 91 applications were reviewed at full committee meetings, while 30 were reviewed through the expedited (low risk) pathway.

Like the other HDECs, NTA faces a year-on-year increase in numbers of applications, whilst at the same time the research in New Zealand continues to grow more complex. The majority of submissions receive provisional approval during the first review round. I am happy to 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. My sincere thanks go to all Members and staff of the HDEC Secretariat for ensuring that the committee functions smoothly, despite the difficulties presented by COVID-19, (which required an agile response in terms of committee processes) and some flux in membership. Dr. Mānuka Hēnare retired from the Committee in December 2019 (and I was subsequently seconded from NTB to act as Chair in the interim). We welcomed new members Dr Sotera Catapang (Non-lay observational studies), Dr Michael Meyer (Non-lay- health/disability service provision) and Professor Graham Mellsop (Non-lay- health/disability service provision) . We farewelled long serving member Dr Christine Crooks (Non-lay- health/disability service provision) and Dr Mellsop. An appointments application process has been undertaken by the Ministry, and new appointments, including that of NTA Chair, and renewals of existing members whose terms have expired, are likely following the General Election. Particular thanks are due to Catherine Garvey (lay – the Law) for the substantial undertaking of the expedited review of low ethical risk applications, amendments, and protocol deviations along with Non-lay members seconded from other HDECs, as well as reviewing Annual Reports. Dr Kate Parker and Ms Garvey also served on the emergency COVID-19 HDEC.

The introduction of the updated NEAC Ethical Standards in December 2019 has lifted the bar in terms of the expectations that the committee has of application documentation, and in the way it communicates their detailed requirements to investigators through the Provisional Response letters, particularly in response to research data (and tissue) management planning. While overseas sponsors are unwilling to alter their protocol to accommodate country-specific data management requirements, the Committee is happy to accept these plans as addendums or research associated documents. The Participant Information Sheet template available on HDECs website has been reviewed and now contains much more explicit guidance for communicating information to potential participants about what happens to their health information during the research life-cycle: identified or de-identified (coded) data is distinguished, and details of who can access data in what forms, use it, sell it, and for what purposes (including future unspecified use) must be given. As such, potential participants are much more informed of the data risks. Data and Tissue Management Plan guides are about to be released on the HDEC’s website which will aid researchers to comply with the current data standards. Grateful thanks are due Ms Rochelle Style (Lay- ethical/moral reasoning) along with Dr Devonie Waaka (from Southern HDEC) for the specialist skills demonstrated in developing these templates. The improvements will have impact across all of the HDECs and the health research sector, especially if they result in a greater proportion of applications receiving a first-time-through Approval as hoped.

Other issues raised by NTA members in the previous Annual Report persist across all four HDECs: there are concerns about medical device trials (including First in Human, and implantables) without a peer review body like SCOTT; ethical concerns about the export of tissue to overseas repositories for future unspecified research (and sometimes embedded mandatory FUR in the main study); potential data harms from the use of technology, algorithms and apps (especially with third-party vendors); complex research designs including adaptive platforms and umbrella, integrated protocols; applications for waiver of consent without sufficient justification; and the lawfulness of intervention research in adults without capacity to consent. In my experience of NTA in the last few months, the Committee attends to these challenges with due diligence and with the interests of participants as the highest priority. With a new Chair in place, I am confident that the committee will continue its careful work of ensuring that ethical standards that aim to protect participants in health research are met, and I recommend that the HRCEC renews its approval of the NTA for another term.

Kate O’Connor

Acting Chair – 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: Design and conduct of intervention studies

Date of appointment: 18th July 2016

Current term expires: 18th July 2016

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 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 also has 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: Design and conduct of intervention studies

Date of appointment: 11th February 2020

Current term expires: 11th February 2023

Kate has worked 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: 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.

**Ms Catherine Garvey**

Membership category: Law

Date of appointment: 19th March 2019

Current term expires: 19th March 2023

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: Provision of health and disability services

Date of appointment: 11th February 2020

Current term expires: 11th February 2023

Dr Meyer is a senior paediatrician in neonatal intensive care at Middlemore Hospital, Counties Manukau and has broad experience in research and ethics, in both clinical and research contexts. He is also an Honorary Associate Professor at the Department of Paediatrics at the University of Auckland. Dr Meyer is active at a national level in paediatric research, including through the ON TRACK (Pilates and Physiotherapy) clinical trials network and the Australian and New Zealand Neonatal Network. He has prior governance experience, including being a member of the Institute of Child Health Research Advisory Committee, the Blood Transfusion Committee and Neonatal Management Group at Middlemore Hospital.

**Dr Sotera Catapang**

Membership category: Design and conduct of observational studies

Date of appointment: 11th February 2020

Current term expires: 11th February 2023

Dr Sotera Catapang studied Doctor of Medicine at the Cebu Institute of Medicine (CIM), Cebu City, Philippines and granted license in 1976; worked with a private firm as GP 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, joined its faculty. She acquired 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 Assistant Professor position by CIM for the Department of Anatomy-Section of Histology & Neuro-Anatomy, 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 academe, focused on research as professor and coordinator of medical and paramedical researches for a couple of medical schools and a national university; hence, had the opportunity to pursue PhD in Education - Major in Research and Evaluation at the Cebu Normal University, completing only its academic requirements.

Before coming to New Zealand in 2016, Sotera was invited by Chong Hua Hospital to be the Biostatistician and research consultant, advising medical staff with their research studies in support of the hospital health service improvement program, and member of the Institutional Review Board (Ethics Committee) of the hospital. In 2018, she received a Certificate of Achievement on Introduction to Statistical Investigation from Open Polytechnic NZ, an online program.

**Dr Christine Crooks**

Membership category: Design and conduct of intervention studies

Date of appointment: 11th November 2015

Current term expires: 2nd October 2019

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.

