

Northern A Health and Disability Ethics Committee

Annual Report
2016

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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

2016 saw a continuation of workload on the committee. The fact that this workload was managed was due to a combination of committee membership and expertise, continued support from the HDEC secretariat and cooperation between the Chairs of the four committees.

As ever, the ability to recruit valuable committee members, with the right expertise, is an ongoing challenge in view of (comparatively) poor financial recognition of their effort and the demands on these people from their normal jobs. The committees could not be adequately staffed if it weren’t for their charitable and altruistic attitude of contributing to the wellbeing of society. This should not be taken for granted. The work is highly challenging, requiring members of high intellectual ability, needed to compete with complex nature of most of our applications. As with other sections of the health sector, this contribution needs to be acknowledged.

As ever, consideration of projects that rely on the recruitment of participants unable to consent, present some of our most complex challenges. Often these are not “new trials” in the sense of new or lightly-tested drugs. Rather, many involve the comparison of two “standard of care” treatments where the evidence is lacking as to the superior treatment and the ability to demonstrate benefit (as per legislation, regulations) poses a challenge for both committees and researchers. Whilst comparing two “standards of care” may not appear to have the status of novel projects, my view is that in the long run, they may well prove of immense health benefit to the public, with significant cost benefits accruing across the health system.

Innovation continues in both drugs and devices; some are “First in Human”, and invariably are multi-country in trial work. Our Peer Review system, developed over 3 years ago, seems to work well. Further, many of the international sponsors continue to want to carry out pharmo-genetic and genetic testing, and storing tissue for future research (sometimes unspecified). New Zealand-based “centres of excellence” seem to be holding their own in terms of trialling on behalf of international sponsors. There is a degree of generic drug research, which may or may not, benefit New Zealand.

In summary, another heavy workload year, but our Committee handled the challenges.

****

Brian Fergus

Chairperson

Northern A Health and Disability Ethics Committee

# Membership and attendance

No meetings were postponed or cancelled due to inability to make quorum. Two new members were appointed to the Committee during 2016.

## Membership

### Lay members

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| **Dr Brian Fergus (Chair)** |
| Membership category: | Community perspectives  |
| Date of appointment: | 1 July 2015 |
| Current term expires: | 1 July 2018 |

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

**Mrs Rosie Abbott**

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| Membership category: | The Law |
| Date of appointment: | 15 March 2016 |
| Current term expires: | 15 March 2019 |

Rosie Abbott is currently practicing as a criminal barrister on her own account in Waitakere, and has also recently been appointed as a Youth advocate practicing in the Youth Jurisdiction. Having graduated from the University of Auckland with a Bachelor of Arts majoring in Māori studies and a Bachelor of Laws (conjoint), Rosie has a keen interest in Restorative justice and has also worked as facilitator for the Marae Restorative justice programme based at Hoani Watiti Marae. Rosie spent time prosecuting in the District Court for the Police Prosecutions Service (2009-2012) and for the Public Defence Service as a defence lawyer (2014–2016). Rosie is partway through her Master in Laws with a special interest in therapeutic jurisprudence. Having worked in the Health sector as a Māori cultural advisor based at the Kari Centre working with children affected by mental illness (2000–2002), she has also worked with at risk youth at Youth Horizons. Rosie is a former board member of the Waitakere Community Law Centre (2006-2007) and is an active member of the Hoani Waititi Marae in Glen Eden, having spent her youth in Te Roopu Manutaki under the guidance of Dr Peter Sharples. Rosie is of Ngati Kahungunu descent and a speaker of Te Reo Māori.

**Mrs Toni Millar**

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| Membership category: | Consumer representative |
| Date of appointment: | 15 March 2015 |
| Current term expires: | 15 March 2019 |

Toni is a former Auckland City Councillor and Eastern Bays Community Board Deputy Chair and Chairman. A business mentor and consultant, Toni has had extensive experience in the not-for-profit sector and in 2009 she was awarded a Paul Harris Fellow for her contribution to the community. Her contributions include the deputy chairmanship of the Arts, Culture and Recreation Committee for Auckland City Council, and chairing the Auckland City Creative Communities Arts Fund. She is also a trustee of the Auckland Arts Festival, Metrowater Community Trust and the Great Kiwi Anzac Day Breakfast.

### Non-lay members

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| **Dr Christine Crooks** |
| Membership category: | Intervention studies  |
| Date of appointment: | 1 July 2013 |
| Current term expires: | 1 July 2016 |

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.

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| **Dr Karen Bartholomew** |
| Membership category: | Intervention studies  |
| Date of appointment: | 1 July 2013 |
| Current term expires: | 1 July 2016 |

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

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| **Dr Charis Brown** |
| Membership category: | Intervention studies  |
| Date of appointment: | 11 November 2015 |
| Current term expires: | 11 November 2018 |

### Dr Charis Brown is a Research Fellow with The University of Auckland, based at the Waikato Clinical Campus in Hamilton. Previously, Dr Brown was a project manager with Auckland UniServices Limited, where she successfully managed several projects including the recently completed Janssen-cilag funded study: “The management of metastatic prostate cancer in high health need ethnic groups” (2012-2014) and the three year HRC funded “Midlands Prostate Cancer Study”, which investigated the costs and complications of screening for prostate cancer in general practice (2011-2014). Currently Charis is managing the HRC funded study entitled “Improving outcomes for women with breast cancer in New Zealand” (2014-2017) and contributes to a programme of research focused on primary care cancer, understanding the patient perspective, identifying inequities and improving outcomes. Dr Brown moved into health research after a managing various projects for the Ministry of Pacific Island Affairs in Auckland and comes to the field with a background in Pacific community health and marketing/communication, having completed her PhD exploring the use of consumption as a method of acculturation.

