

Northern A Health and Disability Ethics Committee

Annual Report
2019

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# About the committee

The Northern A Health and Disability Ethics Committee (HDEC) is a Ministerial committee established under section 11 of the [New Zealand Public Health and Disability Act 2000](http://www.legislation.govt.nz/act/public/2000/0091/latest/DLM80051.html). Its members are appointed by the Minister of Health through the public appointments process.

The primary function of the Committee is to provide independent ethical review of health research and innovative practice in order to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy.

The Committee is required by its [Terms of Reference](http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-about-central#tor) to submit an Annual Report to the Minister of Health. The Annual Report must include information on the membership of the Committee, a summary of the applications reviewed during the year, details of any complaints received (and how they were resolved), and areas of review that caused difficulty when making decisions, among other matters.

### Approvals and registrations

The Northern A HDEC is approved by the Health Research Council Ethics Committee for the purposes of section 25(1)(c) of the [Health Research Council Act 1990](http://legislation.govt.nz/act/public/1990/0068/latest/DLM213017.html).

The Northern A HDEC is registered (number IRB00008714) with the United States’ Office for Human Research Protections. This registration enables the committee to review research conducted or supported by the US Department of Health and Human Services.

# Chairperson’s report

Tēnā koutou

The work of the committee continues according to the Standard Operating Procedures and NEAC and other guidelines.

It has been a difficult year for the committee, with a combination of resignations, workload pressures and Ministry restructuring. Long-standing chairperson Dr. Brian Fergus resigned in 2018 and due to a slow appointments process the committee was without a chair for several months, requiring a co-opt Chair from another committee. A/Prof Mānuka Hēnare was appointed as the new chairperson in March 2019, chairing his first meeting in May 2019.

The committee receives a steady flow of submissions, the majority of which receive provisional approval and require several adjustments before approval can be given. These usually consist of revisions to the participant information sheets and consent forms or study protocol to ensure participants are adequately informed and their safety in the study is ensured. When the committee is unable to approve an application it is typically due to a combination of extensive issues with study documentation, inappropriate future use of genetic samples or data, inadequate insurance or because the study is inconsistent with New Zealand law.

The appointments process has continued to be slow and two sitting members have expired terms. However, the HDEC terms of reference allow members to continue in office until a successor enters office and until the appointments process is concluded the committee shall continue business as usual.

NTA received the resignations of Toni Millar (lay-member with consumer perspectives) and Dr Catherine Jackson (non-lay member health disability service provision). Both membership roles are still vacant.

Other issues of note raised by committee members include:

1. There has been an increasing number of research involving devices. Some of the device research is complex. The absence of a body like SCOTT to review them for technical issues combined with no ethical guidance in the current NEAC Guidelines raises concerns for the robustness and safety of the HDEC review process for devices.
2. Increasing number of multi-national pharmaceutical companies seeking consent for unlimited and unspecified future research (FUR) with participants’ data and tissue, especially for storage and use in offshore repositories.   There are ethical concerns with FUR including the lack of New Zealand representation on repository governance bodies and differing privacy protection to that offered in New Zealand.
3. Some evidence of companies wishing to make FUR genetic analyses as a mandatory part of research.  The Committee’s view has been that this must be optional.
4. Increasing use of new technologies in a variety of research, ranging from e-diaries and fitbits to cognitive assessment apps and medicine compliance tools.  Current NTA experience suggests researchers have not fully considered the potential harms to participants in using these technologies in terms of data use by unknown third parties and data being sold for commercial gain.
5. Increasingly complex and novel trial design which requires more detailed consideration.
6. Lack of understanding on the part of researchers regarding the grounds upon which a waiver of consent may be sought.  Many appear to be unaware of the relevant provisions in the NEAC Guidelines.
7. Increasing willingness on the part of many researchers to try to understand more fully the ethical issues raised by their research.  One researcher thanked the Committee at the end of the discussion for the amount they had learnt during the meeting.

I would like to thank the committee members of NTA for their ongoing support and service to ensuring that New Zealand participants of research are protected, and that the public can trust that research is meeting ethical standards. I would also like to thank Rob and the Ethics Team for ensuring that the NTA are well supported in terms of Secreteriat support.

I look forward to continuing to work alongside the NTA Members and the staff at the Ministry of Health Ethics Team.

Ngā mihi maioha

Mānuka Hēnare

Chairperson Northern A Health and Disability Ethics Committee

## Membership and attendance

### List of EC members within the reporting period

**A/Prof Mānuka Hēnare (Chair)**

Membership category: Lay (community perspectives, Tikanga Māori)

Date of appointment: 19th March 2019

Current term expires: 19th March 2022

Mānuka is the chairperson of the Northern A Health and Disability Ethics Committee. He is currently an Associate Professor in Māori Business Development in the Department of Management and International Business at the University of Auckland and recently completed (December 2014) a twelve year term as Associate Dean (Māori and Pacific Development). Mānuka is also the foundation Director of the Mira Szászy Research Centre for Māori and Pacific Economic Development and leads a number of multidisciplinary research project teams. He is board member of the University of Auckland, Centre of Development Studies, and the Centre of Pacific Studies. He was until 2013 the Academic Coordinator of Te Tohu Huanga Māori Graduate Programme in Business Development within the Graduate School of Management and teaches Māori business and economic history, strategy, and management of tribal enterprises. Mānuka completed a seven year term as government appointee to the Council of Te Wānanga o Aotearoa, NZ's largest tertiary institution, and a five year term as Council member of the Manukau Institute of Technology (May 2015). In 2014 he was appointed a member of the Royal Society of New Zealand Humanities and Social Science Advisory Panel. He is, since 1999, a Visiting Fellow of Corpus Christi College, Cambridge University, UK, and in 2015 did further research and study leave in Cambridge. He has advised New Zealand government departments, local authorities and other institutions on ambicultural or bicultural governance and management policies and also served on government advisory committees on development assistance, peace and disarmament, archives, history, social policy, environmental risk management and number of other ministerial appointments. He was previously a lecturer in Māori studies at Victoria University of Wellington, where he taught courses on the Te Tiriti o Waitangi/Treaty of Waitangi, Māori culture and society and tribal histories. He also lectured in the Masters of Development Studies on culture, religion and economic development. Prior to his university career (his third career), he was CEO of two national non-government organisations involved in international development, justice and peace, and has travelled extensively throughout Asia, the Pacific and Southern Africa.

**Ms Rochelle Style**

Membership category: Lay (ethical/moral reasoning)

Date of appointment: 14th June 2016

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 is a member of an expert Working Party appointed by the Ministry of Health to update the National Ethical Health Research guidelines with particular input on the Health Data Chapter and the Chapter on Artificial Intelligence & Emerging Health Technologies. She also has valuable clinical ethics experience gained through her appointment 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 health data ethics and ethical issues arising in the use of Artificial Intelligence in the health sector, including at the University of Otago, Victoria University of Wellington and the Waitemata DHB’s Clinical Digital Academy.

**Ms Catherine Garvey**

Membership category: Lay (the 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.

**Dr Karen Bartholomew**

Membership category: Non-Lay (intervention studies)

Date of appointment: 13th May 2016

Current term expires: 13th May 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 Masters of Public Health with honours (2011) from the University of Auckland. She has undertaken a range of clinical work, with a focus on women’s health. She holds a specialist qualification in Public Health Medicine, and has an interest in women’s health, maternity, screening and public health genomics. She is also has a strong interest in 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: Non-Lay (observational studies)

Date of appointment: 11th November 2015

Current term expires: 11th November 2018

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

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

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

**Dr Christine Crooks\***

Membership category: Non-Lay (intervention studies)

Date of appointment: 11th November 2015

Current term expires: 11th November 2018

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

**Ms Toni Millar**

Membership category: Lay (consumer/community perspectives)

Date of appointment: 11th November 2016

Current term expires: 11th November 2019

Ms Toni Millar is self-employed, working in a number roles as a trustee, director and board member. Among these, she is Director of the Centre for Social Impact (2015 – present), Chair of the Auckland Council’s Creative Communities Central Assessment Committee (2013 – present), a member of the Ministry of Social Development’s Auckland Central Community Response Forum (2010 – present) and a Trustee of Foundation North (previously ASB Community Trust) (2011 – present). Ms Millar has a Post-Graduate Diploma in Business Management from the University of Auckland (1997), a Diploma in Teaching from North Shore Teachers College (1979), and a Certificate in Company Direction from the Institute of Directors New Zealand (2010). She was appointed a Justice of the Peace in 2005 and awarded the Queens Service Medal for community works in 2015.