**Associate Professor Manuka Henare\***

Membership category: Consumer and community perspectives

Date of appointment: 19th March 2019

Current term expires: 13th January 2020

Manuka Henare, associate professor in Māori business development at Auckland University and a distinguished historian.

**Professor Graham Mellsop**

Membership category: Provision of health and disability services

Date of appointment: 11th February 2020

Current term expires: 20th March 2020

Graham Wilfred Mellsop, New Zealand psychiatrist, educator. Fellow Royal Australian New Zealand College Psychiatrists; member Royal College Psychiatry, IPPNW (chairman New Zealand branch). Junior resident, Auckland (New Zealand) Hospital Board, 1967; medical officer, Victorian Mental Health Authority, Melbourne, Australia, 1968-1970; director post-graduate studies, Victorian Mental Health Authority, 1975-1982; 2d assistant, U. Melbourne, 1971-1972; consultant psychiatrist, Auckland Hospital Board, 1973-1976; professor psychological medicine, U. Otago, Wellington, New Zealand, since 1982.

**Mrs Leesa Russell\*\***

Membership category: Provision of health and disability services

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Mrs Leesa Russell is Business Manager for Planning, Funding and Outcomes at Waitemata DHB. She has just completed a Post Graduate Diploma in Quality Systems at Massey and has been appointed Chair of the University of Auckland Human Participants Ethics Committee B. She has previously worked as a Business Manager in Primary Care, was the Project Manager responsible for System Level Measures in the Metro Auckland Region. She has experience working in clinical quality, improvement and audit related roles, including Quality Lead at Waitemata DHB and Clinical Audit Manager at St John, Process Manager and Extended Storage Co-ordinator at Fertility Associates, and (quality improvement) Data Evaluator at Counties Manukau Health. Her interest in ethics began with the role of Ethics Coordinator at the Health Research Council and prior to this she worked in cardiovascular and respiratory research and was a Research Fellow in Neuropsychology. She has a Masters and a Bachelors degree in (healthcare related) Sociology from the University of Auckland.

**Dr Devonie Waaka\*\***

Membership category: Design and conduct of intervention studies

Date of appointment: 18th July 2016

Current term expires: 18th July 2019

Dr Waaka graduated in medicine from the University of Otago in 1996. She worked as a medical registrar for a number of years, developing an interest in nephrology and rheumatology, before joining an early phase clinical trials unit as a research physician in 2004. Over the past decade she has been involved in the planning and implementation of numerous early phase trials in New Zealand and Australia. In 2011 Devonie completed a Master of Medical Science in Drug Development from the University of New South Wales. In addition to her clinical duties, Dr Waaka has been on the teaching staff for the Pharmaceutical Medicine and Drug Development Master Program, University of New South Wales (2012 – present).

**Mrs Helen Walker\*\***

Membership category: Consumer and community perspectives

Date of appointment: 6th December 2018

Current term expires: 6th December 2020

Mrs Helen Walker is currently the Chairman Central Health and Disability Ethics Committee a Member of the Medical Sciences Council, a Trustee of the Cranford Hospice Trust, Chairman of the New Zealand Singing School and the owner and of 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. Mrs Walker is 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. Chairman 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 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*** ***(L/NL)*** | **July** | **Aug** | **Sept** | **Oct** | **Nov** | **Dec** | **Jan** | **Feb** | **Mar** | **April** | **May** | **June** | **Total** |
| John Smith \* | NL | X  | **Y**  | **Y**  | **Y**  | **Y**  | A  | **Y**  | **Y**  | **Y**  | / | / | / | 7/8 |
| Mrs Kate O’Connor  | L | / | / | / | / | **Y\*\*** | / | X | **Y** | **Y** | **Y** | **Y** | A | 5/6 |
| Dr Karen Bartholomew  | NL | **Y** | **Y** | A | **Y** | **Y** | **Y** | X | **Y** | **Y** | A | **Y** | **Y** | 9/11 |
| Dr Kate Parker  | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Ms Rochelle Style  | L | A | **Y** | **Y** | **Y** | A | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | 9/11 |
| Ms Catherine Garvey  | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Dr Michael Meyer  | NL | / | / | / | / | / | / | X | / | A | **Y** | **Y** | **Y** | 3/4 |
| Dr Sotera Catapang  | NL | / | / | / | / | / | / | X | / | **Y** | **Y** | **Y** | **Y** | 4/4 |
| Dr ChrIstine Crooks | NL | **Y** | **Y** | A | **Y** | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Associate Professor Manuka Henare\* | L | **Y** | **Y** | **Y** | **Y** | **Y** | A | X | / | / | / | / | / | 5/6 |
| Professor Graham Mellsop | NL | / | / | / | / | / | / | X | / | **Y** | **Y** | **Y** | / | 3/3 |
| Mrs Leesa Russell | NL | **Y\*\*** | / | / | / | / | / | X | / | / | / | / | / | 1/1 |
| Dr Devonie Waaka | NL | / | / | **Y\*\*** | / | / | / | X | / | / | / | / | / | 1/1 |
| Mrs Helen Walker | L | / | / | **Y\*\*** | / | / | / | X | / | / | / | / | **Y\*\*** | 2/2 |
| **Total no. of members present** |  | **6** | **6** | **6** | **6** | **6** | **5** | **X** | **6** | **8** | **8** | **9** | **8** |  |
| **No. of applications considered** |  | **11** | **12** | **8** | **9** | **8** | **10** | **X** | **8** | **9** | **9** | **12** | **8** | **104** |

## Training and conferences

### Specify the training undergone by new members

Day-long training of new NEAC Ethical Standards, including framework for perfoming ethical review.

New Member training

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

Day-long training of new NEAC Ethical Standards, including framework for performing ethical review.