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| **Dr Kate Parker** |
| Membership category: | Community perspectives  |
| Date of appointment: | 11 November 2015 |
| Current term expires: | 11 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 a PhD in drug development from the University of Wales (Cardiff) and an MSc in Clinical Pharmacology from the University of Aberdeen.

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| **Dr Catherine Jackson** |
| Membership category: | Community perspectives  |
| Date of appointment: | 11 November 2015 |
| Current term expires: | 11 November 2018 |

Dr Catherine Jackson is currently employed as a Medical Officer of Health at Auckland Regional Public Health Service. She is currently involved in a number of research projects. She qualified with a medical degree in 1995 and a Masters of Public Health with honours in 2011. She has a range of clinical experience in child health and has been an investigator on a number of child health research projects. She holds a specialist qualification in Public Health Medicine and has an interest in vaccine preventable diseases, rheumatic fever, and child health. She is a member of the Health and Disability Ethics Committee Northern A.

### Former Members

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| **Ms Shamim Chagani** |
| Membership category: | Service provision  |
| Date of appointment: | 1 July 2015 |
| Current term expires: | 1 July 2016 |

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| Ms Susan Buckland |
| Membership category: | Consumer perspectives |
| Date of appointment: | 1 July 2015 |
| Current term expires: | 1 July 2016 |

## Attendance

The Northern A HDEC held 12 meetings in 2016.

|  |  |  |
| --- | --- | --- |
| **Members** | **Meetings** | **Total** |
| Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | 6 Dec | 15 Dec |  |
| **Lay and No-Lay members** | Cn | Dr Brian Fergus |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 12/12 |
| Cn | Ms Susan Buckland |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** |  |  |  |  | 7/8 |
| Cm | Dr Kate Parker |  | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | ***A*** |  | 9/11 |
| L | Ms Rosemary Abbott |  |  |  | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | ***A*** |  | 7/9 |
| L | Mr John Hancock (Co-opted from NTB HDEC) |  |  |  |  |  |  |  | **✓** |  |  |  |  |  | 1/1 |
| Cm | Mrs Phyllis Huitema (Co-opted from NTB Committee) |  |  |  |  |  |  |  |  | **✓** |  |  |  |  | 1/1 |
| Cm | Ms Tangihaere Macfarlane (Co-opted from NTB Committee) |  |  |  |  |  |  |  |  |  | **✓** |  |  |  | 1/1 |
| Cn | Ms Toni Millar |  |  |  |  |  |  |  |  |  |  | **✓** | **✓** |  | 2/2 |
| HP | Ms Shamim Chagani |  | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | ***A*** |  |  |  |  | 6/8 |
| E | Dr Angela Ballantyne (Co-opted from CEN Committee) |  |  |  |  |  |  |  |  |  |  |  | **✓** |  | 1/1 |
|  | HR | Dr Charis Brown |  | **✓** | ***A*** | **✓** | ***A*** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 9/12 |
|  | HR | Dr Karen Bartholomew |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 11/11 |
|  | HR | Dr Christine Crooks |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** |  | 10/11 |
|  | HP | Dr Catherine Jackson |  |  |  |  |  |  |  |  |  |  | ***A*** | **✓** |  | 1/2 |
|  | HR | Mrs Leesa Russell (Co-opted from NTB Committee) |  |  |  |  |  |  |  |  | **✓** |  |  | **✓** |  | 2/2 |
|  | Cn | Ms Raewyn Idoine (Co-opted from STH Committee) |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |
|  | HR | Dr Nicola Swain (Co-opted from STH Committee) |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |
|  | HR | Dr Patries Herst (Co-opted from CEN Committee) |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |
|  | L | Dr Cordelia Thomas (Co-opted from CEN Committee) |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |
|  | HR | Dr Peter Gallagher (Co-opted from CEN Committee) |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |
|  | HP | Dr Nora Lynch (Co-opted from NTB Committee) |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |

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| --- | --- | --- | --- | --- | --- | --- |
| Key: | L | Lawyer | P | Pharmacist/pharmacologist | ✓ | present |
|  | **E** | **Ethicist** | **B** | **Biostatistician** | ***A*** | apologies |
|  | **Cm** | **Community representative** | **HP** | **Health practitioner** | **X** | absent |
|  | Cn | Consumer representative | HR | Health researcher |  | not applicable |

## Training and conferences

HDEC members were invited to attend the following conferences in 2016:

* Annual Conference of the New Zealand Association of Clinical Research.

New Member Training was held in March 2016.

This training day covered the following topics:

• Why do we need ethics committees? A history of health research ethics in New Zealand and the current ethics landscape

• Ethical principles and underlying ethical considerations

• The HDEC Processes

• Use of Health Information

• Use of Tissue and Bio-banking

• Future Unspecified Research

• Informed Consent

• Non-consensual Research

• Vulnerable Populations and Studies Involving Children

• Māori and Indigenous Health Development

• Scientific Merit and Peer Review.

