

Northern B Health and Disability Ethics Committee

Annual Report
2018

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

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

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

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

|  |  |
| --- | --- |
| **CCBY** | This work is licensed under the Creative Commons Attribution 4.0 International licence. In essence, you are free to: share ie, copy and redistribute the material in any medium or format; adapt ie, remix, transform and build upon the material. You must give appropriate credit, provide a link to the licence and indicate if changes were made. |

**Contents**

[About the committee 1](#_Toc108678239)

[Chairperson’s report 2](#_Toc108678240)

[Membership and attendance 4](#_Toc108678241)

[Membership 4](#_Toc108678242)

[Attendance 6](#_Toc108678243)

[Training and conferences 6](#_Toc108678244)

[Applications reviewed 7](#_Toc108678245)

[Complaints and overdue application summary 8](#_Toc108678246)

[Complaints received 8](#_Toc108678247)

[Overdue review 9](#_Toc108678248)

[Appendix 1: Details of applications reviewed 10](#_Toc108678249)

[Applications reviewed by full committee 10](#_Toc108678250)

[Declaration by Head of Organisation with Primary Responsibility for the EC 36](#_Toc108678251)

[Declaration by EC Chairperson 36](#_Toc108678252)

[Declaration by Head of Organisation with Primary Responsibility for the EC 36](#_Toc108678253)

# About the committee

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

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

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

### Approvals and registrations

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

The Northern B HDEC is registered (number IRB00008715) 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

I am pleased to present this report of the work of Northern B HDEC over the last year. The continual growth in demand for ethical review reflects a national health research sector which is expanding in both volume and complexity: it is critical that the nation’s ethics review bodies continue to evolve with it in a cohesive and responsive way, so as to maintain the public’s trust in the health and disability network. I confirm that Northern B has functioned effectively in the last year 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.

As the summary of the activities of Northern B over the last year detailed in this report reveals, the applications that come before us cover a very wide range of health and disability research. Our deliberations therefore are equally as wide ranging as we apply the established ethical standards to the detail and context of each study protocol. Our decision making involves a careful balancing of ethical principles, the legal and regulatory requirements, and the demands of scientific rigour whilst giving primacy to the protection of the rights and interests of participants. The applications before us are predominantly clinical research, and a goodly proportion of them are commercial and multi-national. These feature New Zealand investigators and research units who are deservedly esteemed on the international stage. The high regard with which the New Zealand ethics review system is also held is evidenced by the fact that we are often one the first countries of many to be approached for ethics review. HDECs work hard to maintain this reputation for efficient, thorough and principle-based ethical review.

A particular highlight in the last year was the great progress made towards updating the NEAC guidelines. Northern B members Kate O’Connor and Dr Nora Lynch participated in the working group co-ordinated by the HDECs Secretariat which completed the draft NEAC Standards for Health Research, currently out for public consultation. Once implemented, these Standards will necessitate an update to the HDECs operating procedures and this is likely to be a substantial piece of work. We anticipate that the NZ Ethical Standards will provide greater clarity for research practitioners for minimising research harms (including data harms), and provide internationally benchmarked guidance for addressing the ethical challenges in increasingly important research designs, such as cluster randomised trials. We hope that the Standards, along with other national level documents such as the New Zealand Health Research Strategy 2017–2027 will support the vision of maximising the benefits of health research and achieving better health outcomes for all New Zealanders. There remains uncertainty however about distinguishing health research from audit or innovative practice, and in identifying the appropriate review and approval pathways for these between and within localities. I also note the continued calls for greater cohesion and transparency between all components of the research, innovation and medical technologies enterprise, including in the whole-of-country research ethics and governance: in this regard we eagerly anticipate the progress which should be made possible under the forthcoming therapeutic products regulatory regime.

The last year has been notable for a greatly increased focus on non-consensual research (conducted in adults who lack capacity to consent). The HDC’s consultation on Right 7(4) of the Code was a valuable exercise in highlighting the legal expectations around best interest, and igniting discussions around determining capacity, and supporting autonomy to the maximum extent possible. As a result of these conversations we are observing those investigators working in areas such as emergency medicine, or with persons with dementia or Alzheimer’s disease, displaying a deeper and more finely grained understanding of both the ethical and legal implications of their research, as well as implementing responsible strategies for realising beneficial and evidenced-based health outcomes for patients. We are also detecting incremental advances in knowledge about how to minimise and manage the potential harms of ‘big data’ research.

I wish to take this opportunity to acknowledge the commitment of the members of Northern B who admirably discharge their responsibilities, carrying a load which is both time consuming and cognitively demanding. I also sincerely thank all staff of the secretariat who continue to provide the committees with high quality support, despite staffing and structural challenges. It is my privilege to be part of HDECs and to work with you all as we strive to protect the rights and interests of research participants and foster ethical and impactful research.

# 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: 14th December 2015

Current term expires: 14th December 2018

Kate O'Connor is the Chair of Northern B, HDEC, and is the Executive Manager of the AUT Ethics Committee. She is a Master of Arts (Philosophy) and holds a Post Graduate Diploma in Business Administration. Kate’s current doctoral inquiry is of research governmentality, using Michel Foucault’s theories of power and resistance.

**Mrs Stephanie Pollard**

Membership category: Design and conduct of intervention studies

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Mrs Stephanie Pollard is currently employed as an independent Clinical Research Consultant. With a 20 year career in clinical trials she specialises in oncology trials and previously held Research Manager roles at the University of Auckland (2007-2011) and University of Leeds, UK (1996-2006). She obtained a Master’s degree in Healthcare Ethics and Law in 2005.

**Mrs Jane Wylie**

Membership category: Provision of health and disability services

Date of appointment: 20th May 2017

Current term expires: 20th May 2020

Jane Wylie was originally a Medical Laboratory Scientist, and after raising a family and completing a DipSocSci (Massey 1994) she returned to work in 2001 as New Zealand Coordinator for an Australasian research consortium into familial breast cancer. In 2006 she moved to clinical trials work for the Haematology Research Unit at Auckland Hospital, acting as Team Leader for several years, and then in 2014 to new trials development and quality management in Cancer Trials New Zealand at the University of Auckland. During these years she obtained a MHSc (Hons) with post-grad. Studies in medical ethics, health law, research design and cancer therapies. Most recently Jane has been a Research Project Manager at the University of Auckland of studies investigating molecular profiling in blood cancers. Jane also held a part-time research consultancy facilitating projects across a range of health disciplines (2005-2012). Other roles include secondment to the NZ Health Innovation Hub (2012), and she currently serves on the Auckland Health Research Ethics Committee (AHREC) under the Auckland Academic Health Alliance and is a member of several health professional organisations.

**Mrs Leesa Russell**

Membership category: Design and conduct of intervention/observational studies

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Leesa Russell is currently Quality Lead for Specialist Medicine and Health of Older People at Waitemata District Health Board and is studying towards a Post-Graduate Diploma in Quality Systems at Massey University. She has previously worked with the New Zealand Cardiac Network, the National Cardiac Surgical Clinical Network and the Cancer Treatments Advisory Group Haematology Oncology Working Group as national coordinator. She completed a BA (2002) and MA (2004) at University of Auckland, focusing on Sociology of Medicine and writing on the effect of policy changes on the personal and professional lives of General Practitioners in Auckland. Mrs Russell has been involved in clinical research, quality improvement and at the Health Research Council as Executive Secretary to the HRC Ethics Committee and Data Monitoring Committee. In 2006 she received Research Fellowship for her work on the cognitive effects of elective surgery on older adults. On return from maternity leave in 2013, Mrs Russell managed a yearlong national implementation project in the fertility industry prompted by a change in legislation and obtained a management position in quality and process improvement as a result. She went on to manage Clinical Audit at St John. She holds (lapsed) accreditation for spirometry and Phlebotomy competencies and has previously volunteered as a First Responder (Waiuku Station). She previously held a role in the NZACRES executive and membership of the Cardiac Society of New Zealand.