# Applications reviewed

### Summary of applications received by full EC

|  |  |
| --- | --- |
| No. of applications approved | 0 |
| No. of applications approved subject to conditionsApproved NSC | 10 |
| No. of applications deferred and subsequently approvedPA then Approved | 43 |
| No. of applications deferred as at time of reportPA pending response/decision | 8 |
| 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 | 1 |
| No. of applications declined (This excludes those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group)  | 27 |
| No. of applications which do not require ethics committee approval (applications submitted to Committee) (Note this can include incomplete applications) | 17 |
| No. of studies withdrawn by researcher | 2 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC  | 0 |
| **Total number of applications received by full EC**  | **108** |

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

|  |  |
| --- | --- |
| No. of applications approved | 23 |
| No. of applications deferred as at time of report | 0 |
| No. of applications which do not require ethics committee approval (Note this can include incomplete applications) | 3 |
| No. of applications referred for full committee review | 0 |
| No. of applications declined | 7 |
| No. of studies withdrawn by researcher | 0 |
| Total number of applications received under expedited / low risk review | 33 |

|  |  |
| --- | --- |
| Total number of applications received: | **141** |

#

# Complaints and overdue application summary

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

## Complaints received

**Complaint One**

**Study Reference:** 19/NTA/23

**Type of Complaint:** Public Complaint/Participant of Research

**Review Date:** 26 March 2019

**Complaint Received:** 28 October 2019

**Nature of Complaint:**

A daughter of a study participant wrote to the HDEC concerned questioning the recruitment processes of this study. The Participant who resides in an Auckland retirement village was invited along with other residents to what she thought was a session about respiratory health in older adults. There was no information in the invite about the session being related to potential participation in a clinical trial. However, a clinical trial was mentioned at the end of the session and the Participant had decided that she would give consent as she thought ‘the trial would be very good for her’. The Complainant stated that her mother recalled that she did not receive any written information, such as a participant information sheet (PIS) during the session to read over herself or share with her family or her GP. The complaint contacted the research team several times to request this information, but it was never received.

**Actions Taken:**

* Complaint sent to Manager
* Manager acknowledged the complaint.
* Chair of Central HDEC Informed.
* Letter sent to CI asking for following information a) clarification on why targeted information sessions in rest homes was not mentioned in the study documentation; b) to confirm the procedures in place to ensure people who are interested in attending targeted information sessions know that the sessions are about the potential involvement in a clinical trial and c) why a copy of the study participant information sheet was not provided at the initial session or provided when asked via email.
* Apology sent from Researchers

**Outcome:**

The Committee was satisfied with the response that the research team provided and that the research team would apologise to the complainant for any distress that may have been experienced during the recruitment process. Complaint closed.

**Complaint Two**

**Study Reference:** 20/NTA/90

**Type of Complaint:** HDEC and Secretariat Processes

**Review Date:** 25 June 2020

**Complaint Received:** 17 June 2020

**Nature of Complaint:**

Second application, after resubmission after a declined application. The second application was declined. Researcher had tried to contact secretariat regarding a number of issues in the first decline letter but did not receive a response. During the application review, the 31 recommendations highlighted in the first declined letter was not addressed, instead raised other issues with the protocol. During discussion the acting chair suggested a provisional approval but two members who was not present in the first application pushed for a decline.

**Actions Taken:**

* Complaint sent to Manager
* Manager acknowledged the complaint.
* Chair of Northern A HDEC Informed.
* Secretariat met with research team and explained that COVID-19 has impacted on secretariat services.
* Researcher asked for a secretariat review to insure HDEC processes are in line with his application under the Standard Operating Procedures this was completed.
* Researcher informed of outcome

**Outcome:**

Secretariat apologised for delay in service. The Secretariat review concluded that the Committee was correct in declining and there had not been a breach in the Standard Operating Procedures. However, the Secretariat did discuss with the researcher that the outstanding conditions that needed to be met are relatively straightforward. Complaint closed.

**Complaint Three**

**Study Reference:** AKL/2000/270 (amendment assigned to Northern A)

**Type of Complaint:** Committee behaviour

**Review Date:** 22 May 2020

**Complaint Received:** 9 June 2020

**Nature of Complaint:**

An amendment was sent through for review and the NTA HDEC requested that the amendment be sent through for full committee review under the Standard Operating Procedures and invited the research team to attend as they were concerned that the study was no longer in line with NEAC Standards. A complaint was sent through from the research team stating that the NTA members were adversarial in nature, unprofessional and overbearing.

**Actions Taken:**

* Complaint sent to Manager.
* Manager acknowledged the complaint
* Chair of Northern HDEC informed of complaint and process to occur.
* Manager spoke with Chair of the meeting and asked for their account of the meeting.
* Manager met with Secretariat team members at the meeting and asked for their account of the meeting.
* Manager listened to recording of the meeting.
* Letter of apology sent to researcher

**Outcome:**

Manager determined that that the complaint was not upheld, and behaviour of committee members were in line with the Terms of Reference and State Services Code of Conduct. However, a letter was written to the complainant from the Chair of NTA apologising if the comments came across adversarial as that was not the intent of the conversation and alliterated that they were willing to assist the research team in ensuring compliance with the NEAC Standards. Complaint closed.

## 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 30 days for expedited applications. Target timeframe for expedited applications is 15 calendar days. The delay was largely caused by COVID-19 work taking priority, and the strain changes to working arrangements and workloads as a result had on the Secretariat.

Average review time was 44 days for full applications. Target timeframe for full applications is 35 calendar days. The delay in this has been caused primarily by COVID-19 challenges to the Secretariat.

7 outliers have been identified with the expedited applications and are as follows:

19/NTA/144 (103 days) Application clock started 17 October 2019. Decision set to provisional approval 12 November 2019, clock paused. Response received 25 November 2019. Response had not been given by Committee, clock kept running over Ministry shutdown period. Declined decision process 7 February 2020, clock stopped.