Contributors included:

• Associate Professor Martin Wilkinson (National Ethics Advisory Committee)

• Dr Karen Bartholomew (Member, Northern A Committee)

• Dr Angela Ballantyne (Member, Central Committee)

• Nic Aagaard and Philippa Bascand (Ministry of Health)

• Dr Helen Wihongi (ADHB Research Office).

A handbook was developed for new members and sent out prior to the new member training.

**Details of on-going training for EC members**

Pre-meeting training was conducted before a number of meetings throughout the year.

Topics covered included:

• Ethical Features of Health Research

• Use of Health Information for Research

• Non-consensual Research.

## Chairpersons’ meetings

There were two Chairs’ day meetings in 2016. The first meeting was on 29 May and the second meeting was on 1 November. The meetings were held at the Ministry of Health offices in Freyberg Building and Molesworth Street in Wellington. Dr Fergus attended both meetings.

# Applications reviewed

The Northern A HDEC received 173 applications in 2016. From the 173 applications, 109 applications were reviewed by the full committee and 64 were reviewed through the expedited pathway.

|  |  |  |
| --- | --- | --- |
| Full | Approved | 77 |
| Declined | 9 |
| Provisional Approval (as at 31 December 2016) | 23 |
| *Total (with a decision at 31 December 2016)* | 109 |
| Expedited | Approved | 61 |
| Declined | 0 |
| Provisional Approval (as at 31 December 2016) | 3 |
| *Total (with a decision at 31 December 2016)* | 64 |
| **Total applications reviewed** | **173** |

A summary of these applications can be found in Appendix 1.

# Complaints and overdue application summary

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

## Complaints received

The Northern A HDEC did not receive any complaints about the decision making process in 2016.

## Overdue review

During 2016, there were 25 instances where the review time was over 35 days for full applications and 27 where the review time was over 15 days for expedited applications.