**Dr Brian Fergus**

Membership category: Consumer/community perspectives

Date of appointment: 11th November 2015

Current term expires: 11th November 2018

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

**Dr Catherine Jackson**

Membership category: Non-lay (health/disability service provision)

Date of appointment: 11th November 2016

Current term expires: 11th November 2019

Dr Catherine Jackson is a Public Health Medicine Specialist at Auckland Regional Public Health service (2011 – present). Prior to this, she was a data manager and analyst for Youth National Secondary School Survey (2012). Dr Jackson was a member of the Fiji Islands Rheumatic Heart Disease Control and Prevention Advisory Group (2013 – 2015). She is a member of the New Zealand College of the Public Health Medicine Assessment Committee (2014 – present) and was a Registrar of the New Zealand College of Public Health Medicine Council (2009 – 2012). Dr Jackson holds a Bachelor of Medicine, Bachelor of Surgery (1994), a Master of Public Health (2011), and a Diploma in Paediatrics (1996) from the University of Auckland.

**Dr Nora Lynch**

Membership category: Non-lay (health/disability service provision)

Date of appointment: 19th March 2019

Current term expires: 19th March 2022

* Member of a committee of specialist rheumatologists which prepared treatment guidelines for local specialist use.
* Ministry of Health Ethics Committee Member (HDEC- NTB) 2015 –
* Ministry of Health Working Party – National Research Ethics Guidelines Update 2017–
* CMA (Companionship and Morning Activities for the elderly)
* Board Member 2015- Chair 2017-MEMBERSHIPS New Zealand Rheumatology Association- awarded Life Membership 2014
* American College of Rheumatology- International Fellow
* Fellow Royal Australasian College of Physicians

**Ms Sandy Gill\***

Membership category: Lay (consumer/community perspectives)

Date of appointment: 30th July 2015

Current term expires: 30th July 2018

Ms Sandy Gill has her own consulting company and also works on a voluntary basis with various community groups assisting with policy and procedure, writing programmes and evaluations, clinical supervision of staff, business plans and strategic planning.. Her qualifications include an MA in Management (Massey), a MA in Criminal Justice (Victoria), a Certificate in Clinical Supervision(CIT) along with post graduate qualifications in Dispute Resolution (Massey) and Human Resources (Victoria). She has also worked with offenders, youth at risk, and in the area of Maori mental health. She has a lifelong addiction to learning and loves to travel and learn about different cultures and history. She is Nga Puhi and the proud mother of three and nana of one and an Associate Member of AMINZ.

**Mrs Helen Walker**

Membership category: Lay (consumer/community perspectives)

Date of appointment: 1st July 2015

Current term expires: 1st July 2018

Mrs Helen Walker is currently the Chairman of the Medical Sciences Council, Chairman of Audit for Health Hawkes Bay Ltd, a Kaitiaki/Guardian of the Turnbull Library and the owner and financial controller of Kilgaren Farming Partnership. She completed a Bachelor of Science at Massey University (1975) and a Certificate in Company Direction through the New Zealand Institute of Directors (2002). Mrs Walker is a previous Director of Unison Networks Ltd (2004-2010), the Hawke’s Bay District Health Board (2001-2007) and Chairman of the Central Hawke’s Bay Consumers Power Trust (1993-2003). On a voluntary basis she is the President of the Waipawa Musical and Dramatic Club (1999-present), a member of the Waipawa Municipal Theatre Refurbishment Trust and Trustee of the New Zealand Singing School.

**Dr Cordelia Thomas**

Membership category: Lay (the law)

Date of appointment: 20th May 2017

Current term expires: 20th May 2020

Dr Cordelia Thomas LLB (Otago), LLM(Hons) and PhD (VUW). Barrister and Solicitor Cordelia is currently Associate Health and Disability Commissioner – Investigations. She was a Specialist Senior Legal Advisor to the Health and Disability Commissioner. She took up that position in 2009 after working as a Senior Legal Adviser to the Bioethics Council working at the Ministry for the Environment. Earlier, she was for many years a law lecturer at Wellington Polytechnic and then Massey University at Wellington. She is currently the New Zealand Law Society’s National Course Director of the Legal Executive Programme. Cordelia is the author of the 5th and 6th editions of Forsyth’s Outline of the Law Relating to Trusts Wills Executors & Administrators which the textbook recommended by the New Zealand Law Society for Estates Law and Practice. The 6th edition has been published in 2009.

**Miss Tangihaere Macfarlane\***

Membership category: Lay (consumer/community perspectives)

Date of appointment: 20th May 2017

Current term expires: 20th May 2020

Miss Macfarlane (Te Arawa, Ngāti Whakaue, Ngāti Pikiao, Ngāti Rangiwewehi) is Quality and Risk Manager, Complaints Officer and Privacy Officer at Te Roopu Taurima O Manukau Trust (2011 – present). She has previously held positions on the Lakes District Health Board Community & Public Health Advisory Committee (2001 – 2007), Te Kotahitanga o Te Arawa Fisheries Trust (2004 – 2013), and Te Roopu Hauora o Te Arawa Trust (2001 – 2007). Miss Macfarlane has completed a Bachelor of Health Science (2007) and a Diploma in Māori Business (2004), among other studies.

**Mrs Kate O’Connor**

Membership category: Lay (ethical/moral reasoning)

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Kate O'Connor is the Executive Secretary of the AUT Ethics Committee, having been a member of the committee for 5 years whist working as Senior Research Contracts Specialist in AUT's Research Office. Prior to this she worked as a research Contracts Manager for Uni Services Ltd in the University of Auckland's School of Population Health, and was Secretary for the University of Auckland's Human Participants Ethics Committee, and the Biological Safety Committee. She has Master of Arts in philosophy and a Post Graduate Diploma in Business. She is a member of the NZ Branch Executive of the Australasian Research Management Society. In 2014, Kate began a DHSc investigating how Michel Foucault’s theoretical toolbox may be used to inspire transformation in the practice of research ethics committees.

**Mrs Leesa Russell**

Membership category: Non-lay (intervention studies), Non-lay (observational studies)

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Mrs Leesa Russell (F, 34, Auckland, NZ European) is Clinical Audit Manager at St John (2014 – present). Prior to this she was Process Manager and Extended Storage Co-ordinator at Fertility Associates. She has a Masters and a Bachelors degree in Sociology from the University of Auckland

**Dr Nicola Swain**

Membership category: Non-lay (observational studies)

Date of appointment: 27th October 2015

Current term expires: 27th October 2018

Dr Nicola Swain is currently a Senior Lecturer at the University of Otago (2007-present). Prior to this she was a Research Fellow with the Christchurch Health and Development Study. She has completed a Doctor of Philosophy (1998) and a Bachelor of Science, with honours (1994) at the University of Otago. Dr Swain holds professional memberships with the Centre for Applied Positive Psychology, the International Positive Psychology Association and the New Zealand Pain Society. Dr Swain specialises in Health Psychology and pain research. She has published over 40 refereed journal articles and regularly contributes to conferences. She teaches Health Psychology and Pain to medical students at the Dunedin School of Medicine. She also supervises students studying for PhDs, Masters and summer research projects in fields such as Dr-patient communication, child well-being, child-birth satisfaction and on-line interventions for pain.