19/NTA/187 (76 days) Application clock started 10 December 2019. Decision not made by Committee before Ministry shutdown period, clock continued to run. Provisionally Approved decision processed 30 January 2020, clock paused. Response received 26 February 2020. Final approved decision 11 March 2020, clock stopped.

20/NTA/2 (79 days) Application clock started 28 January 2020. COVID-19 caused significant delays and unfortunately decision was not processed until 10 April 2020.

20/NTA/15 (89 days) Application clock started 12 February 2020. COVID-19 and Secretariat staff shortages caused significant delays and unfortunately initial decision was not processed until 01 May 2020, clock paused. Response received 13 May 2020, final decision made 14 May 2020, clock stopped.

20/NTA/18 (94 days) Application clock started 24 February 2020. COVID-19 and Secretariat staff shortages caused significant delays and unfortunately initial decision was not processed until 15 May 2020, clock paused. Response received 10 August 2020, final decision made 20 August 2020, clock stopped.

20/NTA/21 (123 days) Application clock started 10 March 2020. COVID-19 and Secretariat staff shortages caused significant delays and unfortunately declined decision not processed until 19 June 2020.

20/NTA/27 (88 days) Application clock retroactively started 05 March 2020 set back to 12 February 2020. COVID-19 and Secretariat staff shortages caused significant delays and unfortunately initial decision not processed until 11 May 2020. Response was recieved 13 May 2020. Final decision made 15 May 2020, clock stopped.