#

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

## Applications reviewed by full committee

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study reference | Study status | Short title | Co-ordinating investigator | Application type | Date application validated | Date of first decision | Provisional response received | Date of final decision |
| 16/NTA/10 | Approve | AVeNew | Dr Stewart Hawkins | Intervention | 28/01/2016 | 11/02/2016 | 29/03/2016 | 21/04/2016 |
| 16/NTA/6 | Approve | AirSpiral and tracheostomy connector usability with myAIRVO 2 | Dr James Revie | Intervention | 28/01/2016 | 11/02/2016 | 23/02/2016 | 15/03/2016 |
| 16/NTA/18 | Approve | Evaluating the addition of Regional Analgesia to reduce post-operative delirium in patients having Hip Fracture surgery. (RASAPOD) | Dr Tin Chiu | Intervention | 25/02/2016 | 18/03/2016 | 24/03/2016 | 11/04/2016 |
| 16/NTA/21 | Approve | Development of the COMFORT Cohort | Prof. Richard Gearry | Observational | 25/02/2016 | 18/03/2016 | 29/03/2016 | 11/04/2016 |
| 16/NTA/22 | Approve | Prognostic models for women with breast cancer in New Zealand | Professor Mark Elwood | Observational | 25/02/2016 |  |  | 18/03/2016 |
| 16/NTA/23 | Approve | A Randomised, Double Blind, Placebo Controlled Study of Dysport Intradetrusor Treatments for Urinary Incontinence in Neurogenic Detrusor Overactivity Due to Spinal Cord Injury or Multiple Sclerosis | Professor Peter Gilling | Intervention | 25/02/2016 | 18/03/2016 | 11/04/2016 | 26/04/2016 |
| 16/NTA/50 | Approve | COMFORT Cohort Tissue Bank | Prof. Richard Gearry | Intervention | 25/02/2016 | 18/03/2016 | 30/03/2016 | 12/04/2016 |
| 16/NTA/33 | Approve | Top up 4 yr top up. Waikato Rangatahi Rheumatic Heart Disease Secondary Prevention Study  | Prof John Oetzel | Intervention | 31/03/2016 | 22/04/2016 | 25/07/2016 | 12/08/2016 |
| 16/NTA/34 | Approve | SOF/VEL Peri-Operative Transplant | Professor Ed Gane | Intervention | 31/03/2016 |  |  | 22/04/2016 |
| 16/NTA/35 | Approve | Percutaneous cannulation of the thoracic duct | Professor John Windsor | Intervention | 31/03/2016 |  |  | 22/04/2016 |
| 16/NTA/36 | Approve | Primary Prevention of Stroke in the Community | Prof Valery Feigin | Intervention | 31/03/2016 | 22/04/2016 | 3/05/2016 | 16/05/2016 |
| 16/NTA/38 | Approve | Probiotics & Prebiotics in Prediabetes | Ms Christine Barthow | Intervention | 31/03/2016 | 22/04/2016 | 11/05/2016 | 24/05/2016 |
| 16/NTA/40 | Decline | Automated assessment of functional recovery by an assistive device | Mr Michael Sampson | Intervention | 31/03/2016 |  |  | 22/04/2016 |
| 16/NTA/42 | Approve | A study assessing the similarity of Avastin® and the trial drug CBT 124 | Dr Christian Schwabe | Intervention | 31/03/2016 | 22/04/2016 | 6/05/2016 | 17/05/2016 |
| 16/NTA/44 | Approve | Study on the effect of Lambda in patients with Chronic Hepatitis D Infection | Professor Edward John Gane | Intervention | 31/03/2016 |  |  | 22/04/2016 |
| 16/NTA/54 | Approve | BLIS Tonsillitis Trial | Dr Tony Walls | Intervention | 28/04/2016 | 17/05/2016 | 18/05/2016 | 16/06/2016 |
| 16/NTA/55 | Approve | The gene related factors that contribute to chronic pain following breast cancer surgery  | Dr Daniel Chiang | Observational | 28/04/2016 | 17/05/2016 | 14/06/2016 | 4/07/2016 |
| 16/NTA/56 | Approve | ADHD and eye tracking with chiropractic intervention | Dr Kelly Jones | Intervention | 28/04/2016 | 17/05/2016 | 7/07/2016 | 2/08/2016 |
| 16/NTA/57 | Approve | MM-398-07-02-03 | Dr. Ben Lawrence | Intervention | 28/04/2016 |  |  | 17/05/2016 |
| 16/NTA/58 | Approve | A study of ARC-521 in healthy subjects and hepatitis B patients | Professor Ed Gane | Intervention | 28/04/2016 | 17/05/2016 | 23/05/2016 | 8/06/2016 |
| 16/NTA/60 | Approve | Randomized Sitagliptin Withdrawal Study | Dr John Baker | Intervention | 28/04/2016 | 17/05/2016 | 25/05/2016 | 14/06/2016 |
| 16/NTA/61 | Approve | Deprescribing anticholinergic and sedative medicines in residential aged care facilities | Nagham Nagham Ailabouni | Intervention | 28/04/2016 |  |  | 17/05/2016 |
| 16/NTA/63 | Approve | Behavioural Balloon Dilatation in UES Dysfunction | Ms Seh Ling Kwong | Intervention | 28/04/2016 | 17/05/2016 | 9/06/2016 | 27/06/2016 |
| 16/NTA/64 | Approve | Targeting Functional Recovery in Mood Disorders | Professor Richard Porter | Intervention | 28/04/2016 | 17/05/2016 | 23/05/2016 | 14/06/2016 |
| 16/NTA/75 | Approve | Adults coping with cancer mindfully | Mrs. Fernanda Fernandez Zimmermann | Intervention | 2/06/2016 | 21/06/2016 | 10/08/2016 | 6/09/2016 |