**Dr Nora Lynch**

Membership category: Provision of health and disability services

Date of appointment: 24th July 2015

Current term expires: 24th July 2018

Dr Nora Lynch MBChB (Auckland 1979) MMed (Melb. 1987) FRACP 1986, PGCert Public Health (Auckland 2016). Nora is a physician specialising in rheumatology who consulted in both the public and private sectors until 2014. She has held a number of professional advisory roles and leadership positions including member of the Core Services Consensus Development Panel for hip and knee replacement (1995),member of the Royal Australasian College Physicians Specialist Advisory Committee for rheumatology training (1998-2004),executive member (1995-2006) and President(2006-2008) of the New Zealand Rheumatology Association, member PTAC Rheumatology Subcommittee (2010-2014 ), member on the Australasian 3e panel (Evidence, Expertise and Exchange) which prepared treatment guidelines for local specialist use(2010-2013) and member of the North Shore CMA governance team 2015-present. She returned to Auckland University in 2015 where she completed a Postgraduate Certificate in Public Health and is currently undertaking a Graduate Diploma in History.

**Dr Maliaga Erick**

Membership category: Consumer/community perspectives

Date of appointment: 24th July 2015

Current term expires: 24th July 2018

Maliaga Erick is currently working for the Werry Workforce Wharaurau Child and Adolescent mental health workforce development as a Pacific Clinical Advisor. She is a mother of seven children and a grandmother of 12 grandchildren. She has in the past been on School Board of Trustees and non-government agencies. Mali has a background in the Care and Protection of children, Family violence, and Mental Health and Pacific health research projects.

**Ms Tangihaere Macfarlane\***

Membership category: Consumer/community perspectives

Date of appointment: 20th May 2017

Current term expires: 20th May 2020

Miss Macfarlane (Te Arawa, Ngāti Whakaue, Ngāti Pikiao, Ngāti Rangiwewehi) is Quality and Risk Manager, Complaints Officer and Privacy Officer at Te Roopu Taurima O Manukau Trust (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.

**Mr John Hancock**

Membership category: Law

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

John Hancock is an Auckland lawyer who specialises in child, youth and human rights related law and public policy. He was formally Principal Solicitor at YouthLaw in Auckland, Principal Advisor (Legal) at the Office of the Children's Commissioner and a Youth Advocate practising in the Auckland Youth Court. He is currently Senior Legal Adviser at the Human Rights Commission. He also has held advocacy, governance and leadership roles in non-government and community-based organisations and statutory committees.

##

## Attendance

|  |
| --- |
| **LEGEND:** **\*** After name indicates Māori member**Y** = Present **A** = Apology**X** = Meeting cancelled / No meeting scheduled **/** = Not a member of committee during this time |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | **Membership category** **(L/NL)** | **Jul 17** | **Aug 17** | **Sep****17** | **Nov 17** | **Dec 18** | **Feb 18** | **Mar 18** | **Apr 18** | **May 18** | **Jun 18** | **Total** |
| [Mrs Kate O'Connor](https://nz.ethicsdatabase.org/contacts/contactsnew.aspx?id=127401)  | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/10 |
| Mrs Stephanie Pollard | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/10 |
| Mrs Jane Wylie | NL | A | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 8/10 |
|  [[Mrs Leesa Russell](https://nz.ethicsdatabase.org/contacts/contactsnew.aspx?id=128091)](https://nz.ethicsdatabase.org/contacts/contactsnew.aspx?id=128079)  | NL | **Y** | **Y** | **Y** | A | **Y** | **Y** | A | **Y** | **Y** | A | 7/10 |
|  [Dr Nora Lynch](https://nz.ethicsdatabase.org/contacts/contactsnew.aspx?id=128080)  | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/10 |
|  [Dr Maliaga Erick](https://nz.ethicsdatabase.org/contacts/contactsnew.aspx?id=124819)  | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/10 |
| Miss Tangihaere Macfarlane | L | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 9/10 |
|  [Mr John Hancock](https://nz.ethicsdatabase.org/contacts/contactsnew.aspx?id=128092)  | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | A | **Y** | 8/10 |
| Ms Toni Millar (Co-optedmember NTA) | L | / | / | / | **Y** | / | / | / | / | / | / | 1/10 |
| **Total no. of members present** |  | **7** | **7** | **8** | **7** | **8** | **8** | **6** | **8** | **7** | **7** |  |
| **No. of applications considered** |  | **10** | **5** | **11** | **12** | **11** | **11** | **9** | **7** | **6** | **12** |  |

## Training and conferences

### Specify the training undergone by new members

There were no new members appointed during this reporting period.

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

One member enrolled in Te Reo Tahi (Level 1) Unitec, Auckland. Semester 2 2018

Completed University of Auckland Stage 3 paper Semester 1 2018-History 362 Social Welfare in NZ 1840-2000 with A+ pass and First in Course Award.

Has enriched understanding of health and welfare inequalities which underpin much of current NZ research.

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

Full member training is on hold this year as many appointment rounds expire and the ethics standards are pending an update. Full training sessions are planned for 2019 in anticipation of the updated ethics standards and new member appointments.

# Applications reviewed

### Summary of applications received by full EC

|  |  |
| --- | --- |
| No. of applications approved  | 23 |
| No. of applications that were provisionally approved | 48 |
| No. of applications declined (This excludes those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group.)  | 5 |
| No. of applications that were provisionally approved and final decision pending | 5 |
| No. of applications provisionally approved and subsequently approved | 40 |
| No. of applications provisionally approved and subsequently declined | 6 |
| 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 | N/A |
| No. of studies withdrawn by researcher | 0 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC  | N/A |
| No. of studies withdrawn by HDEC | 1 |
| **Total number of applications received by full EC** i.e. no. of full applications with a final decision of approve, decline or provisional approval at time of report | **79** |

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

|  |  |
| --- | --- |
| No. of applications approved | 29 |
| No. of applications that were provisionally approved | 45 |
| No. of studies declined | 2 |
| No. of applications provisionally approved and subsequently approved  | 40 |
| No. of applications provisionally approved and subsequently declined | 5 |
| No. of applications that were provisionally approved and final decision pending | 2 |
| No. of applications referred for full committee review | 0 |
| No. of studies withdrawn by researcher | 2 |
| No. of studies withdrawn by HDEC | 2 |
| Total number of applications received under expedited/low risk review**i.e. no. of expedited applications with a final decision of approve, decline or provisional approval at time of report** | **78** |

|  |  |
| --- | --- |
| Total number of applications received | **157** |

# Complaints and overdue application summary

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

## Complaints received

**17/NTB/86 “Oral Prednisone for the Treatment of Acute Sore throat”**

**Study Approval/Meeting Date:** 18 October 2017 via HDEC Full Review

**Complaint regrading:** Researcher Conduct

**Complaint Received:** 28 May 2018

**Date Complaint Resolved**: 15 June 2018

**Details:**

Participant in research contacted HDEC regarding the treatment and the inadequate research process that had taken place. Participant had a worsening clinical picture which was discounted by the research team, despite the research team knowing the participants past clinical history.