#

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

## Applications reviewed by full committee

| **Study reference** | **Short title** | **CI Name** | **Clock Start** | **Date of provisional approval** | **Study Status** | **Final Decision Date** | **CI Organisation** | **Main Sponsor Type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 19/NTA/100 | Oral health and Oral-Health-Related Quality of Life of mental health service users in Christchurch. | Dr Emma Johnson | 4/07/2019 |  | Decline | 5/08/2019 | University of Otago | academic institution |
| 19/NTA/101 | Riluzole in Spinal Cord Injury | Dr. Michael Fehlings | 4/07/2019 | 5/08/2019 | Approve | 13/11/2019 | University of Toronto | collaborative research , non-governmental organisation (NGO) |
| 19/NTA/102 | GS-US-494-5484 | Dr Sanjeev Deva | 4/07/2019 | 5/08/2019 | Approve | 26/08/2019 | Auckland City Hospital | pharmaceutical company |
| 19/NTA/105 | The Role of Sleep for Health Ageing and Service Requirements | Dr Rosemary Gibson | 2/08/2019 |  | Decline | 4/09/2019 | Massey University | no sponsor |
| 19/NTA/106 | Kick Start, Act Now to Live Well | Ms Sheena Duffy Vakatale | 3/08/2019 |  | Decline | 3/09/2019 | Diabetes NZ Auckland Branch | no sponsor |
| 19/NTA/107 | (duplicate) Urtica ferox exposure | Dr Eric Buenz | 3/08/2019 | 19/08/2019 | Approve | 3/09/2019 |  | academic institution |
| 19/NTA/108 | Comparison of the blood levels of two forms of lenalidomide 25 mg capsules. | Dr Noelyn Hung | 8/08/2019 |  | Approve | 11/09/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/NTA/109 | Comparison of the blood levels of two forms of lenalidomide 15 mg capsules. | Dr Noelyn Hung | 8/08/2019 |  | Approve | 11/09/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/NTA/110 | Comparison of the blood levels of two forms of pomalidomide 4 mg capsules. | Dr Noelyn Hung | 8/08/2019 |  | Approve | 11/09/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/NTA/113 | Depression and psoriasis | Dr Karen Koch | 8/08/2019 |  | Decline | 11/09/2019 | Waikato Hospital | no sponsor |
| 19/NTA/114 | AMPLE-3: a study comparing 2 standard treatments for malignant pleural effusion in patients with cancer | Dr Nicola Ann Smith | 8/08/2019 |  | Approve | 11/09/2019 | Capital and Coast District Health Board | collaborative research |
| 19/NTA/115 | SED and survival after type A aortic dissection repair | Dr Andrei Belyaev | 7/08/2019 |  | Approve | 26/08/2019 | Auckland City Hospital | no sponsor |
| 19/NTA/117 | The P-SSICS Bundle: Prevention of surgical site infection after Caesarean section | Dr Helen Winrow | 8/08/2019 |  | Approve | 11/09/2019 | Auckland District Health Board | no sponsor |
| 19/NTA/119 | CRN00808-03 An open label study to evaluate the safety, PK and efficacy of CRN00808 in patients with acromegaly (ACROBAT EDGE). | Dr Richard Carroll | 8/08/2019 | 11/09/2019 | Approve | 7/10/2019 | Capital & Coast District Health Board | pharmaceutical company |
| 19/NTA/120 | CRN00808-02: A study to evaluate the safety, PK and efficacy of CRN00808 in patients with acromegaly (ACROBAT EVOLVE) | Dr Richard Carroll | 8/08/2019 | 11/09/2019 | Approve | 7/10/2019 | Capital & Coast District Health Board | pharmaceutical company |
| 19/NTA/123 | Headstrong: a chatbot for wellbeing | Dr Karolina Stasiak | 8/08/2019 | 11/09/2019 | Approve | 7/10/2019 | University of Auckland | academic institution |
| 19/NTA/124 | PhD thesis exploring hyperinsulinaemia in pregnancy | Miss Sylvia North | 8/08/2019 | 28/08/2019 | Approve | 9/12/2019 | Auckland University of Technology (AUT) | no sponsor |
| 19/NTA/126 | A crossover trial to investigate bag mask ventilation over the Switching Interface. | Professor Alan F Merry | 21/08/2019 | 11/10/2019 | Approve | 22/11/2019 | The University of Auckland | medical device company |
| 19/NTA/128 | Clinicopathological correlation of renal biopsies in the Midlands Region | Dr Daniel Ninin | 5/09/2019 |  | Decline | 14/10/2019 |  | no sponsor |
| 19/NTA/129 | (duplicate) Oral health and Oral-Health-Related Quality of Life of mental health service users in Christchurch. | Dr Emma Johnson | 5/09/2019 |  | Approve | 11/10/2019 | University of Otago | academic institution |
| 19/NTA/130 | (duplicate) ORATORIO HAND (O'HAND) | Dr Jennifer Taylor | 5/09/2019 | 11/10/2019 | Decline | 19/03/2020 | Capital and Coast District Health Board | pharmaceutical company |
| 19/NTA/131 | Biliary Atresia screening | Dr Stephen Mouat | 5/09/2019 |  | Approve | 11/10/2019 | Starship Children's Health | no sponsor |
| 19/NTA/132 | AVERT DOSE | Mrs Justine Slow | 5/09/2019 |  | Decline | 11/10/2019 | BOPDHB | collaborative research |
| 19/NTA/135 | LOVIT | Dr Shay McGuinness | 3/10/2019 | 8/11/2019 | Approve | 27/02/2020 | Auckland District Health Board | no sponsor |
| 19/NTA/136 | Biomarkers for Weight Loss After Sleeve Gastrectomy | Dr Kirsty Danielson | 27/09/2019 |  | Decline | 17/10/2019 | University of Otago Wellington | no sponsor |
| 19/NTA/137 | A prospective investigation of timelines to diagnosis for New Zealand AYA cancer patients. | Heidi Watson | 3/10/2019 |  | Decline | 8/11/2019 | AYA Cancer Network Aotearoa | other government agency |
| 19/NTA/138 | The Effect of Trampolining on Incontinence and Bone Density | Mr Tane Clement | 9/10/2019 |  | Decline | 7/11/2019 | University of Canterbury | other |
| 19/NTA/140 | Discontinuing nucleos(t)ide analogue therapy for chronic hepatitis B with the aim of achieving HBsAg seroconversion | Dr Tien Huey Lim | 3/10/2019 |  | Decline | 8/11/2019 | Middlemore Hospital | no sponsor |