| 16/NTA/76 | Approve | Prescription medicine use in pregnancy | Dr Sarah Donald | Observational | 2/06/2016 |  |  | 21/06/2016 |
| 16/NTA/81 | Decline | Assessing the safety of co-administering medication and blood components | Dr Nicole Chien | Intervention | 2/06/2016 |  |  | 21/06/2016 |
| 16/NTA/82 | Approve | ZYN2-CL-03: STAR 1 | Dr Ian Rosemergy | Intervention | 2/06/2016 |  |  | 21/06/2016 |
| 16/NTA/83 | Approve | The DESappear Study | Associate Professor Andrew Holden | Intervention | 2/06/2016 |  |  | 21/06/2016 |
| 16/NTA/89 | Approve | CLIP Study | Dr Shay McGuinness | Intervention | 30/06/2016 |  |  | 21/07/2016 |
| 16/NTA/90 | Approve | The DIAMOND trial | Mrs Tanith Alexander | Intervention | 30/06/2016 |  |  | 21/07/2016 |
| 16/NTA/91 | Approve | KEEP IT | Dr Derisha Naicker | Observational | 30/06/2016 |  |  | 21/07/2016 |
| 16/NTA/92 | Approve | Safety and Efficacy of suvorexant (MK4305)for the treatment of insomnia in AD subjects | Dr Nigel Gilchrist | Intervention | 30/06/2016 | 21/07/2016 | 22/08/2016 | 23/08/2016 |
| 16/NTA/94 | Approve | Comparison of the blood levels of two forms of alitretinoin 30 mg capsule in healthy male volunteers under fed conditions | Dr Noelyn Hung | Intervention | 30/06/2016 |  |  | 21/07/2016 |
| 16/NTA/95 | Approve | Comparison of the blood levels of two forms of phentermine 40 mg in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | Intervention | 30/06/2016 |  |  | 21/07/2016 |
| 16/NTA/96 | Approve | The Chocolate Touch Study | Associate Professor Andrew Holden | Intervention | 30/06/2016 |  |  | 21/07/2016 |
| 16/NTA/97 | Approve | BIOSOLVE-IV | Prof Mark Webster | Intervention | 30/06/2016 | 21/07/2016 | 10/10/2016 | 11/10/2016 |
| 16/NTA/98 | Approve | A two-arm, randomised, parallel group study to evaluate the effect of fluticasone/formoterol breath actuated inhaler (BAI) or Relvar® Ellipta® DPI on ventilation heterogeneity in asthma | Dr Andrew Veale | Intervention | 30/06/2016 | 21/07/2016 | 29/07/2016 | 2/09/2016 |
| 16/NTA/99 | Approve | (duplicate) Study to Improve Adherence to Type 2 Diabetes Oral Medications Through Personalised Multi-Channel Interventions | Dr Jodie Main | Intervention | 30/06/2016 | 21/07/2016 | 9/08/2016 | 25/08/2016 |
| 16/NTA/108 | Approve | PROSPER | Dr Michelle Wilson | Observational | 26/07/2016 | 23/08/2016 | 30/08/2016 | 6/09/2016 |
| 16/NTA/109 | Approve | FAST Feasibility Study | Dr. Seif El-Jack | Intervention | 26/07/2016 | 23/08/2016 | 16/09/2016 | 26/09/2016 |
| 16/NTA/110 | Approve | Evaluation of the Safety of N1539 Following Major Surgery | Dr John Currie | Intervention | 26/07/2016 | 23/08/2016 | 26/08/2016 | 8/09/2016 |
| 16/NTA/111 | Approve | The REACTOR trial. Randomised Evaluation of Active Control of Temperature versus ORdinary temperature management  | Dr Paul Young | Intervention | 26/07/2016 |  |  | 23/08/2016 |
| 16/NTA/112 | Approve | The NZ PrEP study: A demonstration project | Dr Sunita Azariah | Intervention | 28/07/2016 | 23/08/2016 | 5/09/2016 | 15/09/2016 |
| 16/NTA/113 | Approve | Treatment of mild-moderate Impetigo | Dr Alison Leversha | Intervention | 28/07/2016 | 23/08/2016 | 18/10/2016 | 26/10/2016 |
| 16/NTA/116 | Approve | MS1819-SD phase IIa clinical trial for EPI caused by CP and/or distal pancreatectomy  | Dr Richard Stubbs | Intervention | 28/07/2016 | 23/08/2016 | 20/09/2016 | 27/09/2016 |
| 16/NTA/118 | Approve | He Kura: Asthma in Schools PHASE 2 (Asthma Trial) | Mrs Bernadette Jones | Intervention | 28/07/2016 | 23/08/2016 | 8/11/2016 | 17/11/2016 |
| 16/NTA/120 | Approve | Prediction of a response to treatment during first episode psychosis | Associate Professor Bruce Russell | Observational | 29/07/2016 | 23/08/2016 | 16/11/2016 | 28/11/2016 |
| 16/NTA/121 | Approve | Margins Project | A/Prof Ian Campbell | Observational | 29/07/2016 |  |  | 23/08/2016 |
| 16/NTA/123 | Approve | Prucalopride in postoperative ileus | Associate Professor Ian Bissett | Intervention | 29/07/2016 |  |  | 23/08/2016 |
| 16/NTA/124 | Decline | DARTS Study | Mr. Parma Nand | Intervention | 29/07/2016 |  |  | 23/08/2016 |
| 16/NTA/131 | Approve | Riociguat rEplacing PDE-5i therapy evaLuated Against Continued PDE-5i thErapy | Prof Lutz Beckert | Intervention | 1/09/2016 | 21/09/2016 | 30/11/2016 | 14/12/2016 |
| 16/NTA/132 | Approve | Acerta 309 | Dr Peter Ganly | Intervention | 1/09/2016 | 21/09/2016 | 18/11/2016 | 2/12/2016 |