**Actions Taken:**

* Ethics Secretariat formally acknowledged the complaint on the day it was received and contacted the NTB Chair.
* The Chair contacted the complainant by phone and checked to ensure appropriate medical care had been obtained.
* The Chair also clarified points made in the complaint letter.
* Non Lay Members reviewed clinical elements of the study and the complaint.
* A formal request for further information was made to the CI of the project. This letter asked the research team to review their inclusion criteria to ensure that only the least vulnerable participants are considered for participation, that they review their procedures in managing study harm, review their follow up call procedures and review the costs incurred associated with follow up consultations.

**Outcome:**

Researcher apologised for the experience. Participant Information Sheet was amended and sent for review. Approved on the 15 June 2018. Outcome was also communicated by the Chair to the complainant.

**17/NTB/265 Severe anaemia risk prediction in Jehovah's Witnesses**

**Study Approval/Meeting Date:** 05 April 2018 via HDEC Expedited Review

**Complaint regrading:** Ethics Process – Declined Application

**Complaint Received**: 11 April 2018

**Date Complaint Resolved**: 12 April 2018

**Details:**

Researcher unhappy with a declined result received. It was in research team view that application should be successful because they are trying to find treatment for severely anaemic Jehovah's Witnesses who refuse blood transfusion. Research team has sought advice from HRC.

**Actions Taken:**

Ethics Secretariat formally acknowledged the complaint on the day it was received and contacted the NTB Chair. As the HRC had forwarded the researcher back to HDEC, the HDEC contacted the research team with instructions on how to apply for a second opinion from another HDEC.

**Outcome:**

HDEC received an appealed application which was then heard and declined by STH HDEC, for similar reasons that was given in the initial application.

## Overdue review

Average review times take into account the time taken for the Secretariat to process applications and the time taken for the Committee to review applications. The clock is stopped when a decision letter is emailed to applicants. Average review times exclude time taken for researchers to respond to requests for further information.

Average review time was 17 days for expedited applications. Target timeframe for expedited applications is 15 calendar days.

Average review time was 32 days for full applications. Target timeframe for full applications is 35 calendar days.