| 19/NTA/141 | GastroIntestinal dysFunction in criTical illness(GIFT):Gut BiOmarker(BOx)study | Ms Varsha Asrani | 3/10/2019 | 8/11/2019 | Decline | 12/03/2020 | ADHB / University of Auckland | academic institution, district health board (DHB) |
| 19/NTA/142 | Being a teenager can be stressful. Does being kinder to yourself increase coping? | Mrs Amanda Helen Smith | 3/10/2019 |  | Decline | 8/11/2019 |  | no sponsor |
| 19/NTA/144 | Human cell study | Assoc Prof Rinki Murphy | 17/10/2019 | 12/11/2019 | Decline | 7/02/2020 |  | academic institution |
| 19/NTA/146 | Feasibility of Care for Osteoarthritis through Pharmacy Education (F-COPER) | Dr Ben Darlow | 3/10/2019 | 12/11/2019 | Approve | 19/12/2019 | University of Otago | no sponsor |
| 19/NTA/147 | Psychological impacts of the Mosque attacks | Associate Professor Caroline Bell | 4/10/2019 | 8/11/2019 | Approve | 16/12/2019 | University of Otago, Christchurch | academic institution |
| 19/NTA/148 | Diagnosing hyperglycaemia in patients with chronic liver disease | Dr Helen Lunt | 8/10/2019 |  | Approve | 5/11/2019 |  | no sponsor |
| 19/NTA/149 | Physiological measures after PSF | Dr Kelly Jones | 4/10/2019 |  | Approve | 8/11/2019 | Auckland University of Technology | academic institution |
| 19/NTA/150 | A community group for older adults with loneliness | Dr Gary Cheung | 4/10/2019 | 8/11/2019 | Approve | 9/12/2019 | University of Auckland | academic institution |
| 19/NTA/151 | EpiNet case control study of SUDEP | Dr Peter Bergin | 3/10/2019 | 8/11/2019 | Approve | 19/12/2019 | Auckland City Hospital | collaborative research |
| 19/NTA/152 | (duplicate) The Role of Sleep for Health Ageing and Service Requirements | Dr Rosemary Gibson | 4/10/2019 |  | Approve | 12/11/2019 | Massey University | academic institution, other |
| 19/NTA/155 | Verb usage in Alzheimer’s disease | Mr Eric Williams | 7/11/2019 | 4/12/2019 | Decline | 18/06/2020 | University of Canterbury | no sponsor |
| 19/NTA/156 | Immunoglobulin Replacement in New Zealand Children | Dr Annaliesse Blincoe | 7/11/2019 | 4/12/2019 | Approve | 12/12/2019 | Starship Children's Hospital | no sponsor |
| 19/NTA/157 | (duplicate) Study 212669: A Phase I Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of GSK2798745 in Participants with Diabetic Macular Edema | Professor Russell Scott | 7/11/2019 | 4/12/2019 | Approve | 14/02/2020 | CDHB | pharmaceutical company |
| 19/NTA/158 | Respond PICU | Dr David Buckley | 7/11/2019 | 4/12/2019 | Approve | 12/12/2019 | Starship Child Health | no sponsor |
| 19/NTA/159 | Bioadaptor Study | Dr Mark Webster | 7/11/2019 |  | Approve | 4/12/2019 | Auckland District Health Board | medical device company |
| 19/NTA/160 | The Vascular Spasm Study | Dr Mark Webster | 7/11/2019 | 4/12/2019 | Decline | 12/12/2019 | Auckland District Health Board | no sponsor |
| 19/NTA/161 | The EDGI study | Dr Jennifer Jordan | 7/11/2019 |  | Decline | 4/12/2019 | University of Otago, Christchurch | no sponsor |
| 19/NTA/163 | Generation of a measure of Quality of Life in Valvular Disease | Dr Sean Coffey | 24/11/2019 | 20/12/2019 | Approve | 14/02/2020 |  | no sponsor |
| 19/NTA/164 | BIO/MASTER.BIOMONITOR III | Dr Nigel Lever | 5/12/2019 | 29/01/2020 | Provisionally approve |  | Auckland City Hospital | medical device company |
| 19/NTA/166 | Evaluation of Safety, Tolerability and Preliminary Efficacy of EHP-101 in Patients with Diffuse Cutaneous Systemic Sclerosis | Dr Ketna Parekh | 5/12/2019 | 29/01/2020 | Decline | 11/03/2020 | CCDHB | pharmaceutical company |
| 19/NTA/167 | Rights of Child Voice in Health Data | Dr Yvonne Anderson | 5/12/2019 |  | Decline | 29/01/2020 |  | non-governmental organisation (NGO) |
| 19/NTA/168 | Effect of recency of childbirth on breast cancer survival | Assoc. Prof. Brian Cox | 29/11/2019 |  | Approve | 20/12/2019 |  | other government agency, other |
| 19/NTA/169 | Investigating SCS using EEG | Dr Matthew Moore | 5/12/2019 | 29/01/2020 | Approve | 18/05/2020 |  | no sponsor |
| 19/NTA/172 | Comparison of the blood levels of two forms of bexarotene capsule. | Dr Noelyn Hung | 5/12/2019 |  | Approve | 30/01/2020 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/NTA/173 | Bloodspot Steroid Profiling to Improve Newborn Screening for CAH | Mr Mark de Hora | 5/12/2019 | 30/01/2020 | Approve | 11/03/2020 |  | district health board (DHB) |
| 19/NTA/174 | Evaluation of a CBT-sensory modulation intervention for children with anxiety. | Mr Tafadzwa MAVHUNGA | 5/12/2019 |  | Decline | 30/01/2020 | AUT University | academic institution |
| 19/NTA/175 | Axon FIH Clinical Study | Professor Rob Doughty | 5/12/2019 | 30/01/2020 | Approve | 15/05/2020 | Auckland City Hospital | medical device company |
| 19/NTA/177 | ARCOS V: Incidence and outcomes of stroke | Professor Valery L Feigin | 4/12/2019 | 20/12/2019 | Approve | 21/02/2020 | Auckland University of Technology | no sponsor |
| 19/NTA/178 | Feasibility study of an IUD insertion device | Associate Professor Michael Stitely | 5/02/2020 |  | Decline | 6/03/2020 | University of Otago | academic institution |
| 19/NTA/179 | MEASURE-AD | DR. Gerhard Eichhoff | 4/12/2019 | 20/12/2019 | Approve | 10/03/2020 | Capital and Coast Health Board | pharmaceutical company |
| 19/NTA/180 | Mitigation of concussive and sub-concussive events in junior rugby players | Professor Nick Draper | 5/12/2019 |  | Decline | 30/01/2020 | University of Canterbury | academic institution |
| 19/NTA/182 | Probing the Cellular Causes of Muscle Degeneration in Cerebral Palsy | Miss Stephanie Khuu | 5/12/2019 |  | Decline | 30/01/2020 | Auckland Bioengineering Institute | academic institution |