| 16/NTA/133 | Approve | Whare Aroha transition study | Associate Professor Stephen Neville | Observational | 1/09/2016 | 21/09/2016 | 7/10/2016 | 27/10/2016 |
| 16/NTA/134 | Approve | KEYNOTE-355 for Triple Negative Breast Cancer | Dr Marion Kuper-Hommel | Intervention | 1/09/2016 | 21/09/2016 | 21/11/2016 | 13/12/2016 |
| 16/NTA/139 | Approve | Consolidation of Breast Cancer Registers | Ms Reena Ramsaroop | Observational | 1/09/2016 |  |  | 21/09/2016 |
| 16/NTA/140 | Decline | Effects of milk oligosaccharides on the gut-brain axis | Dr Caroline Thum | Intervention | 1/09/2016 |  |  | 21/09/2016 |
| 16/NTA/141 | Approve | ICON 2 Validation | Ms Hansinie Laing | Intervention | 1/09/2016 | 21/09/2016 | 19/10/2016 | 2/11/2016 |
| 16/NTA/142 | Approve | Keratin4VLU; A randomised trial | Dr Andrew Jull | Intervention | 1/09/2016 |  |  | 21/09/2016 |
| 16/NTA/144 | Approve | Dyspnoea during exercise | Dr Kevin Ellyett | Intervention | 1/09/2016 | 21/09/2016 | 4/10/2016 | 19/10/2016 |
| 16/NTA/146 | Approve | PREDICT KT Study | Dr Stuart Dalziel | Intervention | 1/09/2016 |  |  | 21/09/2016 |
| 16/NTA/148 | Approve | The SPACE Trial | Dr Natalie Walker | Intervention | 1/09/2016 |  |  | 21/09/2016 |
| 16/NTA/149 | Approve | A study of the Relative Oral Bioavailability of AL-3778 Capsules and Tablets and Drug Interaction in healthy subjects | Dr Christian Schwabe | Intervention | 1/09/2016 | 22/09/2016 | 22/09/2016 | 7/10/2016 |
| 16/NTA/156 | Approve | The EMBLEM UNTOUCHED Study | Dr Margaret Hood | Intervention | 29/09/2016 |  |  | 19/10/2016 |
| 16/NTA/157 | Provisionally approve | ITACS | Dr Shay McGuinness | Intervention | 29/09/2016 | 19/10/2016 |  |  |
| 16/NTA/158 | Approve | The feasibility of assessing changes in muscle strength in children with Cerebral Palsy following Chiropractic care  | Mrs Jenna Salmons | Intervention | 29/09/2016 | 19/10/2016 | 25/10/2016 | 16/11/2016 |
| 16/NTA/159 | Approve | The ACT-F Trial: Does active follow-up of invitation lead to higher participation in bowel screening by Māori, Pacific and Asians? | Dr Peter Sandiford | Intervention | 29/09/2016 |  |  | 19/10/2016 |
| 16/NTA/160 | Decline | A pilot randomised control trial (RCT) of group Cognitive Behaviour Therapy (CBT)to assist prisoners with symptoms of Traumatic Brain Injury (TBI)  | Ms Tracey Mitchell | Intervention | 29/09/2016 |  |  | 19/10/2016 |
| 16/NTA/162 | Approve | Long term outcomes following Traumatic Brain Injury (TBI) in Childhood | Dr Kelly Jones | Observational | 29/09/2016 | 19/10/2016 | 8/11/2016 | 24/11/2016 |
| 16/NTA/163 | Approve | Levels of cognitive dysfunction in service users of community mental health teams at Counties Manukau Health | Dr Melodie Barr | Observational | 29/09/2016 | 19/10/2016 | 25/10/2016 | 9/11/2016 |
| 16/NTA/164 | Approve | Prelude Study | Associate Professor Andrew Holden | Intervention | 29/09/2016 |  |  | 19/10/2016 |
| 16/NTA/165 | Approve | The Benzathine Penicillin G Formulation Preferences Study | Dr Dianne Sika-Paotonu | Observational | 29/09/2016 | 19/10/2016 | 30/11/2016 | 14/12/2016 |
| 16/NTA/166 | Approve | Community water supplies: ensuring microbial safety for disease prevention | Dr Liping Pang | Observational | 29/09/2016 |  |  | 19/10/2016 |
| 16/NTA/167 | Approve | A study of RO7020531 in healthy subjects and patients with chronic hepatitis B | Professor Ed Gane | Intervention | 29/09/2016 | 19/10/2016 | 25/10/2016 | 9/11/2016 |
| 16/NTA/169 | Approve | Pain Free TRUS B | Mr Nicholas Buchan | Intervention | 29/09/2016 | 19/10/2016 | 11/11/2016 | 1/12/2016 |
| 16/NTA/177 | Approve | ICU-ROX TRIPS | Ms Diane Mackle | Observational | 3/11/2016 | 28/11/2016 | 30/11/2016 | 8/12/2016 |
| 16/NTA/178 | Approve | Comparison of the blood levels of two forms of lorazepam 2. 5 mg in healthy volunteers under fasting conditions | Dr Noelyn Hung | Intervention | 3/11/2016 |  |  | 29/11/2016 |
| 16/NTA/179 | Provisionally approve | Study of safety, tolerability, pharmacokinetics and efficacy of LMB763 in patients with non-alcoholic steatohepatitis (NASH) | Dr Dean Quinn | Intervention | 3/11/2016 | 28/11/2016 | 14/12/2016 |  |
| 16/NTA/180 | Approve | Blood biomarkers for detection of disease burden in patients with melanoma | Prof. Cristin G Print | Observational | 3/11/2016 |  | 2/11/2016 | 28/11/2016 |
| 16/NTA/181 | Provisionally approve | NIVORAD | Mr Louis Lao | Intervention | 3/11/2016 | 29/11/2016 |  |  |
| 16/NTA/183 | Provisionally approve | Arthroresis screw in tibialis posterior reconstruction | Dr David Kieser | Intervention | 3/11/2016 | 29/11/2016 |  |  |