#

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

## Applications reviewed by full committee

| **Study reference** | **Short title** | **CI Name** | **Validation date** | **Pause date (i.e. provisional approval)** | **Date of final decision** | **Study status at time of report** | **Locality/ies** | **Funder** | **Consultation Undertaken** | **Review Type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 17/NTB/138 | Sprinting to prevent hypoglycaemia | Dr Ryan Paul | 14/07/2017 | 31/08/2017 | 24/07/2017 | Approve | Sarah Brodnax |  | Locality | HDEC-Expedited Review |
| 17/NTB/139 | EPICCS | Dr Andrew Wilson | 17/07/2017 | 30/08/2017 | 11/08/2017 | Approve | Dr Kenneth Clark,Dr Michael Roberts,Marina Dzhelali,Marina Dzhelali,Mary-Anne Woodnorth,Ruth Sharpe,Sarah Brodnax | Auckland City Hospital | Locality | HDEC-Full Review |
| 17/NTB/140 | DXA precision study | Mr Terrence O'Donnell | 17/07/2017 |  | 7/08/2017 | Approve | William Levack | Southern District Health Board | Locality | HDEC-Expedited Review |
| 17/NTB/142 | A prospective evaluation of KXL II system for photorefractive intrastromal cross-linking (PiXL) for the treatment of Myopia and Hyperopia | Doctor Andrew Logan | 20/07/2017 | 30/08/2017 | 17/11/2017 | Withdrawn by HDEC | Andrew Logan | University of Auckland |  | HDEC-Full Review |
| 17/NTB/146 | Comparison of the blood levels of two forms of ferrous sulfate in healthy male volunteers under fasting conditions with diet control | Dr Noelyn Hung | 20/07/2017 | 31/08/2017 | 8/08/2017 | Approve | Linda Folland,Linda Folland | Unitec Institute of Technology | Locality | HDEC-Expedited Review |
| 17/NTB/148 | Comparison of the blood levels of two forms of acamprosate tablets in healthy male and female volunteers under fasting conditions | Dr Noelyn Hung | 20/07/2017 | 9/09/2017 | 8/08/2017 | Approve | Linda Folland,Linda Folland | Auckland District Health BOard | Locality | HDEC-Expedited Review |
| 17/NTB/149 | Comparison of the blood levels of two forms of acamprosate tablets in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | 20/07/2017 |  | 8/08/2017 | Approve | Linda Folland,Linda Folland | University of Otago, Wellington | Locality | HDEC-Expedited Review |
| 17/NTB/150 | Phase 2 of Filgotinib in patients with active non-infectious uveitis | Dr Joanne Sims | 20/07/2017 | 4/10/2017 | 19/09/2017 | Approve |  | Liggins Institute | Locality | HDEC-Expedited Review |
| 17/NTB/145 | Brain blood flow and type 2 diabetes. | Dr (PhD) Luke Wilson | 21/07/2017 | 1/12/2017 | 22/09/2017 | Approve | Ruth Sharpe |  | Locality | HDEC-Full Review |
| 17/NTB/152 | OL@-OR@ (WellTEXT) | Professor Cliona Ni Mhurchu | 28/07/2017 | 4/10/2017 | 14/08/2017 | Approve | Cliona Ni Mhurchu |  | Locality | HDEC-Full Review |
| 17/NTB/153 | Evaluation of trauma experiences. | Dr Angela Beaton | 4/08/2017 | 7/11/2017 | 6/09/2017 | Approve |  |  | Locality | HDEC-Full Review |
| 17/NTB/154 | Impact of late referral to nephrology care | Dr Suetonia Palmer | 7/08/2017 | 6/11/2017 | 16/08/2017 | Approve |  | Zenith Technology Corporation Limited | Locality | HDEC-Full Review |
| 17/NTB/155 | Bone health for premenopausal women | Ms Tracey Clissold | 7/08/2017 | 7/11/2017 | 7/09/2017 | Approve |  | Zenith Technology Corporation Limited | Locality | HDEC-Full Review |
| 17/NTB/156 | Study 2 Diagnosed Colorectal Cancer | Professor Ross Lawrenson | 11/08/2017 | 12/12/2017 | 7/09/2017 | Approve | Barry Smith,Jim Green,Peter Gilling,Sarah Brodnax |  | Locality | HDEC-Full Review |
| 17/NTB/157 | Study 1 The Detection Period: Suspected Colorectal Cancer | Professor Ross Lawrenson | 11/08/2017 |  | 27/08/2017 | Approve | Barry Smith,Jim Green,Peter Gilling,Sarah Brodnax |  | Locality | HDEC-Expedited Review |
| 17/NTB/171 | Jaw opening forces in subjects diagnosed with Temporomandibular disorder | Prof. Paul Brunton | 21/08/2017 | 8/12/2017 | 26/10/2017 | Approve | Ruth Sharpe |  | Locality | HDEC-Expedited Review |
| 17/NTB/158 | RUBATO | Doctor Kathryn Rice | 24/08/2017 |  | 15/03/2018 | Approve | Mary-Anne Woodnorth | Christchurch Clinical Studies Trust Ltd | Locality | HDEC-Expedited Review |
| 17/NTB/159 | M15-991 | Prof Richard Gearry | 24/08/2017 |  | 20/12/2017 | Approve | CDHB Research Advisor,Marina Dzhelali,Ruth Sharpe | University of Otgao | Locality | HDEC-Full Review |
| 17/NTB/160 | M16-000 | Prof Richard Gearry | 24/08/2017 | 21/12/2017 | 20/12/2017 | Approve | CDHB Research Advisor,Marina Dzhelali |  | Locality | HDEC-Expedited Review |
| 17/NTB/161 | M16-006 | Prof Richard Gearry | 24/08/2017 | 21/12/2017 | 20/12/2017 | Approve | CDHB Research Advisor,Marina Dzhelali | Waitemata District Health Board | Locality | HDEC-Expedited Review |
| 17/NTB/162 | Clinical Application of pharyngeal high resolution manometry. | Dr Kristin Gozdzikowska | 24/08/2017 | 21/12/2017 | 20/12/2017 | Withdrawn by HDEC |  | University of Auckland |  | HDEC-Expedited Review |
| 17/NTB/164 | CK-301-101: Phase 1 Study of CK-301 in Advanced Cancers | Dr Dean Harris | 24/08/2017 | 11/01/2018 | 3/11/2017 | Approve | CDHB Research Advisor | Waikato Hospital and University of Waikato | Locality | HDEC-Expedited Review |
| 17/NTB/165 | ATB200/AT2221 Pompe | Dr Andrew Veale | 24/08/2017 |  | 19/09/2017 | Withdrawn by Researcher | Andrew G. Veale |  |  | HDEC-Expedited Review |
| 17/NTB/166 | Neonatal conjunctivitis in the New Zealand Midland region (2nd application) | Dr Samuel Newlands | 24/08/2017 | 11/01/2018 | 19/10/2017 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/167 | Pau te Hau. High intensity interval training for young adolescents | Dr Nigel Harris | 24/08/2017 | 1/02/2018 | 19/09/2017 | Approve |  |  | Locality | HDEC-Full Review |
| 17/NTB/169 | Open WATER Study | Professor Peter Gilling | 24/08/2017 |  | 26/09/2017 | Approve | Rachael Hamill |  | Locality | HDEC-Full Review |
| 17/NTB/172 | Midodrine to prevent Orthostatic Intolerance after Hip and Knee Arthroplasty | Dr Michal Kluger | 24/08/2017 | 1/02/2018 | 19/09/2017 | Decline |  | Zenith Technology Corporation Limited | Locality | HDEC-Full Review |
| 17/NTB/173 | Clinical feasibility of the Re-Link Trainer | Dr Sarah Ward | 4/09/2017 | 1/08/2017 | 18/10/2017 | Approve | Mary-Anne Woodnorth | University of Auckland | Locality | HDEC-Full Review |
| 17/NTB/174 | North Shore Orthopaedic Registry | Mr Simon Young | 7/09/2017 |  | 12/10/2017 | Approve |  | Capital and Coast Health District Health Board and Malghan Institue of Medical Research | Locality | HDEC-Expedited Review |
| 17/NTB/176 | Video VS Verbal | Dr Cameron Schauer | 8/09/2017 | 8/12/2017 | 18/10/2017 | Approve |  |  | Locality | HDEC-Full Review |
| 17/NTB/177 | Epidemiology and long-term outcomes in patients with Autoimmune liver diseases | Dr Mehul Lamba | 12/09/2017 | 28/08/2017 | 2/10/2017 | Decline |  | Waikato DHB | Locality | HDEC-Full Review |
| 17/NTB/178 | Using Dogs for Lung Cancer Screening | Dr Timothy Edwards | 13/09/2017 |  | 2/10/2017 | Approve | Sarah Brodnax |  | Locality | HDEC-Full Review |
| 17/NTB/184 | Maternal responses to position change | Ms Hanna Fontinha | 22/09/2017 | 3/10/2017 | 2/10/2017 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 17/NTB/186 | Social Rhythm Therapy for Treatment-resistant Bipolar Disorder | Prof Marie Crowe | 22/09/2017 | 3/10/2017 | 12/10/2017 | Approve |  |  | Locality | HDEC-Full Review |
| 17/NTB/185 | Examining Emergency Department Inequities (EEDI): | Dr Elana Curtis | 25/09/2017 |  | 2/10/2017 | Approve |  | The University of Auckland | Locality | HDEC-Full Review |
| 17/NTB/187 | SCAD (Spontaneous coronary artery dissection). | Dr Mark Webster | 26/09/2017 |  | 31/10/2017 | Approve | Mary-Anne Woodnorth | Auckland City Hospital | Locality | HDEC-Full Review |