##

## 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)* | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Total |
| A/Prof Mānuka Hēnare\* | L | / | / | / | / | **Y** | **Y** | / | / | / | / | / | / | 2 |
| Ms Rochelle Style | L | X | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | A | **Y** | X | 8 |
| Ms Catherine Garvey | L | / | / | / | / | **Y** | **Y** | / | / | / | / | / | / | 2 |
| Dr Karen Bartholomew | NL | X | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | X | 8 |
|  Dr Kate Parker  | NL | X | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | X | 9 |
| Dr Christine Crooks\* | NL | X | **Y** | A | A | **Y** | **Y** | **Y** | A | A | **Y** | **Y** | X | 6 |
| Ms Toni Millar | L | X | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | X | 10 |
| Dr Brian Fergus | L | X | / | / | / | / | / | **Y** | **Y** | **Y** | **Y** | **Y** | X | 5 |
| Dr Catherine Jackson | NL | X | / | / | / | / | / | **Y** | **Y** | A | **Y** | **Y** | X | 4 |
| Dr Nora Lynch | NL | / | / | / | / | / | / | / | / | **Y** | / | / | / | 1 |
| Ms Sandy Gill\* | L | / | / | / | / | / | / | / | / | **Y** | / | / | / | 1 |
| Mrs Helen Walker | L | / | / | Y | / | / | / | / | / | / | **Y** | / | / | 2 |
| Dr Cordelia Thomas | L | / | / | / | / | / | / | / | / | / | **Y** | / | / | 1 |
| Miss Tangihaere Macfarlane\* | L | / | / | / | / | / | / | / | / | / | / | **Y** | / | 1 |
| Mrs Kate O’Connor | L | / | **Y** | / | **Y** | / | / | / | / | / | / | **Y** | / | 3 |
| Mrs Leesa Russell | NL | / | / | **Y** | / | / | / | / | / | / | / | / | / | 1 |
| Dr Nicola Swain | NL | / | / | **Y** | / | / | / | / | / | / | / | / | / | 1 |
| Total no. of members present |  | **X** | **5** | **6** | **5** | **7** | **7** | **6** | **6** | **7** | **8** | **8** | **X** |  |
| No. of applications considered |  | **X** | **11** | **12** | **5** | **5** | **12** | **5** | **10** | **12** | **12** | **11** | **X** |  |

## Training and conferences

### Specify the training undergone by new members

|  |  |  |
| --- | --- | --- |
| **Date**  | **Details of training for new members** | **No. of attendees** |
| 21/05/2019 | Informed consent (Right 7(4), HIPC, and HDC Code) | **2** |
| 26/06/2019 | Online RED training  | **1** |
| 20/08/2019 | Challenging HDEC Decisions (SOPs para 152-165) | **3** |
| 17/09/2019 | HDEC processes and guidance | **1** |

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

Multiple lectures and workshops on data use in the NZ health sector (member initiated).

# Applications reviewed

### Summary of applications received by full EC

|  |  |
| --- | --- |
| No. of applications approved  | 6 |
| No. of applications approved subject to non-standard conditions | 4 |
| No. of applications deferred and subsequently approved | 60 |
| No. of applications deferred as at time of report | 5 |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | n/a |
| No. of applications that were declined because of no/insufficient consultation with appropriate cultural group | n/a |
| No. of applications declined (This excludes those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group.) | 20 |
| No. of applications which do not require ethics committee approval (**out of HDEC scope across all 4 HDEC)\*** | 473 |
| 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** \*Does not include No. of applications which do not require ethics committee approval | **96** |

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

|  |  |
| --- | --- |
| No. of applications approved | 44 |
| No. of applications declined  | 3 |
| No. of applications which do not require ethics committee approval  | 8 |
| No. of applications referred for full committee review |  |
| **Total number of applications received under expedited / low risk review** | **48** |

|  |  |
| --- | --- |
| Total number of applications received: | **144** |

# Complaints and overdue application summary

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

## Complaints received

### Complaint One

**Type of Complaint:** Participant of Research Complaint

**Review Date**: 10 June 2014

**Complaint Received:** 15 October 2018

**Nature of Complaint:**

Participant asked for pain relief before the research intervention as per the Patient Information Sheet. Request declined by the attending researcher as it was too late for pain relief to be administered. Researcher proceeded and despite yelling out in pain the procedure continued. No Koha for patients was not offered at any time during the study with no mention in the Patient Information Sheet.

**Actions Taken:**

* Secretariat acknowledged complainant and NTA Chair notified.
* NTA Chair contacted participant for more information.
* Letter written from committee to asking CI to review: case notes of the participant in question, study procedures, qualifications of researchers performing procedures, literature/evidence of appropriateness of pain relief before procedures, review and amend PIS based on any new findings from the literature and to consider Koha to be paid.

**Outcome:**

* CI Responded to questions satisfactorily and amended relevant study documentation through the post approval process.
* CI wrote to the participant and apologised for the treatment given.

### Complaint Two

**Type of Complaint:** Public Complaint

**Review Date:** 23 December 2017

**Complaint Received:** 28 May 2018

**Nature of Complaint:**

Study had a Facebook page that was not closed which published photos of baby to include their name, region, and month/year of child. Member of the public questioned if the CI had ethics approval to do this.

**Actions Taken:**

* Secretariat acknowledged complainant and NTA Chair notified.
* Letter written from the committee to the research team. Informing them that they had not received ethical approval for this form of recruitment.

**Outcome:**

* All photos and information pertaining to participants removed from Facebook.
* CI to submit amendment through the post approval process for Facebook advertising/recruitment.

### Complaint Three

**Type of Complaint:** Committee Decision Making

**Review Date:** 19 June 2019

**Complaint Received:** 12 July 2019

**Nature of Complaint:**

CI questioned the provisional approval outcome. This study was a duplicate application to a previously declined HRC funded study. The CI questioned why Information requested for this provisional approval was not requested as part of the previous declined application or previous successful applications that had been reviewed by NTA. The CI disagreed with the committee, who stated that another peer review was required as the HRC independent review was not adequate.

CI also felt there was lack of transparency as the members who declined the application did not verbally state why, and they felt that the comments made by committee members were insulting and requested that these members be removed as they did not understand a Māori solution to a Māori issue. The CI also felt that there was inadequate Māori membership for NTA and as a result member should be removed and replaced.

**Actions Taken:**

* Secretariat acknowledged complainant and NTA Chair notified.
* Complaint discussed at 17 July 2018 Meeting.
* Letter written from the committee to CI, stating that there were no formal grounds for a complaint to be made as a result of a provisional approval as per the HDEC SOPs an applicant may only challenge a decline to approve. The Complaints against committee members were not upheld and it was felt that there was adequate representation for this meeting in providing a Maori lens.

**Outcome:**

CI accepted Actions and proceeded with provisional application. Application was approved. CI was notified that the HDEC SOPs will be reviewed and updated in due course.

### Complaint Four

**Type of Complaint:** Committee Processes

**Review Date:** 19 March 2019

**Complaint Received:** 07 June 2019

**Nature of Complaint:**

Secretariat received CI Provisional Approval Response on 01 May 2019. On the date the complaint received the CI had not received an outcome despite stating following up via email and through the HDEC 0800 number. No record of Secretariat follow-up with relevant committee members assigned to review the Provisional Approval Response.

**Actions Taken:**

* Ethics Manager formally apologised to CI for delay.
* NTA Chair notified and provisional approval response reassigned.
* Ethics Manager discussed incident at Administrator Team meeting and highlighted the importance of documentation and follow up.

**Outcome:**

Provisional Response reviewed and 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 32 days for expedited applications. Target timeframe for expedited applications is 15 calendar days.

Average review time was 46 days for full applications. Target timeframe for full applications is 35 calendar days. The increase in delay was due to a variety of factors such as committee resignations, Ministry restructuring and secretariat staffing issues.