| 16/NTA/184 | Decline | Are k-wires better to be buried or unburied | Dr David Kieser | Intervention | 3/11/2016 |  |  | 29/11/2016 |
| 16/NTA/188 | Approve | A study of RO7062931 in healthy subjects and patients chronically infected with hepatitis B virus infection | Professor Ed Gane | Intervention | 3/11/2016 | 28/11/2016 | 6/12/2016 | 19/12/2016 |
| 16/NTA/190 | Provisionally approve | Child and Famly Unit patient and whānau feedback | Dr Josephine Stanton | Observational | 3/11/2016 | 28/11/2016 | 21/12/2016 |  |
| 16/NTA/192 | Provisionally approve | Comparison of the blood levels of two forms of phentermine 40 mg in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | Intervention | 3/11/2016 | 29/11/2016 |  |  |
| 16/NTA/194 | Provisionally approve | GALACTIC-HF | Professor Russell Scott | Intervention | 3/11/2016 | 28/11/2016 |  |  |
| 16/NTA/197 | Provisionally approve | Ketamine and Cognitive Behavioural Therapy for Treatment Resistant Depression | Ms Ella Kroch | Intervention | 24/11/2016 | 13/12/2016 |  |  |
| 16/NTA/199 | Decline | Beta-blocker adherence in LQTS | Dr Kathryn Waddell-Smith | Observational | 24/11/2016 |  |  | 13/12/2016 |
| 16/NTA/200 | Provisionally approve | Whānau Pakari on Orimupiko marae | Dr Yvonne Anderson | Intervention | 24/11/2016 | 13/12/2016 |  |  |
| 16/NTA/202 | Provisionally approve | GSK ASCEND-D 200807 | Dr Kannaiyan Rabindranath | Intervention | 24/11/2016 | 13/12/2016 |  |  |
| 16/NTA/203 | Provisionally approve | GSK ASCEND-ND 200808 | Dr Kannaiyan Rabindranath | Intervention | 24/11/2016 | 13/12/2016 |  |  |
| 16/NTA/204 | Provisionally approve | The Attain Study | Dr Kate Gardner | Intervention | 24/11/2016 | 13/12/2016 |  |  |
| 16/NTA/205 | Approve | (duplicate) Antibiotic Timing and Culture Yields in Paediatric Musculoskeletal Infection | Mr Matthew Boyle | Observational | 24/11/2016 |  |  | 13/12/2016 |
| 16/NTA/208 | Provisionally approve | The CREEDS Study | Assoc. Prof Jeremy Krebs | Intervention | 24/11/2016 | 13/12/2016 |  |  |
| 16/NTA/209 | Provisionally approve | NIMO-Prem | Dr Maria Saito Benz | Observational | 24/11/2016 | 13/12/2016 |  |  |
| 16/NTA/211 | Provisionally approve | Experiences of prescription and over-the-counter opioid dependence | Ms Carina Walters | Observational | 24/11/2016 | 13/12/2016 |  |  |
| 16/NTA/215 | Decline | Emergency treatment of anterior shoulder dislocations | Dr. Mark Sagarin | Observational | 24/11/2016 |  |  | 13/12/2016 |
| 16/NTA/227 | Provisionally approve | Nasal high flow in acute respiratory failure in AECOPD – A feasibility study | Dr James Fingleton | Observational | 1/12/2016 | 22/12/2016 |  |  |
| 16/NTA/228 | Provisionally approve | A Treatment Study of ACH-0144471 in Patients with Paroxysmal Nocturnal Hemoglobinuria | Dr Peter Browett | Intervention | 1/12/2016 | 22/12/2016 |  |  |
| 16/NTA/229 | Provisionally approve | A study comparing Filgotinib and placebo in Subjects with Moderately to Severely Active Crohn’s Disease | Dr Ben Griffiths | Intervention | 1/12/2016 | 22/12/2016 |  |  |
| 16/NTA/230 | Provisionally approve | A Long-Term Extension Study to Evaluate Filgotinib in Subjects with Crohn’s Disease | Dr Ben Griffiths | Intervention | 1/12/2016 | 22/12/2016 |  |  |
| 16/NTA/231 | Decline | REDUCCTION | Dr David Semple | Intervention | 1/12/2016 |  |  | 22/12/2016 |
| 16/NTA/232 | Approve | M16-126: A Study of Glecaprevir/Pibrentasvir in Adults with Chronic Hepatitis C Virus Genotype 5 or 6 | Prof Edward Gane | Intervention | 1/12/2016 |  |  | 22/12/2016 |
| 16/NTA/233 | Approve | Comparison of the blood levels of four forms of isotretinoin 10mg and 25mg capsules in healthy male volunteers under fasting conditions | Dr Noelyn Hung | Intervention | 1/12/2016 |  |  | 22/12/2016 |
| 16/NTA/234 | Approve | Can a new blood test predict dementia | Dr Joanna Williams | Observational | 1/12/2016 |  |  | 22/12/2016 |
| 16/NTA/235 | Provisionally approve | EFC14335\_ICARIA MM | Dr Hilary Blacklock | Intervention | 1/12/2016 | 22/12/2016 |  |  |
| 16/NTA/236 | Provisionally approve | An exploratory Safety Study of 480 Biomedical Mometasone Furoate Sinus Drug Depot (MFSDD) in Adult Subjects with Chronic Sinusitis | A/Prof Richard Douglas | Intervention | 1/12/2016 | 22/12/2016 |  |  |
| 16/NTA/237 | Provisionally approve | Endoform Dental Membrane - Clinical Feedback Study | Dr. Warwick Duncan | Intervention | 1/12/2016 | 22/12/2016 |  |  |
| 16/NTA/238 | Provisionally approve | Vitamin C for Severe Sepsis | Dr Anitra Carr | Intervention | 1/12/2016 | 22/12/2016 |  |  |