| 17/NTB/188 | Screening for structural heart disease among people with AF | Dr Katrina Poppe | 27/09/2017 | 28/09/2017 | 12/10/2017 | Approve | Nancy Malloy | Auckland City Hospital | Locality | HDEC-Expedited Review |
| 17/NTB/191 | Using CMDHB data to establish an outcome risk score for older people | DR SARAH CULLUM | 2/10/2017 |  | 18/10/2017 | Approve |  | Auckland District Health Board | Locality | HDEC-Full Review |
| 17/NTB/193 | Linking oral and gut bacteria, inflammation and heart disease | Dr Gregory Jacobson | 5/10/2017 | 4/12/2017 | 31/10/2017 | Approve | Sarah Brodnax | Auckland District Health Board | Locality | HDEC-Full Review |
| 17/NTB/194 | CONSCIOUS2 | Dr Amy Gaskell | 9/10/2017 |  | 26/10/2017 | Approve | Mary-Anne Woodnorth,Sarah Brodnax | Waikato DHB | Locality | HDEC-Expedited Review |
| 17/NTB/204 | The impact of transfer on outcomes of major burns in NZ | Dr Alex Kazemi | 24/10/2017 | 19/12/2017 | 17/01/2018 | Approve |  | Canterbury DHB | Locality | HDEC-Full Review |
| 17/NTB/189 | BEST - CLI Trial | Mr Andrew Hill | 26/10/2017 | 19/12/2017 | 22/11/2017 | Approve | Marina Dzhelali,Mary-Anne Woodnorth,Reenu Arora,Sarah Brodnax |  | Locality | HDEC-Full Review |
| 17/NTB/195 | 64041575RSV 2004 | Dr. Thorsten Stanley | 26/10/2017 | 11/01/2018 | 22/02/2018 | Approve | Service Leader, Research office |  | Locality | HDEC-Expedited Review |
| 17/NTB/197 | Connected Catheter Clinical Feasibility Study (CFS) | Mr. Giovanni Losco | 26/10/2017 |  | 4/01/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/198 | 64041575RSV2002 | Dr. Thorsten Stanley | 26/10/2017 |  | 15/02/2018 | Approve | Service Leader, Research office |  | Locality | HDEC-Expedited Review |
| 17/NTB/199 | CPAP Interface Product Evaluation | Dr Arun Nair | 26/10/2017 | 21/12/2017 | 4/01/2018 | Approve | Angela Bennett,Sarah Brodnax |  | Locality | HDEC-Expedited Review |
| 17/NTB/206 | SACNZS | Dr Donald Campbell | 26/10/2017 | 11/01/2018 | 20/12/2017 | Approve | Dr Kenneth Clark,Hamish Neave,Louise Allsopp,Mary-Anne Woodnorth,Samantha White |  | Locality | HDEC-Expedited Review |
| 17/NTB/209 | The SCORED Trial | Dr Jocelyne Benatar | 26/10/2017 | 11/01/2018 | 18/01/2018 | Approve | Alison Strong,Bobby McEwan,CDHB Research Advisor,CDHB Research Advisor,Dom Madell,Dr Kenneth Clark,Hamish Neave,Katie Kennett,Lisa Varga,Marina Dzhelali,Mary-Anne Woodnorth,Philippa Williams,Rachel Harris,Ruth Sharpe,Sarah Brodnax,Simon Carson |  | Locality | HDEC-Expedited Review |
| 17/NTB/210 | Mongo Guide Wire First In Man Study | Prof Scott Harding | 26/10/2017 | 24/01/2018 | 20/12/2017 | Approve | Marina Dzhelali |  | Locality | HDEC-Expedited Review |
| 17/NTB/212 | REVISE trial | Dr Paul Young | 26/10/2017 |  | 13/03/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/213 | Establishing the prevalence of delirium in hospital inpatient settings. | Professor Roger T Mulder | 26/10/2017 | 14/02/2018 | 7/12/2017 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/214 | Swallowing skill-training in neurodegenerative disease | Ms Emma Burnip | 26/10/2017 |  | 20/12/2017 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/215 | (duplicate) Upper limb muscle characteristics in Cerebral Palsy | Mr Lukas Wiedemann | 26/10/2017 | 19/07/2017 | 18/12/2017 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Expedited Review |
| 17/NTB/216 | WellConnectedNZ | Dr Michael Epton | 27/10/2017 | 24/07/2017 | 13/12/2017 | Approve | CDHB Research Advisor |  | Locality | HDEC-Expedited Review |
| 17/NTB/218 | Self harm and suicidality in Rural Youth | Dr Steve Withington | 27/10/2017 | 24/07/2017 | 14/11/2017 | Approve | CDHB Research Office |  | Locality | HDEC-Expedited Review |
| 17/NTB/221 | Patterns of glucose self-monitoring in type 1 diabetes | Dr Helen Lunt | 31/10/2017 | 3/08/2017 | 14/11/2017 | Approve | CDHB Research Office |  | Locality | HDEC-Expedited Review |
| 17/NTB/222 | Epidemiology of type one diabetes in the Waikato region | Dr Ryan Paul | 1/11/2017 |  | 14/11/2017 | Approve | Sarah Brodnax |  | Locality | HDEC-Full Review |
| 17/NTB/223 | Cardiac Radiotherapy for Atrial Fibrillation | Ms Suzanne Lydiard | 6/11/2017 | 19/09/2017 | 14/11/2017 | Approve |  |  | Locality | HDEC-Full Review |
| 17/NTB/224 | Low Carb Leaders | Dr Caryn Zinn | 9/11/2017 |  | 29/11/2017 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/226 | Pancreatitis in Ehlers-Danlos Syndrome | Dr Marianne Elston | 13/11/2017 |  | 29/11/2017 | Approve | Sarah Brodnax |  | Locality | HDEC-Expedited Review |
| 17/NTB/227 | The effects of thoracic spine mobilizations in individuals with cervical spine pain. | Professor Duncan Reid | 14/11/2017 | 19/10/2017 | 13/12/2017 | Decline |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/228 | Perioperative care in chronic sinusitis | Associate Professor Richard Douglas | 20/11/2017 | 22/11/2017 | 14/02/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 17/NTB/229 | Circulating miRNA and clozapine-induced cardiotoxicity | Mr Kieran Deane-Alder | 22/11/2017 | 22/11/2017 | 8/12/2017 | Approve |  |  | Locality | HDEC-Full Review |
| 17/NTB/245 | Starting the conversation: Explaining biosimilars to patients | Prof Keith Petrie | 1/12/2017 | 4/01/2018 | 15/01/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 17/NTB/246 | Community pharmacy services in New Zealand | Professor Jacqueline Cumming | 1/12/2017 | 20/12/2017 | 4/01/2018 | Approve | Isobel Cairns |  | Locality | HDEC-Expedited Review |
| 17/NTB/251 | Clubfoot follow up study | Dr James Recordon | 4/12/2017 | 4/01/2018 | 21/02/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Expedited Review |
| 17/NTB/230 | POPE-flow | Dr Nicola Broadbent | 7/12/2017 | 4/01/2018 | 8/01/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 17/NTB/234 | Clostridium Difficile Infection: Prospective ribotype analysis from a rural secondary care centre | Dr Matthew Johnston | 7/12/2017 | 4/01/2018 | 4/04/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/235 | BE10-1003: Study of the safety of increased doses of Citramel inhalation in healthy volunteers | Dr Bridget Maher | 7/12/2017 |  | 14/02/2018 | Approve | David G Cranna |  | Locality | HDEC-Full Review |
| 17/NTB/236 | KCP-330-009: SADAL: Selinexor Against Diffuse Aggressive Lymphoma | Dr Ruth Spearing | 7/12/2017 |  | 13/03/2018 | Approve | CDHB Research Advisor,Rose Smart |  | Locality | HDEC-Full Review |
| 17/NTB/237 | Assess Safety and Efficacy of Vilaprisan in Subjects with Uterine Fibroids | Dr Katrina L. Allen | 7/12/2017 | 19/07/2017 | 26/02/2018 | Approve | Alison Strong,Katie Kennett |  | Locality | HDEC-Expedited Review |
| 17/NTB/238 | The effect of antibiotic prophylaxis on human microbiological flora in total knee arthroplasty: Intra-osseous Vancomycin vs. IV Vancomycin vs. IV Cephazolin. | Dr Mustafa Saffi | 7/12/2017 | 19/07/2017 | 4/01/2018 | Decline |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/239 | He Tapu Te Whare Tangata - Offer of HPV self-testing to under-screened women | Professor Beverley Lawton | 7/12/2017 |  | 19/02/2018 | Approve | Dr Michael Roberts |  | Locality | HDEC-Expedited Review |
| 17/NTB/240 | A Study To Evaluate Fasinumab In Patients With Pain Due To Osteoarthritis Of The Knee Or Hip (R475-OA-1688) | Dr Nigel Gilchrist | 7/12/2017 | 31/07/2017 | 6/04/2018 | Decline |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/241 | Evaluation of infection control advice and infection-related change in treatment plan. | Dr Scott Macfarlane | 7/12/2017 |  | 4/01/2018 | Approve | CDHB Research Office,Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 17/NTB/242 | SHARP-C | Prof Edward Gane | 7/12/2017 | 31/07/2017 | 11/04/2018 | Approve | CDHB Research Advisor,Lesley McTurk,Tarati Blair-Hunt |  | Locality | HDEC-Expedited Review |