| 19/NTA/186 | In Vitro Study to Determine Responses to Potential Vaccine Candidate Molecules in HBV subjects & Healthy Controls | Prof Edward Gane | 6/12/2019 |  | Approve | 28/01/2020 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 19/NTA/187 | The Effect of Trampolining on Incontinence and Bone Density | Mr Tane Clement | 6/12/2019 | 30/01/2020 | Approve | 11/03/2020 | University of Canterbury | other |
| 19/NTA/97 | CHOC-DIP: Children on Cefalexin Dose Interval with Probenecid study | A/Prof Tony Walls | 4/07/2019 | 5/08/2019 | Approve | 16/10/2019 | CDHB | academic institution |
| 19/NTA/98 | A study assessing the similarity of Avastin and the trial drug BP01 | Dr Christian Schwabe | 4/07/2019 | 5/08/2019 | Approve | 22/08/2019 | Auckland Clinical Studies | pharmaceutical company |
| 20/NTA/10 | Vaping as a substitute for smoking | Dr Hayden McRobbie | 6/02/2020 | 4/03/2020 | Provisionally approve |  | Lakes District Health Board | district health board (DHB) |
| 20/NTA/108 | Traditional acupuncture for treating irritable bowel syndrome | Dr Li Feng | 9/07/2020 |  | Decline | 12/08/2020 | New Zealand College of Chinese Medicine | academic institution |
| 20/NTA/110 | ASCEND | Dr John Beca | 9/07/2020 | 12/08/2020 | Provisionally approve |  | Auckland District Health Board | no sponsor |
| 20/NTA/12 | FLASH-1 Study | A/Prof Craig Jefferies | 6/02/2020 | 4/03/2020 | Approve | 10/04/2020 | Auckland District Health Board | no sponsor |
| 20/NTA/15 | Dietary regulation of mitochondrial derived peptides | Dr Troy Merry | 4/02/2020 | 1/05/2020 | Approve | 14/05/2020 | University of Auckland | academic institution |
| 20/NTA/18 | Identifying changes in physiological variables resulting from accentuated eccentric strength training combined with a hypocaloric high protein diet. | Associate Professor James Stinear | 24/02/2020 | 15/05/2020 | Approve | 20/08/2020 | University of Auckland | other |
| 20/NTA/2 | Waitematā DHB patient survey on data use | Dr Rosie Dobson | 22/01/2020 |  | Approve | 10/04/2020 |  | academic institution |
| 20/NTA/20 | Phase 1 single ascending dose study of ARCT-810 in Healthy Adult Subjects | Mr Christian Schwabe | 27/02/2020 | 5/04/2020 | Approve | 23/04/2020 | Auckland Clinical Studies | pharmaceutical company |
| 20/NTA/21 | Accuracy of aortic annulus measurement on CT | Dr Minesh Prakash | 17/02/2020 |  | Decline | 19/06/2020 |  | no sponsor |
| 20/NTA/22 | Artificial Intelligence Support for Skin Lesion Triage in Primary Care and Dermatology | A/Prof Amanda Oakley | 17/02/2020 | 9/03/2020 | Approve | 10/04/2020 | Waikato District Health Board/Auckland University | medical device company |
| 20/NTA/23 | Identifying the cell of Origin for Lymphangioleiomyomatosis (LAM). | Mr Ryan Powell | 6/03/2020 |  | Decline | 5/04/2020 |  | academic institution |
| 20/NTA/24 | Histopathology of Volcanic Burns | Dr Orazio Di Bartolo | 6/03/2020 |  | Withdrawn by Researcher | 6/04/2020 |  | no sponsor |
| 20/NTA/25 | Retreatment study for DAA-experienced Hep C patient with NS5A resistance | Prof Edward John Gane | 6/03/2020 | 6/04/2020 | Approve | 10/07/2020 | New Zealand Liver Transplant Unit | no sponsor |
| 20/NTA/26 | AIRVO study | Dr Paul Dawkins | 6/03/2020 |  | Decline | 6/04/2020 | Middlemore Clinical Trials | no sponsor |
| 20/NTA/27 | Incidence and Prevalence of Inflammatory Bowel Disease in the North Island | Dr Sam Seleq | 17/02/2020 | 11/05/2020 | Approve | 15/05/2020 |  | no sponsor |
| 20/NTA/28 | Wrist movement after surgery for wrist fracture | Mrs Julie Collis | 6/03/2020 | 6/04/2020 | Approve | 18/05/2020 | Auckland University of Technology | academic institution |
| 20/NTA/29 | Peripheral chemoreflex and the veins in hypertension | Dr James Fisher | 6/03/2020 | 6/04/2020 | Approve | 6/08/2020 | University of Auckland | academic institution |
| 20/NTA/3 | Asthma SNP Chip | Dr. William Abbott | 6/02/2020 |  | Decline | 4/03/2020 | Auckland City Hospital | no sponsor |
| 20/NTA/30 | Pacific-led bariatric surgery support trial at Auckland City Hospital | DR Tamasin Taylor | 6/03/2020 | 6/04/2020 | Approve | 30/06/2020 | University of Auckland | academic institution |
| 20/NTA/37 | The ANCHOR Study | Professor Jane Harding | 1/04/2020 | 18/05/2020 | Approve | 28/07/2020 | University of Auckland | academic institution |
| 20/NTA/38 | DOXY-RC: Phase II Trial of Doxycycline with Radiotherapy for Rectal Cancer | Dr Natalie Briggs | 9/04/2020 | 19/05/2020 | Approve | 10/07/2020 | Waikato District Health Board | no sponsor |
| 20/NTA/39 | Understanding Altered Muscle in Cerebral Palsy | Miss Stephanie Khuu | 9/04/2020 | 19/05/2020 | Approve | 8/07/2020 | Auckland Bioengineering Institute | academic institution |
| 20/NTA/4 | AAA-SHAPE | Associate Professor Andrew Holden | 6/02/2020 | 4/03/2020 | Approve | 18/06/2020 | Auckland City Hospital | medical device company |
| 20/NTA/41 | iMODERN | Dr Aniket Puri | 9/04/2020 | 19/05/2020 | Approve | 20/08/2020 | Canterbury District Health Board | academic institution |
| 20/NTA/42 | Analysis of Laboratory Results Patterns | Mr Samuel Wong | 9/04/2020 |  | Decline | 19/05/2020 | Vensa Health | other |
| 20/NTA/43 | MOGNZ: a prevalence and incidence study of Myelin Oligodendrocyte Glycoprotein antibody disease (MOGAD) in New Zealand | Dr Sean Lance | 9/04/2020 |  | Decline | 19/05/2020 | CCDHB | district health board (DHB) |
| 20/NTA/44 | Comparison of early phase Amyloid PET and FDG-PET imaging | Dr Campbell Le Heron | 9/04/2020 | 19/05/2020 | Approve | 20/08/2020 | New Zealand Brain Research Institute | no sponsor |
| 20/NTA/45 | The CELF-P3 Research Project | Ms Claudia Squire | 9/04/2020 |  | Decline | 20/05/2020 | Ministry of Education | other |