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

## Applications reviewed by full committee

| **Study reference** | **Short title** | **CI Name** | **Clock Start** | **Outcome of first review[If date = provisional]** | **Study status** | **Date of final decision** | **CI Organisation[locality not captured]** | **Main sponsor type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 18/NTA/107 | Lateral Ankle Ligament Augmentation Trial (LALA) | Dr Shea Timoko-Barnes | 5/07/2018 | 24/07/2018 | Approve | 9/01/2019 | CCDHB | no sponsor |
| 18/NTA/108 | Objective measures and gender differences of sports-related mTBI | Josh McGeown | 5/07/2018 | 24/07/2018 | Approve | 20/09/2018 | Auckland University of Technology | no sponsor |
| 18/NTA/109 | DAOH after hepatic resection | Mr. Harry Alexander | 6/07/2018 | 31/08/2018 | Approve | 10/12/2018 |  | no sponsor |
| 18/NTA/110 | B-FAST: BLOOD-FIRST ASSAY SCREENING TRIAL B-FAST: BLOOD-FIRST ASSAY SCREENING TRIAL | Dr Laird Cameron | 5/07/2018 | 24/07/2018 | Approve | 3/10/2018 | Auckland District Health Board | pharmaceutical company |
| 18/NTA/111 | Major Head and Neck Surgery with Free Tissue Transfer | Dr Nola Ng |  |  | Invalid Application | 6/07/2018 | ADHB | no sponsor |
| 18/NTA/112 | Evaluation of alternative source for detection of Campylobacter outbreak | Dr. Mehnaz Adnan | 10/07/2018 |  | Approve | 3/08/2018 |  | other government agency |
| 18/NTA/114 | Validation Study of Gynaecological Molecular Panel | Doctor Joanne Moses | 12/07/2018 |  | Approve | 3/08/2018 |  | no sponsor |
| 18/NTA/115 | Posterior tibial slope | Dr Timothy Roberts |  |  | Invalid Application | 12/07/2018 | Starship Children's Hospital | no sponsor |
| 18/NTA/116 | Increased malignancies in our Waikato cohort of patients with Systemic Sclerosis | Dr Kamal Solanki | 16/07/2018 | 31/07/2018 | Approve | 27/08/2018 | Waikato Hospital | no sponsor |
| 18/NTA/118 | Renal replacement therapies in non-resident patients in New Zealand | Dr Hari Talreja | 1/08/2018 | 27/08/2018 | Approve | 26/10/2018 |  | no sponsor |
| 18/NTA/119 | HEAD Study | Dr Sinan Kamona | 9/08/2018 | 5/09/2018 | Approve | 26/10/2018 | Auckland District Health Board | no sponsor |
| 18/NTA/120 | WeCare Intervention Development | Mr Karol Czuba | 2/08/2018 |  | Approve | 27/08/2018 |  | academic institution |
| 18/NTA/121 | Transcend Study | Associate Professor Andrew Holden | 9/08/2018 | 5/09/2018 | Approve | 26/09/2018 | Auckland District Health Board | medical device company |
| 18/NTA/122 | Reliability and Retrospective-Assessment Validity of Pre-Surgical Patient-Reported Outcome Measures | Dr Catherine Bacon | 2/08/2018 |  | Approve | 23/08/2018 | Orthosports North Harbour Limited | collaborative research |
| 18/NTA/123 | A study looking at the effects of the trial drug Selonsertib on kidney function, in adults with chronic kidney disease. | Dr. Richard Robson | 9/08/2018 | 5/09/2018 | Approve | 7/11/2018 | Christchurch Clinical Studies Trust Ltd. | pharmaceutical company |
| 18/NTA/125 | OAKS | Dr James Borthwick | 9/08/2018 | 5/09/2018 | Approve | 7/11/2018 | Southern Eye Specialists | pharmaceutical company |
| 18/NTA/126 | (duplicate) Teledermatology for scabies | Dr Simon Thornley | 9/08/2018 | 5/09/2018 | Approve | 28/09/2018 |  | academic institution |
| 18/NTA/127 | Predicting Outcomes in Patients with C3-Glomerulopathy | Dr Luke Sutherland |  |  | Invalid Application | 8/08/2018 |  | no sponsor |
| 18/NTA/128 | ACCENT survey | Dr Timothy O'Neill |  |  | Invalid Application | 10/08/2018 | Counties Manukau District Health Board (Middlemore Hospital) | no sponsor |
| 18/NTA/129 | Latte dosage trial | Dr Jane Alsweiler | 9/08/2018 |  | Approve | 5/09/2018 | University of Auckland | academic institution |
| 18/NTA/130 | Safety, Tolerability, and Pharmacokinetics of AB-452 in Healthy Subjects and Subjects with Chronic HBV Infection | Prof Edward Gane | 9/08/2018 | 5/09/2018 | Approve | 20/09/2018 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 18/NTA/132 | The DynamX Sirolimus Study | Dr Mark Webster | 9/08/2018 | 5/09/2018 | Approve | 15/10/2018 | Auckland District Health Board | medical device company |
| 18/NTA/134 | PDPH audit - 10 yrs | Dr Yvonne Wagner |  |  | Invalid Application | 9/08/2018 |  | no sponsor |
| 18/NTA/135 | Intraoperative CT and rapid prototyping in orbital reconstruction | Dr Jamie Lockyer | 10/08/2018 | 31/08/2018 | Approve | 10/12/2018 | Canterbury District Health Board | no sponsor |
| 18/NTA/136 | Clinical Assessment of Gallus Mask | Dr Robert Martynoga | 9/08/2018 | 5/09/2018 | Approve | 15/10/2018 | Waikato District Health Board | medical device company |
| 18/NTA/137 | Medicine information needs tool | Ms Kim Brackley | 9/08/2018 | 31/08/2018 | Approve | 15/10/2018 | Auckland District Health Board | no sponsor |
| 18/NTA/139 | MR lung study | Dr Margaret Wilsher | 20/08/2018 | 10/09/2018 | Approve | 17/10/2018 | Auckland District Health Board | academic institution |
| 18/NTA/140 | EEG & general level of health (EEGLoH) | Assoc Prof Dr R Ross Kennedy | 20/08/2018 | 10/09/2018 | Approve | 15/10/2018 | Canterbury District Health Board | other |
| 18/NTA/141 | Heart Rate Variability in COPD. | Dr Kevin Ellyett | 17/08/2018 | 10/09/2018 | Approve | 17/10/2018 | Auckland District Health Board | no sponsor |
| 18/NTA/142 | World Bleeding Disorders Registry (WBDR) | Dr Mark Smith | 6/09/2018 | 25/09/2018 | Approve | 6/03/2019 | Canterbury District Health Board | other |
| 18/NTA/143 | Evaluation of a programme of universal risk assessment and targeted care for infants at higher risk of sudden unexpected death in infancy. | Dr Christine McIntosh |  |  | Invalid Application | 5/09/2018 | University of Auckland | academic institution |
| 18/NTA/144 | Liberal glucose control in critically ill patients with pre-existing type 2 diabetes | Dr Colin McArthur | 6/09/2018 | 28/09/2018 | Approve | 9/11/2018 | Auckland District Health Board | collaborative research |
| 18/NTA/145 | Starship Pain Review (SPaR) | Ms Elaine McCall | 6/09/2018 | 28/09/2018 | Withdrawn by Researcher | 28/01/2019 | Auckland District Health Board | no sponsor |
| 18/NTA/146 | (duplicate) Lithium and Fampridine EEG | Professor Paul Glue | 6/09/2018 | 4/10/2018 | Approve | 10/12/2018 |  | no sponsor |
| 18/NTA/147 | (duplicate) Atopy & Allergies following Paediatric Solid Organ Transplantation | Dr Amin Sheikh | 6/09/2018 |  | Decline | 28/09/2018 | Starship Child Health, ADHB | academic institution |
| 18/NTA/148 | The heat vs. HIIT study | Dr Kate Thomas | 6/09/2018 | 28/09/2018 | Approve | 31/10/2018 | University of Otago | academic institution, other government agency |