| 17/NTB/243 | Metronidazole After Haemorrhoidectomy | Professor Andrew Hill | 7/12/2017 |  | 14/02/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/249 | Mana Tū: a mana whanau approach to improving diabetes outcomes | Dr Matire Harwood | 7/12/2017 |  | 15/03/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 17/NTB/261 | The effects of feedback on brain-computer interface (BCI) and rehabilitation | Dr Imran Niazi | 8/12/2017 | 18/08/2017 | 21/02/2018 | Approve | Imran Khan Niazi |  | Locality | HDEC-Expedited Review |
| 17/NTB/262 | Analgesia and osteotomies at Starship Hospital | Dr Andrew Liley | 11/12/2017 |  | 4/04/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 17/NTB/263 | Sepsis-3 in Critically Ill Children | Dr Anusha Ganeshalingham | 13/12/2017 | 7/11/2017 | 4/01/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 17/NTB/265 | Severe anemia risk prediction in Jehovah's Witnesses | Prof. Colleen Bergin | 14/12/2017 |  | 5/04/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 17/NTB/264 | Socio-economic deprivation and heart transplant recipients' survival | Dr Peter Ruygrok | 18/12/2017 |  | 12/04/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 18/NTB/13 | Evaluation of the Mobility Action Programme(MAP) | Ms Marnie Carter | 12/01/2018 |  | 5/04/2018 | Approve | Julie Palmer |  | Locality | HDEC-Full Review |
| 18/NTB/1 | One bar a day for diabetes prevention (1BarDDP) | Professor Sally D Poppitt | 15/01/2018 | 25/10/2017 | 13/03/2018 | Approve | Eileen McLaughlin,Marina Dzhelali |  | Locality | HDEC-Full Review |
| 18/NTB/2 | Shear wave elastography to predict outcomes in chronic liver disease | Dr Ashok Raj | 15/01/2018 |  | 16/04/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/14 | Scoliosis Pain Management in Starship Hospital | Dr Lorna Rankin | 16/01/2018 | 3/10/2017 | 14/02/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Expedited Review |
| 18/NTB/15 | Pain symptoms following repeat laparoscopic excision of endometriosis | Dr Tess Nagy | 17/01/2018 | 19/10/2017 | 8/06/2018 | Withdrawn by HDEC |  |  |  | HDEC-Expedited Review |
| 17/NTB/266 | DecubICUs | Dr Rachael Parke | 25/01/2018 |  | 20/02/2018 | Approve | B KING,Dom Madell,Dr Michael Roberts,Lisa Varga,Marina Dzhelali,Mary-Anne Woodnorth,Peter Gilling,Rose Smart,Ruth Sharpe |  | Locality | HDEC-Expedited Review |
| 18/NTB/10 | Effect of retinopathy of prematurity screening on regional oxygenation and cardiorespiratory stability of neonates | Dr Angus Goodson | 25/01/2018 | 8/11/2017 | 20/02/2018 | Approve | Marina Dzhelali |  | Locality | HDEC-Expedited Review |
| 18/NTB/11 | Periosteal Block vs. Biers Block a randomized clinical trial | Dr Sierra Beck | 25/01/2018 |  | 19/03/2018 | Approve | Ruth Sharpe |  | Locality | HDEC-Expedited Review |
| 18/NTB/12 | Optimising PCIT | Dr Melanie Woodfield | 25/01/2018 | 28/11/2017 | 4/04/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 18/NTB/17 | Improving detection and management of AF | Dr Katrina Poppe | 25/01/2018 |  | 29/03/2018 | Decline |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/18 | Modulating appetite in overweight women | Dr John Ingram | 25/01/2018 | 21/11/2017 | 13/03/2018 | Approve | Jocelyn r eason |  | Locality | HDEC-Expedited Review |
| 18/NTB/3 | MK3475-679 | Dr Carmel Jacobs | 25/01/2018 |  | 1/05/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 18/NTB/4 | Paediatic ctDNA (revised) | Prof Parry Guilford | 25/01/2018 | 28/11/2017 | 8/05/2018 | Approve | CDHB Research Advisor |  | Locality | HDEC-Full Review |
| 18/NTB/5 | The CHAMPIONZ Study | Professor Richard Troughton | 25/01/2018 | 28/11/2017 | 6/04/2018 | Approve | CDHB Research Advior |  | Locality | HDEC-Full Review |
| 18/NTB/6 | Microvascular Protection in Major Abdominal Surgery | Dr Chang Joon Kim | 25/01/2018 | 28/11/2017 | 22/05/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 18/NTB/7 | (duplicate) (duplicate) Microbiology of posterior spine surgical wounds in a paediatric population | Dr Haemish Crawford | 25/01/2018 | 22/11/2017 | 30/05/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/8 | Lens protein adhesives for use in ocular surgery | Professor Trevor Sherwin | 25/01/2018 |  | 24/05/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/9 | Blood product usage and cost pre and post introduction of TEG in cardiac intensive care. | Dr Scott Robinson | 25/01/2018 | 28/11/2017 | 20/02/2018 | Approve | Sarah Brodnax |  | Locality | HDEC-Full Review |
| 18/NTB/22 | the Beliefs of Non-Religious Hospital Patients | Mr Wyatt Butcher | 31/01/2018 |  | 8/05/2018 | Approve | CDHB Research Advisor |  | Locality | HDEC-Full Review |
| 18/NTB/21 | Genetics of Antidepressant Side-Effects (GO-A study) | Dr James Foulds | 5/02/2018 |  | 15/03/2018 | Approve | Kosta Tabakakis |  | Locality | HDEC-Full Review |
| 18/NTB/23 | Access to secondary mental health services | Dr Sara Filoche | 5/02/2018 |  | 13/03/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/24 | MDR Acinetobacter baumannii | Dr Matthew Blakiston | 8/02/2018 |  | 19/03/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 18/NTB/32 | Management and outcomes of critical limb ischemia in dialysis patients at Waikato Hospital | Dr Kannaiyan Rabindranath | 19/02/2018 | 16/07/2018 | 4/04/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/28 | Retrospective review of Sudden Unexplained death in epilepsy (SUDEP) in New Zealand | Dr Peter Bergin | 21/02/2018 |  | 8/05/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/25 | Resolving the research gap - what factors may influence cleft lip and cleft palate? | Associate Professor John Thompson | 22/02/2018 |  | 7/05/2018 | Approve | Marina Dzhelali,Marina Dzhelali,Mary-Anne Woodnorth,Sarah Brodnax |  | Locality | HDEC-Expedited Review |
| 18/NTB/26 | Unravelling mechanisms of cross protection to gonorrhoea | Dr Fiona Radcliff | 22/02/2018 |  | 22/03/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/27 | In-Vitro Blood Reactivity to Xenoantigens | Professor Stephen Munn | 22/02/2018 |  | 26/04/2018 | Approve | Mary-Anne Woodnorth,Peter Flanagan |  | Locality | HDEC-Expedited Review |
| 18/NTB/33 | Do Cardio selective Beta-Blockers Affect the Use of Beta-Agonist Inhalers Following Bronchoconstrictionin Asthma? | Dr Miriam Bennett | 22/02/2018 | 8/03/2018 | 25/05/2018 | Decline |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/34 | A novel model of care for Māori with chronic airways disease | Dr Sandra Hotu | 22/02/2018 | 9/03/2018 | 16/04/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/35 | (duplicate) Effective therapy method for obstructive sleep apnea | Professor Ahmed Al-Jumaily | 22/02/2018 | 9/03/2018 | 11/05/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/36 | Comparison of Mindfulness and Exercise During and After Cancer Treatment | Ms Virginia Eggleston | 22/02/2018 |  | 12/04/2018 | Approve | GFJ Brooks |  | Locality | HDEC-Expedited Review |
| 18/NTB/37 | AEGIS-II - Study to Investigate CSL112 in Subjects with Acute Coronary Syndrome. (AEGIS-II). | Professor Harvey Douglas White | 22/02/2018 | 8/02/2018 | 1/05/2018 | Approve | CDHB Research Advisor,Lisa Varga,Marina Dzhelali,Mary-Anne Woodnorth,Rose Smart,Ruth Sharpe,Sarah Brodnax |  | Locality | HDEC-Expedited Review |
| 18/NTB/38 | Epidemiology of primary cutaneous lymphoma in South Auckland | Dr Yena Kim | 22/02/2018 |  | 4/04/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/40 | A study on the effects of oral everolimus alone or in combination with BEZ235 on the immune response to influenza vaccine in the elderly | Dr Simon Carson | 22/02/2018 |  | 6/04/2018 | Approve | Alison Strong,Dean Quinn,Rachel Harris,Vivienne King |  | Locality | HDEC-Full Review |