| 20/NTA/46 | Electric fences to treat arrhythmia | Dr Martin Stiles | 9/04/2020 |  | Decline | 20/05/2020 |  | no sponsor |
| 20/NTA/5 | Galactosemia screening threshold study | Dr Callum Wilson | 6/02/2020 | 4/03/2020 | Approve | 22/04/2020 | Starship Children's Hospital | no sponsor |
| 20/NTA/52 | Malnutrition and complications in Lower Limb Arthroplasty: A prospective observational study | Dr William Caughey | 14/04/2020 | 12/05/2020 | Approve | 19/05/2020 |  | no sponsor |
| 20/NTA/53 | The Narratives of Maori referred for colonoscopy | Dr Clarence Kerrison | 28/04/2020 |  | Approve | 14/05/2020 |  | no sponsor |
| 20/NTA/55 | Ataxia-Prev | A/Prof Richard Roxburgh | 7/05/2020 | 9/06/2020 | Approve | 19/06/2020 | Auckland District Health Board | no sponsor |
| 20/NTA/57 | Feasibility study of a non-mesh sling anchoring system | Associate Professor Michael Stitely | 7/05/2020 | 11/06/2020 | Approve | 13/07/2020 | University of Otago | academic institution |
| 20/NTA/6 | GT-30 Personalised Neoantigen DNA Vaccine + IL-12 for Advanced HCC | Prof Edward John Gane | 5/02/2020 | 4/03/2020 | Approve | 20/03/2020 | New Zealand Liver Transplant Unit | pharmaceutical company |
| 20/NTA/60 | Virtual Reality as analgesia for TRUS prostate biopsy | Dr Christian Robinson | 5/05/2020 |  | Approve | 20/05/2020 |  | academic institution |
| 20/NTA/61 | BOLD | Dr Helen Evans | 7/05/2020 | 11/06/2020 | Approve | 25/08/2020 | Auckland District Health Board | pharmaceutical company |
| 20/NTA/63 | BGB-A317-290-LTE1 | Dr Sanjeev Deva | 7/05/2020 | 11/06/2020 | Approve | 10/07/2020 | Auckland City Hospital | pharmaceutical company |
| 20/NTA/68 | Dyspnoea and exercise limitation in interstitial lung disease | Dr Charlotte Chen | 7/05/2020 | 11/06/2020 | Approve | 29/07/2020 |  | academic institution |
| 20/NTA/7 | A clinical study to test the efficacy and safety of CSL312 on catheter-associated blood clot formation in subjects with cancer who receive chemotherapy through a PICC line (CSL312\_1002) | Dr Laura Young | 5/02/2020 | 4/03/2020 | Withdrawn by Researcher | 11/05/2020 | Auckland District Health Board | pharmaceutical company |
| 20/NTA/70 | Study Evaluating AZR-MD-001 in Patients with Meibomian Gland Dysfunction (MGD). | Professor Dean Corbett | 7/05/2020 | 11/06/2020 | Approve | 7/07/2020 | Auckland Eye Limited | pharmaceutical company |
| 20/NTA/72 | Listen Up New Zealand | Chief Executive Natasha Gallardo | 7/05/2020 | 11/06/2020 | Approve | 29/07/2020 | National Foundation for Deaf & Hard of Hearing | no sponsor |
| 20/NTA/73 | (duplicate) Emerging Biomarkers for Monitoring of Congenital Adrenal Hyperplasia | Mrs Lauren Bresnahan | 7/05/2020 | 11/06/2020 | Provisionally approve |  | LabPlus, Auckland DHB | no sponsor |
| 20/NTA/74 | BIOFLOW-DAPT | Dr Jithendra Somaratne | 7/05/2020 | 11/06/2020 | Approve | 28/07/2020 | Auckland District Health Board | medical device company |
| 20/NTA/75 | GPX Embolic Device Study | Associate Professor Andrew Holden | 7/05/2020 | 11/06/2020 | Approve | 20/08/2020 | Auckland District Health Board | medical device company |
| 20/NTA/83 | Outcome of primary constrained knee arthroplasty | Dr. MARLA Ross | 14/05/2020 |  | Approve | 30/05/2020 | Northland DHB | no sponsor |
| 20/NTA/84 | IOPB study | Dr. Matthew Mackey | 25/05/2020 |  | Approve | 30/05/2020 | Waikato District Health Board | no sponsor |
| 20/NTA/85 | Evaluation of commercial SARS-CoV-2 antibody test kits | Dr Erasmus Smit | 18/05/2020 | 30/05/2020 | Approve | 26/06/2020 | Institute of Environmental Science & Research Ltd | other government agency |
| 20/NTA/86 | Nebulization of manuka honey | Dr Chris McMahon | 4/06/2020 |  | Decline | 7/07/2020 |  | non-governmental organisation (NGO) |
| 20/NTA/87 | The EFEMORAL I Clinical Investigation | Associate Professor Andrew Holden | 5/06/2020 | 7/07/2020 | Approve | 20/08/2020 | Auckland District Health Board | medical device company |
| 20/NTA/88 | Study of ALXN1840 in Patients with Wilson Disease | Prof Edward John Gane | 5/06/2020 | 7/07/2020 | Provisionally approve |  | New Zealand Liver Transplant Unit | pharmaceutical company |
| 20/NTA/89 | Patient responses to nasal high flow therapy (PRNHFT): a pilot study | Dr Troy Browne | 5/06/2020 |  | Decline | 7/07/2020 | BOP DHB | medical device company |
| 20/NTA/9 | The SUN Study | Associate Professor Clare Wall | 6/02/2020 | 4/03/2020 | Approve | 19/05/2020 | The University of Auckland | no sponsor |
| 20/NTA/90 | Analysis of Laboratory Results Patterns (revised) | Mr Samuel Wong | 5/06/2020 |  | Decline | 25/06/2020 | Vensa Health | other |
| 20/NTA/91 | AC-055H302 - A clinical study to measure the safety and impact of a drug called macitentan in teenage and adult Fontan patients | Dr Kathryn Rice | 5/06/2020 | 7/07/2020 | Provisionally approve |  | Starship Children's Hospital | pharmaceutical company |
| 20/NTA/92 | Sleep in Children with a Mild Traumatic Brain Injury | Dr Jacki Henderson | 5/06/2020 | 7/07/2020 | Provisionally approve |  | University of Canterbury | academic institution |
| 20/NTA/93 | Nasal high flow therapy in bronchiectasis | Dr Paul Dawkins | 5/06/2020 | 7/07/2020 | Provisionally approve |  | Middlemore Clinical Trials | 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: 7 October 2020**

## 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:** Mr Nic Aagaard

 Title First Name Last Name

**Position :** Acting Manager – Ethics, Quality Assurance and Safety, Health System Improvement and Innovation, Ministry of Health

**E-mail :** hdecs@moh.govt.nz nz



**Signature: Date:** 7 October 2020

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)