| 18/NTA/149 | Fatigue After STroke Educational Recovery trial (FASTER) | Dr Kelly Jones | 6/09/2018 | 28/09/2018 | Decline | 31/10/2018 | AUT University | academic institution |
| 18/NTA/150 | BP40657. A Phase Ib/II dose-finding / confirmation study of Atezolizumab (Tecentriq) Subcutaneous. | Dr Anthony Rahman | 6/09/2018 | 28/09/2018 | Approve | 1/11/2018 | Canterbury District Health Board | pharmaceutical company |
| 18/NTA/151 | E-SACS use in Schools | Ms Michelle Fowler | 6/09/2018 | 28/09/2018 | Approve | 11/01/2019 | Auckland Uniservices | other government agency |
| 18/NTA/152 | PROTECT in IgAN | Dr Kannaiyan Rabindranath | 6/09/2018 | 28/09/2018 | Approve | 7/11/2018 | Waikato District Health Board | pharmaceutical company |
| 18/NTA/153 | Phase 1b CONCOCT trial in head and neck cancer | Dr Navin Wewala | 6/09/2018 | 28/09/2018 | Approve | 6/11/2018 | MidCentral District Health Board | no sponsor |
| 18/NTA/154 | Maori experience of Anaesthesia in the perioperative setting: A qualitative assessment | Doctor Courtney Thomas | 6/09/2018 |  | Decline | 28/09/2018 | Canterbury District Health Board | no sponsor |
| 18/NTA/155 | Havelock North Campylobacter Outbreak: Renal and Other Complications | Dr Bridget Wilson | 4/09/2018 |  | Approve | 4/10/2018 | Hawke's Bay District Health Board | district health board (DHB), other government agency |
| 18/NTA/156 | Real B | Dr Hannah Giles |  |  | Invalid Application | 13/09/2018 |  | no sponsor |
| 18/NTA/158 | The effect of early postnatal bracing on Rectus Abdominis Diastasis | Ms Jill Depledge | 7/09/2018 | 17/10/2018 | Approve | 31/10/2018 | ADHB | no sponsor |
| 18/NTA/159 | Long term outcomes of removal of trans-obturator slings | Dr Eva Fong | 13/09/2018 |  | Approve | 15/10/2018 | Waitemata district health board | no sponsor |
| 18/NTA/160 | Glycaemic potency of kibbled grain breads | Dr John Monro | 13/09/2018 |  | Approve | 17/10/2018 | The New Zealand Institute of Plant and Food Research | no sponsor |
| 18/NTA/161 | Should Ankle Syndesmosis Screws Be Removed? | Dr Ryan Gao | 14/09/2018 |  | Approve | 17/10/2018 |  | no sponsor |
| 18/NTA/162 | (duplicate) Gut Dysfunction in Critical Illness | Ms Varsha Asrani | 13/09/2018 |  | Approve | 23/10/2018 | Auckland City Hospital/ University of Auckland | no sponsor |
| 18/NTA/164 | From whakamā to whakamana: He aha tēnei? | Ms Karis Knight | 19/09/2018 | 12/10/2018 | Approve | 24/10/2018 | University of Auckland | no sponsor |
| 18/NTA/165 | POISE-3 | Dr Elizabeth Maxwell | 24/09/2018 | 25/10/2018 | Approve | 5/02/2019 | Auckland District Health Board | collaborative research |
| 18/NTA/166 | Spinal Cord Stimulation in the treatment of Chronic, Intractable Pain using the Nalu Neurostimulation System | Professor Alan Merry | 27/09/2018 |  | Decline | 25/10/2018 | University of Auckland | medical device company |
| 18/NTA/167 | NLP for Prediction of Psychosis in Māori | Dr. Jamuna Gopal Krishnan | 27/09/2018 | 17/10/2018 | Approve | 5/12/2018 | Mid-Central DHB | no sponsor |
| 18/NTA/168 | ICON 9 | Dr Michelle Vaughan | 4/10/2018 |  | Decline | 25/10/2018 | Christchurch Hospital | collaborative research |
| 18/NTA/170 | Neurodevelopmental outcomes in preschool children following enteroviral and parechoviral meningitis | Dr Natalie Martin | 4/10/2018 | 25/10/2018 | Approve | 10/12/2018 |  | no sponsor |
| 18/NTA/171 | Freestyle Libre alternative site study | Mr Lindsay McTavish | 4/10/2018 | 25/10/2018 | Approve | 7/12/2018 | Capital & Coast DHB | no sponsor |
| 18/NTA/172 | Neonatal Bubble CPAP Comparison Study | Mr Jonathan Barrett | 4/10/2018 | 25/10/2018 | Approve | 7/12/2018 | Middlemore Hospital | medical device company |
| 18/NTA/173 | The CHEWY Trial | Dr Robyn Billing | 4/10/2018 | 25/10/2018 | Approve | 21/12/2018 | Auckland District Health Board | no sponsor |
| 18/NTA/174 | Glucose in Well Babies and their later Neurodevelopment (GLOWiNg) | Dr Deborah Harris | 4/10/2018 | 25/10/2018 | Approve | 3/12/2018 | Waikato District Health Board | no sponsor |
| 18/NTA/175 | A Phase 1 Study of ABI-H2158 in Healthy Volunteers | Prof Ed Gane | 4/10/2018 |  | Approve | 25/10/2018 | Auckland District Health Board | pharmaceutical company |
| 18/NTA/176 | Is a dementia prevalence study feasible in New Zealand? | DR SARAH CULLUM | 4/10/2018 | 25/10/2018 | Approve | 17/12/2018 | University of Auckland | academic institution |
| 18/NTA/177 | Phase I/II pharmacokinetic multi-tumour study of subcutaneous formulation of Nivolumab monotherapy | Dr Richard North | 4/10/2018 | 25/10/2018 | Approve | 3/12/2018 | Bay of Plenty District Health Board | pharmaceutical company |
| 18/NTA/178 | A research project testing the performance of the ellume·lab Group A Strep test device compared to collecting swabs for culturing, in participants with strep throat (Acute Pharyngitis). | Dr Barney Montgomery | 4/10/2018 | 25/10/2018 | Decline | 10/12/2018 | Optimal Clinical Trials | medical device company |
| 18/NTA/184 | Analysis of Auckland region patients with metastatic prostate cancer receiving taxane and/or platinum chemotherapy | Dr Rebecca Roberts |  |  | Invalid Application | 5/10/2018 |  | no sponsor |
| 18/NTA/186 | Impact of bariatric surgery on unplanned hospital attendances | Professor Tim Cundy |  |  | Invalid Application | 11/10/2018 | Dept of Medicine, FMHS | no sponsor |
| 18/NTA/187 | Diabetes prevalence in two Gisborne general practices | Dr Angus Murray |  |  | Invalid Application | 11/10/2018 | RNZCGP/HWFNZ | no sponsor |
| 18/NTA/188 | Enteral Tube Feeding Back-Pressure Study | Professor John Windsor | 12/10/2018 | 31/10/2018 | Approve | 13/11/2018 | University of Auckland | academic institution, collaborative research |
| 18/NTA/189 | Maori experience of Anaesthesia in the perioperative setting: A qualitative assessment. | Doctor Courtney Thomas | 12/10/2018 | 31/10/2018 | Approve | 7/11/2018 | Canterbury District Health Board | no sponsor |
| 18/NTA/190 | Gastric cancer ctDNA | Prof Parry Guilford | 15/10/2018 | 31/10/2018 | Approve | 10/12/2018 | University of Otago | no sponsor |
| 18/NTA/191 | HABITs: Evaluation of an app to support emotional wellbeing of adolescents. | Dr Karolina Stasiak | 8/11/2018 | 5/12/2018 | Approve | 21/03/2019 | The University of Auckland | academic institution |
| 18/NTA/192 | Keratoconus in Down syndrome (KinD 21) | Professor Dipika Patel | 8/11/2018 | 5/12/2018 | Approve | 18/12/2018 | University of Auckland | academic institution |
| 18/NTA/193 | Seafood safety | Dr Pradip Gyawali | 8/11/2018 | 8/12/2018 | Approve | 1/03/2019 | Institute of Environmental Science and Research LTD | other |