| 18/NTB/41 | Skin and soft tissue infections in Tuvaluan people | Dr john kennelly | 26/02/2018 |  | 21/03/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 18/NTB/43 | Vaccination in Pharmacy (VIP) Study | Dr Natalie Gauld | 6/03/2018 | 9/04/2018 | 20/03/2018 | Approve | Dr John Gommans,Dr Michael Roberts,Sarah Brodnax |  | Locality | HDEC-Full Review |
| 18/NTB/51 | Fight the fever: The app | Dr Alison Leversha | 20/03/2018 | 5/05/2018 | 13/07/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/49 | CGA patient experience study | Ms Rosemary Hoyt | 22/03/2018 | 5/05/2018 | 8/05/2018 | Approve | Ruth Sharpe |  | Locality | HDEC-Full Review |
| 18/NTB/50 | Access to Services | Mr Dorian Gray | 22/03/2018 | 5/05/2018 | 13/04/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 18/NTB/55 | MASTERSTROKE | Dr Douglas Campbell | 22/03/2018 | 9/03/2018 | 29/05/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 18/NTB/56 | Improving Quality of Life Through Preference Based Teaching | Mrs Jocelyn Davis | 22/03/2018 |  | 7/05/2018 | Approve | Jocelyn Davis |  | Locality | HDEC-Full Review |
| 18/NTB/59 | EV-ICD Pilot Study (MDT17034) | Dr Ian Crozier | 22/03/2018 |  | 12/06/2018 | Approve | CDHB Research Advisor |  | Locality | HDEC-Full Review |
| 18/NTB/60 | Sensor Performance Under Free-living Conditions Comparing Guardian™ Sensor 3 With Capillary Glucose Monitoring | Dr Martin de Bock | 22/03/2018 |  | 31/05/2018 | Approve | Russell S Scott |  | Locality | HDEC-Expedited Review |
| 18/NTB/61 | Anaesthetists Be Clean (the ABC study). | Professor Alan Merry | 22/03/2018 |  | 31/07/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/58 | Relapse Prevention (RP) Trial | Dr Hayden McRobbie | 23/03/2018 | 8/02/2018 | 22/08/2018 | Withdrawn by Researcher |  |  |  | HDEC-Expedited Review |
| 18/NTB/66 | Trans Health Survey | Dr Jaimie Veale | 17/04/2018 | 20/03/2018 | 8/05/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/62 | Cognitive Stimulation Therapy and Chair Yoga in Dementia | Dr Gary Cheung | 19/04/2018 | 30/01/2018 | 20/06/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/63 | Development of mSACSBI – a mobile SACS brief intervention | Dr Grant Christie | 19/04/2018 | 12/03/2018 | 20/06/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/65 | (duplicate) Improving detection and management of AF | Dr Katrina Poppe | 19/04/2018 |  | 22/05/2018 | Approve | Dr Micheal Brown |  | Locality | HDEC-Expedited Review |
| 18/NTB/67 | Testing of a patient lifting and transfer device | Dr Erin Mansell | 19/04/2018 | 29/03/2018 | 15/05/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 18/NTB/68 | Upfront pembrolizumab for unfit patients with Hodgkin Lymphoma - PLIMATH STUDY | Dr Leanne Berkahn | 19/04/2018 | 29/03/2018 | 7/06/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Full Review |
| 18/NTB/75 | Is Activation Therapy Effective for Depressed Inpatients? | Dr. Richard J. Porter | 19/04/2018 | 29/03/2018 | 1/06/2018 | Approve | CDHB Research Advisor |  | Locality | HDEC-Full Review |
| 18/NTB/69 | SORTED - Study of road trauma evidence and data | Ms Siobhan Isles | 20/04/2018 | 29/03/2018 | 8/05/2018 | Approve | Bridget Dicker |  | Locality | HDEC-Full Review |
| 18/NTB/73 | Monitoring of Patients Previously in FAP studies CS2 or CS3 | Professor Edward (Ed) Gane | 20/04/2018 | 20/03/2018 | 24/05/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/74 | REACH-C NZ | Prof Edward Gane | 20/04/2018 | 26/03/2018 | 14/05/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Expedited Review |
| 18/NTB/77 | GlobalSurg 3: Quality and outcomes in global cancer surgery | Professor Ian Bissett | 26/04/2018 |  | 25/05/2018 | Approve | CDHB Research Advisor,Rachel Matthews,Rose Smart |  | Locality | HDEC-Full Review |
| 18/NTB/78 | Comparison of Bowel Preparation Regimes for Colonoscopy | Dr Jophia Kommunuri | 30/04/2018 | 26/04/2018 | 9/07/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/84 | Breast tumour volume to breast volume ratio and axillary node positivity rates | Dr Janine Rayen | 16/05/2018 |  | 6/07/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/86 | (duplicate) Socio-economic deprivation and heart transplant recipients' survival | Dr Peter Ruygrok | 18/05/2018 | 21/06/2018 | 28/05/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/92 | SHEBANG Study | Prof David Cameron-Smith | 23/05/2018 | 28/06/2018 | 20/06/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/100 | Testing of a patient lifting and transfer device | Dr Erin Mansell | 24/05/2018 | 28/06/2018 | 12/07/2018 | Approve | Erin Mansell,Jack Haughton |  | Locality | HDEC-Full Review |
| 18/NTB/101 | MK3475-587(00)Extension Study for Participants With Advanced Tumors in Pembrolizumab Trials. | Prof Matthew Strother | 24/05/2018 |  |  | Provisionally approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/81 | Qualitative Research into the Lived Experience of Dementia in New Zealand | Mrs Elizabeth Smith | 24/05/2018 | 28/06/2018 | 2/08/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/83 | Implementation of a risk assessment tool to enable targeted SUDI prevention care. | Dr Christine McIntosh | 24/05/2018 |  | 15/06/2018 | Decline |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/87 | Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of EDP-305 in Subjects with NASH | Prof Edward Gane | 24/05/2018 |  | 15/06/2018 | Approve | David G Cranna |  | Locality | HDEC-Expedited Review |
| 18/NTB/88 | Effect of warm humidified CO2 insufflation on de-airing | Dr David McCormack | 24/05/2018 |  |  | Provisionally approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/89 | Infant muscle growth at risk | Professor Susan Stott | 24/05/2018 | 28/06/2018 | 2/08/2018 | Approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/90 | Outcomes following Traumatic Brain Injury | Mrs Hemisha Patel | 24/05/2018 | 14/02/2018 | 15/06/2018 | Decline |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/93 | BGB3111\_BGBA317\_Study\_001 | Dr David Simpson | 24/05/2018 |  |  | Provisionally approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/94 | Ventilatory limitation during exercise | Mr Ryan Welch | 24/05/2018 | 21/06/2018 | 25/07/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Expedited Review |
| 18/NTB/96 | Usability Assessment of Evatherm 2 | Dr Robert Martynoga | 24/05/2018 | 28/06/2018 | 15/06/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 18/NTB/97 | Usability Assessment of Gallus Mask | Dr Robert Martynoga | 24/05/2018 | 28/06/2018 | 15/06/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 18/NTB/102 | Surviving the Fontan | Dr Abby Walsh | 18/06/2018 |  | 3/07/2018 | Approve | Mary-Anne Woodnorth |  | Locality | HDEC-Expedited Review |
| 18/NTB/104 | Infant Mental Health Outcomes after Involvement in a Perinatal Mental Health Service | Associate Professor Sue Luty | 18/06/2018 |  | 29/06/2018 | Decline |  |  | Locality | HDEC-Full Review |
| 18/NTB/103 | ILUMIEN IV Clinical Study | Prof Scott Harding | 21/06/2018 |  |  | Provisionally approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/105 | THE AFR-PROPHET TRIAL | Assoc Prof Gerard Wilkins | 21/06/2018 |  |  | Provisionally approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/107 | Two Trials for Treatment of Anxiety | Professor Bruce Arroll | 21/06/2018 |  | 22/08/2018 | Approve |  |  | Locality | HDEC-Expedited Review |
| 18/NTB/109 | The RiCoDIFy study: A Phase 3, randomized, double-blind, active controlled study to compare the efficacy and safety of ridinilazole (200 mg, bid) for 10 days with vancomycin (125 mg, qid) for 10 days | Dr Nicholas Gow | 21/06/2018 | 13/04/2018 |  | Provisionally approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/112 | DERBY | A/Prof Philip Polkinghorne | 21/06/2018 | 20/02/2018 |  | Provisionally approve |  |  | Locality | HDEC-Full Review |
| 18/NTB/115 | CT-FFR | Dr Bijan Jahangiri | 28/06/2018 | 13/04/2018 | 29/08/2018 | Approve | CDHB Research Advisor |  | Locality | HDEC-Full Review |
| 17/NTB/144 | The role of PET CT in the Head and Neck cancer pathyway | Dr Tary Yin |  | 20/06/2018 | 18/07/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/168 | VTE in orthopaedic patients in Tauranga Hospital August 2011 – July 2016 | Dr Frances Stringfellow |  |  | 16/08/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/170 | Malaghan Institute Human Tissue Bank | Dr Robert Weinkove |  | 20/06/2018 | 23/11/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/196 | The effects of thoracic spine mobilizations in individuals with cervical spine pain. | Professor Duncan Reid |  | 20/06/2018 | 17/10/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/200 | Micro-tensile bond strength of different pit and fissure sealants to intact enamel. | Dr Manorika Ratnaweera |  |  | 24/10/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/201 | Measurement of human mitochondrial function | Dr Andree Pearson |  |  | 24/10/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/205 | Molecular classification of colorectal cancers and its clinical significance Molecular classification of colorectal cancers and its clinical significance Molecular classification of colorectal can | Dr Magreet Strauss |  |  | 24/10/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/207 | Use of EWS (Early Warning Score) modification prior to MET call: A Retrospective Audit. | Dr William Blackburne |  | 8/02/2018 | 24/10/2017 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 17/NTB/208 | Concussions in amateur rugby league | Dr Doug King |  | 22/06/2018 | 25/10/2017 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 17/NTB/211 | Pilot study to test a novel device that tests for eye mobility after trauma to the orbit | Mr Jason Erasmus |  | 20/06/2018 | 9/11/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/217 | Audit and retrospective review of patients treated with meta-acromion fractures | Dr Georgios Konstantinidis |  | 20/06/2018 | 30/10/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/219 | The effect of exercise induced plasma acidosis on peak power after a simulated 4000 m Individual Pursuit on a bicycle ergometer. | Mr Mathew Mildenhall |  |  | 30/10/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/220 | Perinatal Mortality in Pregnancies complicated by Diabetes | Dr Joanne Dixon |  | 20/06/2018 | 31/10/2017 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 17/NTB/248 | Local anaesthetic tonsillectomy with or without sedation | Dr Christopher Low |  | 27/06/2018 | 16/01/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 17/NTB/253 | Acute on Chronic Liver Failure (ACLF) | dr debi prasad |  | 12/07/2018 | 11/12/2017 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 17/NTB/255 | MRO study | Miss Sarah Mills |  | 1/08/2018 | 11/12/2017 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 17/NTB/257 | Odyssey Legacy Study | Dr Jocelyne Benatar |  | 26/07/2018 | 12/12/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/259 | Reducing exposure to whole-body-vibration and the incidence of back pain in locomotive engineers | Dr Andrew Snell |  | 18/02/2018 | 12/12/2017 | Invalid Application |  |  |  | HDEC-Full Review |
| 17/NTB/267 | Outcomes of surgical treatment of CRC in patients aged over 80 years old. | Prof Frank Frizelle |  |  | 16/01/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/106 | L8 PACU acute pain outcome analysis | Ms Vicki Ward |  |  | 19/06/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/16 | Management and outcomes of critical limb ischemia in dialysis patients at Waikato Hospital | Dr Kannaiyan Rabindranath |  | 9/03/2018 | 17/01/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/19 | Comparison of Bowel Preparation Regimes for Colonoscopy | Dr Jophia Kommunuri |  |  | 30/04/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/30 | Auckland DHB, Tupu Ora Eating Disorders service: bone density changes study | Dr Andrew Inglis |  | 23/03/2018 | 19/02/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/31 | E Oho Rangatahi | Dr Kahu McClintock |  | 23/04/2018 | 20/02/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/42 | EGL Waikato - Phase Three Evaluation | Mrs Louise Were |  |  | 27/02/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/44 | TARPAS | Dr David Sainsbury |  |  | 15/03/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/45 | Housing crisis and health outcomes | Dr Eilya Torshizian |  | 18/04/2018 | 27/03/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/47 | (duplicate) Severe anemia risk prediction in Jehovah's Witnesses | Prof. Colleen Bergin |  | 23/04/2018 | 19/03/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/48 | Can variation in the androgen receptor explain why Māori men have poorer prostate cancer outcomes? | Dr Joshua Silverman |  |  | 19/03/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/52 | Improving Quality of Life Through Preference Based Teaching | Mrs Jocelyn Davis |  | 23/04/2018 | 20/03/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/53 | Fundamentals of Care | Dr Luis Villa |  |  | 21/03/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/54 | Sensor Performance Under Free-living Conditions Comparing Guardian™ Sensor 3 With Capillary Glucose Monitoring | Professor Tim Jones |  |  | 22/03/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/64 | (duplicate) (duplicate) Visualisation rate of duodenal ampulla with and without a capped wide-viewing gastroscope | Dr Wayne Bai |  | 26/04/2018 | 16/04/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/70 | Paediatric trauma in the Midland Region of New Zealand, 2012-2017 | Dr Grant Christey |  | 26/04/2018 | 19/04/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/72 | ATLAS Injury: Pilot Study | Dr Samuel Moon |  |  | 20/04/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/76 | Staff wellbeing following the Kaikōura earthquake | Dr Jennifer Jordan |  | 26/04/2018 | 23/04/2018 | Invalid Application | CDHB Research Advisor |  |  | HDEC-Full Review |
| 18/NTB/79 | Intertester reliability study | Mr Darragh Kenny |  |  | 11/05/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/82 | Implementation of a risk assessment tool to enable targeted SUDI prevention care. | Dr Christine McIntosh |  |  | 14/05/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/91 | L4 Perioperative normothermia audit | Ms Vicki Ward |  |  | 23/05/2018 | Invalid Application |  |  |  | HDEC-Expedited Review |
| 18/NTB/95 | International Anaesthesia Training and Supervision Survey | DR Elizabeth Fontaine |  |  | 24/05/2018 | Invalid Application |  |  |  | HDEC-Full Review |
| 18/NTB/99 | Validation Study of Gynaecological Molecular Panel | Doctor Joanne Moses |  |  | 24/05/2018 | Invalid Application |  |  |  | HDEC-Full Review |

# 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:** 28 September 2018

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

**Name of EC: Northern B 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 Rob McHawk

 Title First Name Last Name

**Position :** Acting Manager – Ethics

**E-mail :** hdecs@moh.govt.nz



**Signature: Date:** 28 September 2018

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)