| 18/NTA/194 | Nasal High Flow via a Single, Sealed Nostril in Patients | Dr Anthony Williams | 8/11/2018 | 11/12/2018 | Approve | 28/02/2019 | Middlemore Hospiatal | medical device company |
| 18/NTA/195 | CA045-001 | Dr Catherine Barrow | 8/11/2018 |  | Decline | 11/12/2018 | Wellington Regional Hospital | pharmaceutical company |
| 18/NTA/196 | Airway oxygen concentration with high flow nasal oxygen | Dr Nick Abbott | 8/11/2018 | 22/02/2019 | Approve | 22/02/2019 | Canterbury district health board | no sponsor |
| 18/NTA/197 | Novel urinary biomarkers in IBD | Dr Akhilesh Swaminathan | 8/11/2018 | 11/12/2018 | Approve | 7/02/2019 |  | academic institution |
| 18/NTA/198 | Epidermolysis Bullosa in New Zealand | Doctor Russell Gear |  |  | Invalid Application | 8/11/2018 | Capital and Coast District Health Board | non-governmental organisation (NGO) |
| 18/NTA/199 | A deep learning platform for GP referral triage | Dr Edmond Yiwen Zhang | 8/11/2018 |  | Decline | 11/12/2018 | Orion Health | no sponsor |
| 18/NTA/200 | (duplicate) Smart Search | Dr Edmond Yiwen Zhang | 8/11/2018 | 11/12/2018 | Approve | 6/03/2019 | Orion Health | no sponsor |
| 18/NTA/201 | N-finity REFUNCTION Study | Dr Stephen Merrilees | 8/11/2018 | 10/12/2018 | Decline | 13/02/2019 | Auckland District Health Board | medical device company |
| 18/NTA/202 | Pharmacokinetic clearance of vancomycin using two different dialyzers | Dr Hussain Allawati |  |  | Invalid Application | 16/11/2018 | Hawkes Bay DHB | district health board (DHB) |
| 18/NTA/203 | Robots for independence | Professor Ngaire Kerse |  |  | Invalid Application | 8/11/2018 | The University of Auckland | other government agency |
| 18/NTA/204 | (duplicate) Robots for independence | Professor Ngaire Kerse | 8/11/2018 | 11/12/2018 | Approve | 4/06/2019 | The University of Auckland | other government agency |
| 18/NTA/206 | Scopolamine for Depression | Dr Suresh Muthukumaraswamy | 7/02/2019 | 4/03/2019 | Approve | 8/04/2019 | The University of Auckland | academic institution |
| 18/NTA/209 | International Intestinal Failure Registry - Pilot Study | Dr Amin J Roberts | 7/11/2018 | 6/12/2018 | Decline | 11/03/2019 | Starship Child Health, ADHB | no sponsor |
| 18/NTA/217 | Audit of discharge analgesia after total knee or hip arthroplasty | Dr Daniel Wood |  |  | Invalid Application | 6/08/2019 |  | no sponsor |
| 18/NTA/218 | Association between sweet drink intake and dental decay in children and adolescents with obesity | Dr Yvonne Anderson | 9/11/2018 |  | Approve | 10/12/2018 |  | no sponsor |
| 18/NTA/219 | Paediatric Acute Haematogenous Osteomyelitis | Dr Anna C.E McDonald |  |  | Invalid Application | 20/11/2018 | Auckland District Health Board | no sponsor |
| 18/NTA/220 | Health check before surgery | Dr Maria Gibbons | 16/11/2018 | 10/12/2018 | Approve | 9/01/2019 | HVDHB | no sponsor |
| 18/NTA/222 | INTENT | Dr Shay McGuinness | 7/03/2019 | 4/04/2019 | Approve | 16/05/2019 | Auckland District Health Board | no sponsor |
| 18/NTA/223 | Cultural Identity and Health | Mrs Teresa Kirkwood | 30/11/2018 | 11/01/2019 | Approve | 6/05/2019 | Ngati Tamaoho Trust | other |
| 19/NTA/1 | Understanding the utilisation of an insulin-to-protein ratio in people with type 1 diabetes who follow a carbohydrate restricted diet | Assoc. Prof Jeremy Krebs | 22/12/2018 | 28/01/2019 | Approve | 20/02/2019 | University of Otago and Capital and Coast DHB | no sponsor |
| 19/NTA/10 | Outcomes in Triple Receptor Negative Early Breast Cancer | Dr David Okonji |  |  | Invalid Application | 17/01/2019 | Capital and Coast District Healthbaord | no sponsor |
| 19/NTA/103 | Micronutrients and traumatic brain injury in children: a feasibility study. | Prof Julia Rucklidge | 27/06/2019 | 5/08/2019 | Provisionally approve |  | University of Canterbury | no sponsor |
| 19/NTA/11 | This study tests whether BI 425809 together with brain training using a computer improves mental functioning in patients with schizophrenia | Assoc Prof Wayne Miles | 7/02/2019 | 4/03/2019 | Approve | 1/05/2019 | WDHB | pharmaceutical company |
| 19/NTA/12 | Long term outcomes from acute musculoskeletal sepsis in the Paediatric Intensive Care Unit | Dr Anna McDonald | 25/01/2019 |  | Decline | 4/03/2019 | Starship Childrens Hospital | no sponsor |
| 19/NTA/13 | Blunt chest trauma score validation study | Dr Saptarshi Mukerji | 11/02/2019 |  | Approve | 21/02/2019 |  | collaborative research |
| 19/NTA/14 | Perseveration in Post-Stroke Aphasia | Miss Jessica Tranter |  |  | Invalid Application | 4/02/2019 | The University of Queensland | no sponsor |
| 19/NTA/16 | Myocardial work in stress echos | Dr Andrew Borrie |  |  | Invalid Application | 4/02/2019 |  | no sponsor |
| 19/NTA/17 | M18-891, Moderate to Severe Atopic Dermatitis: Evaluation of Upadacitinib in Adolescent and Adult Subjects |  |  |  | Invalid Application | 7/02/2019 |  | pharmaceutical company |
| 19/NTA/18 | SafePass.2 | Dr Mark Webster | 7/02/2019 | 4/03/2019 | Approve | 3/04/2019 | Auckland District Health Board | medical device company |
| 19/NTA/19 | Ready to Eat: Home-based behavioural intervention to help children progress from tube to oral feeding | Dr Sarah Leadley | 7/02/2019 | 4/03/2019 | Approve | 11/04/2019 |  | academic institution |
| 19/NTA/2 | Optical coherence tomography - predictor for macular hole surgical outcomes | Dr Yu-Chieh Hung | 1/01/2019 | 28/01/2019 | Approve | 22/02/2019 | Canterbury District Health Board | no sponsor |
| 19/NTA/20 | PERN Pneumonia study | Dr Stuart Dalziel | 7/02/2019 | 4/03/2019 | Approve | 11/06/2019 | Auckland District Heatlh Board | no sponsor |
| 19/NTA/21 | Emergency Department Safety Aotearoa New Zealand (EDSANZ). | Dr Stuart Dalziel | 7/02/2019 | 4/03/2019 | Approve | 2/07/2019 | Auckland District Heatlh Board | no sponsor |
| 19/NTA/22 | Prospective Study of SUDEP in New Zealand | Dr Peter Bergin | 7/02/2019 |  | Decline | 4/03/2019 | Auckland District Health Board | district health board (DHB), non-governmental organisation (NGO) |
| 19/NTA/23 | Restorbio RTB101-204 "A Multicenter, Randomized, Double Blind, Placebo-Controlled, Phase 3 Study to Determine if RTB101 Prevents Symptomatic Respiratory Illness Associated with Laboratory-Confirmed Pa | Dr Dean Quinn | 7/02/2019 | 4/03/2019 | Approve | 26/03/2019 | P3 Research Ltd | pharmaceutical company |
| 19/NTA/24 | A Phase 2, Randomized, Placebo-Controlled, Double-Masked Study to Assess Safety and Efficacy of Multiple Doses of IONIS-FB-LRX, an Antisense Inhibitor of Complement Factor B, in Patients with Geograph | Dr Philip Polkinghorne | 7/02/2019 | 4/03/2019 | Approve | 30/05/2019 | Auckland Eye Limited | pharmaceutical company |
| 19/NTA/25 | Evaluating ITM Administration post C-Section | Dr Melanie Hwang | 8/02/2019 | 5/03/2019 | Approve | 10/06/2019 | Auckland District Health Board | no sponsor |
| 19/NTA/27 | Opioid use after primary unilateral knee arthroplasty | Dr Chen Zhou | 7/02/2019 | 6/03/2019 | Approve | 7/05/2019 | Counties Manukau District Health Board | no sponsor |
| 19/NTA/3 | The use of intermittent short-term selective head-neck cooling for the management of acute concussion and post-concussion syndrome | Dr Doug King | 16/01/2019 | 28/01/2019 | Approve | 4/03/2019 | Auckland University of Technology | no sponsor |
| 19/NTA/31 | The PRESERVE pilot study (Prevent delirium through Eating and drinking, Sleep, Exercise, Reorientation, Vision and hearing, and Enabling family) | Dr Aileen Collier | 28/02/2019 |  | Decline | 4/04/2019 | University of Auckland | non-governmental organisation (NGO) |
| 19/NTA/34 | Preventing Smoking Relapse to Extend Breastfeeding | Doctor Marewa Glover | 7/03/2019 | 3/04/2019 | Approve | 15/05/2019 | Centre of Research Excellence: Indigenous Sovereignty & Smoking | no sponsor |
| 19/NTA/35 | Medical issues in expedition adventure racing | Dr Thomas Reynolds | 7/03/2019 |  | Invalid Application | 13/03/2019 |  | no sponsor |
| 19/NTA/36 | Breathlessness Exertion and Morphine Sulphate (BEAMS) | Dr Michael Epton | 7/03/2019 | 4/04/2019 | Approve | 20/05/2019 | Canterbury District Health Board | academic institution |
| 19/NTA/37 | SMA Prev | A/Prof Richard Roxburgh | 7/03/2019 | 4/04/2019 | Approve | 7/06/2019 | Auckland City Hospital | pharmaceutical company |
| 19/NTA/39 | ESG for fatty liver disease and metabolic syndrome | Dr David Orr | 7/03/2019 |  | Decline | 4/04/2019 | NZLTU | district health board (DHB) |
| 19/NTA/4 | Evaluation of a new Swallow Test Bolus | Mrs Marie Jardine | 15/01/2019 | 29/01/2019 | Approve | 21/02/2019 | The University of Auckland | academic institution |
| 19/NTA/40 | High Technology Augmentative and Alternative Communication (AAC) in Post Stroke Aphasia | Mrs Shannon Taylor | 7/03/2019 |  | Decline | 4/04/2019 |  | no sponsor |
| 19/NTA/41 | Investigating genetic causes on non-immune hydrops fetalis | Dr Polona Le Quesne Stabej | 7/03/2019 | 4/04/2019 | Approve | 29/04/2019 |  | academic institution |
| 19/NTA/42 | SCARLET-2 | Dr Colin McArthur | 7/03/2019 | 4/04/2019 | Withdrawn by Researcher | 27/05/2019 | Auckland District Health Board | pharmaceutical company |
| 19/NTA/43 | Evaluating the IR experiences of young people in hospital (2) | Dr Hiran Thabrew | 7/03/2019 | 4/04/2019 | Approve | 21/06/2019 | ADHB | no sponsor |
| 19/NTA/44 | The Period Project | Dr Whitney Pickering | 7/03/2019 | 4/04/2019 | Approve | 21/05/2019 | Auckland District Health Board | no sponsor |
| 19/NTA/45 | Comparison of the blood levels of two forms of dimethyl fumarate capsules in healthy volunteers under fasting conditions. | Dr Noelyn Hung | 7/03/2019 |  | Approve | 4/04/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/NTA/46 | Long-term outcomes from acute musculoskeletal sepsis in the Paediatric Intensive Care Unit. | Dr Anna McDonald | 4/04/2019 | 6/05/2019 | Approve | 30/05/2019 | Starship Childrens Hospital | no sponsor |
| 19/NTA/48 | SpeechATAX Study | A/Prof Richard Roxburgh | 1/04/2019 | 16/04/2019 | Approve | 6/05/2019 | University of Auckland | academic institution, collaborative research |
| 19/NTA/49 | ZiPP-LTE | Professor Stuart Ralston |  |  | Invalid Application | 3/04/2019 | University of Edinburgh | academic institution |
| 19/NTA/5 | RTB-101-301: Identifying patients with mild to moderate stage Parkinson's Disease (PD) carrying a GBA mutation (GBA-PD) | Prof Tim Anderson | 15/01/2019 | 4/02/2019 | Withdrawn by Researcher | 11/04/2019 | New Zealand Brain Research Institute | pharmaceutical company |
| 19/NTA/50 | MK-1308 | Mr Andrew Conley | 4/04/2019 | 6/05/2019 | Decline | 15/07/2019 |  | pharmaceutical company |
| 19/NTA/51 | Balloon Angioplasty versus Shockwave Intravascular Lithotripsy for calcified coronary stenoses | Dr Seif El-Jack |  |  | Invalid Application | 3/04/2019 | Waitemata District Health Board | no sponsor |
| 19/NTA/53 | Phase 3 Study of Pembrolizumab plus Docetaxel in mCRPC | Dr Jim Edwards | 4/04/2019 | 6/05/2019 | Decline | 31/07/2019 | Canterbury District Health Board | pharmaceutical company |
| 19/NTA/54 | PRAX-944-221: Study of the Efficacy, Safety, Tolerability, and Pharmacokinetics of PRAX-944 in Adults with Essential Tremor | Prof Tim Anderson | 4/04/2019 | 6/05/2019 | Approve | 2/07/2019 | University of Otago, C/- NZBRI | pharmaceutical company |
| 19/NTA/55 | Flu Vaccine Side Effects in Children From 6 Months to 9 Years of Age | Dr Craig King | 4/04/2019 | 6/05/2019 | Approve | 20/06/2019 | Totara Clinical Research-trading as SCT-Totara | pharmaceutical company |
| 19/NTA/57 | Anterior knee subcutaneous thickness not related to infection after total knee replacement | Dr Vikesh Gupta |  |  | Invalid Application | 8/04/2019 | Taranaki District Health Board | no sponsor |
| 19/NTA/58 | Mortality After EVAS vs EVAR | Associate Professor Andrew Holden | 5/04/2019 |  | Approve | 23/04/2019 | Auckland District Health Board | no sponsor |
| 19/NTA/59 | Myeloma Patient Experience | Ms Maarie Hutana |  |  | Invalid Application | 5/04/2019 | Canterbury District Health Board | district health board (DHB) |
| 19/NTA/6 | Rangatahi Māori Primary Mental Health Project | Associate Professor Sue Crengle |  |  | Invalid Application | 16/01/2019 |  | no sponsor |
| 19/NTA/60 | Prone and oscillation trial | Dr Anusha Ganeshalingham | 9/05/2019 | 28/05/2019 | Provisionally approve |  |  | no sponsor |
| 19/NTA/61 | Christchurch Cleft Clinic Audit. | Dr Peter Fowler |  |  | Invalid Application | 7/05/2019 | CDHB | no sponsor |
| 19/NTA/62 | Unstable Intertrochanteric Neck of Femur Fractures in the Geriatric Population: Short or Long Proximal Femoral Nail (PFN)? | Mr Joseph Baker | 9/05/2019 |  | Decline | 28/05/2019 | Waikato District Health Board | district health board (DHB) |
| 19/NTA/63 | Young Reverse Shoulder Arthroplasty (YRSA) Study | Dr Michael van der Merwe | 7/05/2019 | 20/05/2019 | Approve | 2/08/2019 | Starship Children's Hospital | no sponsor |
| 19/NTA/64 | Antibiotic prophylaxis in sinus surgery | Dr Andrew James Wood | 9/05/2019 | 28/05/2019 | Approve | 2/08/2019 | The University of Auckland | other |
| 19/NTA/65 | International IF Registry - Pilot Study | Dr Amin J Roberts | 8/05/2019 |  | Approve | 20/05/2019 | Starship Child Health, ADHB | no sponsor |
| 19/NTA/66 | Dose-ranging efficacy and safety study of topical rapamycin cream | Dr Caroline Mahon | 9/05/2019 | 28/05/2019 | Approve | 16/07/2019 | CDHB Corporate Office, Canterbury DHB, 32 Oxford Terrace, Christchurch 8011, New Zealand | pharmaceutical company |
| 19/NTA/67 | Pelvic pain recurrence post excision of endometriosis | Dr. Stephanie Sequeira |  |  | Invalid Application | 9/05/2019 |  | no sponsor |
| 19/NTA/68 | Stoma-Output Recycling Device for Ileostomy Reversal | Dr. Chen Liu | 9/05/2019 | 4/07/2019 | Approve |  | University of Auckland | academic institution |
| 19/NTA/69 | Discontinuing nucleos(t)ide analogue therapy for chronic hepatitis B with the aim of achieving HBsAg seroconversion | Dr Tien Huey Lim | 9/05/2019 |  | Decline | 28/05/2019 |  | no sponsor |
| 19/NTA/7 | Longitudinal chronic rhinosinusitis study | Dr Tary Yin | 15/01/2019 |  | Approve | 28/01/2019 | Counties Manukau District Health Board | academic institution |
| 19/NTA/71 | (duplicate) Prospective Study of SUDEP in New Zealand | Dr Peter Bergin | 6/06/2019 | 4/07/2019 | Approve | 23/08/2019 | Auckland City Hospital | district health board (DHB), non-governmental organisation (NGO) |
| 19/NTA/72 | (duplicate) KCAD Psych Study | Dr Chanel Prestidge | 6/06/2019 | 4/07/2019 | Provisionally approve |  |  | academic institution, collaborative research |
| 19/NTA/74 | mPR | Dr Rosie Dobson | 1/06/2019 | 11/06/2019 | Approve | 21/06/2019 | University of Auckland | academic institution |
| 19/NTA/75 | Outcomes of Haematopoietic Stem Cell Transplant in Primary Immunodeficiency: A Report from the Transplant and Primary Immune Deficiency Group (TAPID) | Dr Annaliesse Blincoe |  |  | Invalid Application | 5/06/2019 |  | no sponsor |
| 19/NTA/76 | Evaluation of a new, multi-compartment model for field-based body composition assessment | Dr Jennifer Miles-Chan | 1/06/2019 |  | Approve | 11/06/2019 | University of Auckland | academic institution |
| 19/NTA/77 | The effect of Flash Glucose Monitoring Systems (FGMS) on children with Type One Diabetes Mellitus (T1DM) | Dr Maryam Mussa | 6/06/2019 | 4/07/2019 | Withdrawn by Researcher | 31/07/2019 | Waikato Hospital | no sponsor |
| 19/NTA/78 | Antimicrobial use in Māori vs Non-Māori respiratory patients | Mr Rajan Ragupathy | 5/06/2019 |  | Approve | 19/06/2019 |  | no sponsor |
| 19/NTA/79 | (duplicate) Synbiotics and liver transplantation | Associate Professor Lindsay Plank | 5/06/2019 | 5/08/2019 | Approve | 29/08/2019 | University of Auckland | no sponsor |
| 19/NTA/8 | Australasian Interstitial Lung Disease (ILD) Registry | Dr Margaret Wilsher |  |  | Invalid Application | 17/01/2019 | Auckland District Health Board | district health board (DHB) |
| 19/NTA/80 | TSANZ NZ National Asthma Audit | Dr James Fingleton |  |  | Invalid Application | 6/06/2019 |  | non-governmental organisation (NGO) |
| 19/NTA/81 | ORATORIO HAND (O'HAND) | Dr Jennifer Taylor | 6/06/2019 |  | Decline | 4/07/2019 | Capital and Coast District Health Board | pharmaceutical company |
| 19/NTA/82 | Mepolizumab as Add-on Treatment IN participants with COPD characterized by frequent Exacerbations and Eosinophil Level (MATINEE) | Dr Andrew Veale | 6/06/2019 | 4/07/2019 | Approve | 3/09/2019 | The New Zealand Respiratory & Sleep Institute | pharmaceutical company |
| 19/NTA/83 | Short term temperature changes and physiological performance. | Mr Terrence O'Donnell | 6/06/2019 |  | Approve | 25/06/2019 |  | no sponsor |
| 19/NTA/84 | Comparison of the blood levels of two forms of lenalidomide 10 mg capsules. | Dr Noelyn Hung | 6/06/2019 |  | Approve | 4/07/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/NTA/85 | Comparison of the blood levels of two forms of lenalidomide 25 mg capsules. | Dr Noelyn Hung | 6/06/2019 |  | Approve | 4/07/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/NTA/86 | SAGE-ANZ | Dr Rachael Parke | 6/06/2019 | 4/07/2019 | Valid Application |  | Auckland District Health Board | no sponsor |
| 19/NTA/87 | Headstrong: a chatbot for wellbeing | Dr Karolina Stasiak | 7/06/2019 | 20/06/2019 | Decline | 2/08/2019 | University of Auckland | academic institution |
| 19/NTA/89 | EQUIP-Study evaluating EQ001 in patients with Moderate-to-Severe Uncontrolled Asthma | Dr Andrew Veale | 6/06/2019 | 4/07/2019 | Approve | 20/08/2019 | The New Zealand Respiratory & Sleep Institute | pharmaceutical company |
| 19/NTA/9 | Methods of delivery of local anaesthesia through adductor canal catheters after total knee arthroplasty | Dr David Choi | 17/01/2019 |  | Approve | 29/01/2019 | Counties Manukau District Health Board | district health board (DHB) |
| 19/NTA/90 | Urtica ferox exposure | Dr Eric Buenz | 7/06/2019 |  | Decline | 26/06/2019 |  | academic institution |
| 19/NTA/91 | AB928CSP0002 | Dr Michelle Wilson | 30/05/2019 | 4/07/2019 | Provisionally approve |  | Auckland City Hospital | pharmaceutical company |
| 19/NTA/92 | VAC18193RSV2001 - A study to assess if an investigational vaccine can prevent lower respiratory tract disease caused by respiratory syncytial virus (RSV) in adults aged 65 years and older. | Dr Jackie Kamerbeek | 4/07/2019 | 5/08/2019 | Provisionally approve |  | P3 Research Limited (Tauranga) | pharmaceutical company |
| 19/NTA/93 | NHFO2: Inpatient study | Dr James Harper | 4/07/2019 |  | Approve | 5/08/2019 | Medical Research Institute New Zealand | medical device company |
| 19/NTA/94 | ISIS 696844-CS4: A study assessing the effectiveness and safety of the trial drug ISIS 696844, in adults with IgA nephropathy. | Dr Richard Robson | 4/07/2019 | 5/08/2019 | Approve | 2/09/2019 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 19/NTA/95 | Evaluation of staff training for sleep problems | Dr Laurie McLay | 4/07/2019 |  | Withdrawn by Researcher | 5/07/2019 | University of Canterbury | no sponsor |
| 19/NTA/96 | VascDiab | Dr Janak de Zoysa | 4/07/2019 |  | Decline | 5/08/2019 |  | no sponsor |

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

## Declaration by EC Chairperson

**Name of EC: Northern A 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:** Mānuka Hēnare \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Signature: Date: 30** September 2019

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

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

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

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

**Name:** Mr Rob McHawk

 Title First Name Last Name

**Position :** Manager – Ethics

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



**Signature: Date:** 30 September 2019

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