## Applications reviewed by expedited review

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study reference | Study status | Short title | Co-ordinating investigator | Application type | Date application validated | Date of first decision | Provisional response received | Date of final decision |
| 16/NTA/1 | Approve | Midwifery experience and perinatal outcomes | Dr Lynn Sadler | Observational | 21/01/2016 |  |  | 2/02/2016 |
| 16/NTA/2 | Approve | Feasibility study for detecting AF | Dr Katrina Poppe | Observational | 22/01/2016 |  |  | 2/02/2016 |
| 16/NTA/9 | Approve | Chiropractic and muscle haemodynamics | Dr Imran Khan Niazi | Intervention | 27/01/2016 |  |  | 9/02/2016 |
| 16/NTA/11 | Approve | Chiropractic care and perceived ankle instability chiropractic care and perceived ankle instability Chiropractic care and perceived ankle instability | Dr Imran Khan Niazi | Intervention | 1/02/2016 | 12/02/2016 | 29/02/2016 | 2/03/2016 |
| 16/NTA/12 | Approve | Ultrasound Assessment of Intimal Hyperplasia: A Feasibility Study | Mrs Jo Krysa | Observational | 3/02/2016 | 17/02/2016 | 22/02/2016 | 22/02/2016 |
| 16/NTA/13 | Approve | VTEC Auckland and Northland communities | Dr Arlo Upton | Observational | 3/02/2016 | 16/02/2016 | 19/02/2016 | 22/02/2016 |
| 16/NTA/14 | Approve | S-AVANT | Mrs Glenys Mahoney | Observational | 11/02/2016 |  |  | 23/02/2016 |
| 16/NTA/17 | Approve | MTR Sub-Study: MT in Liver Transplant Patients | Dr Kerry Gunn | Observational | 23/02/2016 | 9/03/2016 | 21/03/2016 | 24/03/2016 |
| 16/NTA/19 | Approve | Genetics in children with unilateral hearing loss | Dr. Maayan Gruber | Observational | 24/02/2016 | 9/03/2016 | 11/04/2016 | 15/04/2016 |
| 16/NTA/26 | Approve | A large increase in cases of infectious syphilis presenting to Auckland A large increase in cases of infectious syphilis presenting to Auckland Sexual Health Service in 2015 Sexual Health Service | Dr Sunita Azariah | Observational | 17/03/2016 | 30/03/2016 | 11/04/2016 | 18/04/2016 |
| 16/NTA/27 | Approve | Comprehensive pain assessment tool for chronic pancreatitis | Professor John Windsor | Observational | 17/03/2016 | 1/04/2016 |  | 1/04/2016 |
| 16/NTA/30 | Approve | Imaging of Anastomotic Intimal Hyperplasia: A Feasibility Study | Mrs Jo Krysa | Intervention | 24/03/2016 | 7/04/2016 | 14/04/2016 | 15/04/2016 |
| 16/NTA/32 | Approve | Talking about Health | Dr Claire Budge | Observational | 30/03/2016 | 13/04/2016 | 18/04/2016 | 20/04/2016 |
| 16/NTA/39 | Approve | 30 day post-operative mortality at Starship Hospital 2010-2015 | Dr Morgan Edwards | Observational | 31/03/2016 | 13/04/2016 | 23/05/2016 | 25/05/2016 |
| 16/NTA/41 | Approve | Osteomyelitis- Myositis Complex at CMDHB | Dr Bonnie Leung | Observational | 1/04/2016 | 14/04/2016 | 18/04/2016 | 20/04/2016 |
| 16/NTA/43 | Approve | HPV vaccination status and delivery outcomes | Dr Beverley Lawton | Observational | 1/04/2016 | 18/04/2016 | 5/05/2016 | 6/05/2016 |
| 16/NTA/29 | Approve | WellText | Professor Cliona Ni Mhurchu | Observational | 4/04/2016 |  |  | 19/04/2016 |
| 16/NTA/48 | Approve | Prevalence, Impact and Characteristics of Persistent Pain after Breast Cancer Surgery | Dr Daniel Chiang | Observational | 7/04/2016 | 20/04/2016 | 9/05/2016 | 10/05/2016 |
| 16/NTA/49 | Approve | Exploring the medicines information needs of patients | Ms Amy Chan | Observational | 11/04/2016 | 26/04/2016 | 13/06/2016 | 14/06/2016 |
| 16/NTA/51 | Approve | Laparoscopic Silastic Ring Omega Loop Gastric Bypass (SR-OLGBP): 10 year results from a single centre | Mr Michael Booth | Observational | 15/04/2016 |  |  | 4/05/2016 |
| 16/NTA/53 | Approve | Parkinson’s disease: A voice, singing and music Study | Mr Robin Martin Matthews | Intervention | 21/04/2016 | 4/05/2016 | 17/05/2016 | 23/05/2016 |
| 16/NTA/62 | Approve | Historical incidence of earthquake-related fatalities in New Zealand | Ms Shannon Abeling | Observational | 29/04/2016 | 11/05/2016 | 20/07/2016 | 5/08/2016 |
| 16/NTA/66 | Approve | Comparative effectiveness and safety of metformin versus insulin for gestational diabetes | Dr. Sarah Radke | Observational | 3/05/2016 | 17/05/2016 | 23/05/2016 | 24/05/2016 |
| 16/NTA/65 | Approve | Effects of human gut microbiome encapsulation, storage, and digestion on microbial populations | Professor Wayne Cutfield | Observational | 9/05/2016 |  |  | 25/05/2016 |
| 16/NTA/67 | Approve | Reliability of Point of Care Ketone Trial (ROCKET) | Dr Deborah Harris | Observational | 16/05/2016 |  |  | 30/05/2016 |
| 16/NTA/69 | Approve | Supporting on-line health information needs | Dr Susan Wells | Observational | 17/05/2016 | 30/05/2016 | 9/06/2016 | 10/06/2016 |
| 16/NTA/70 | Approve | Characterising the immune response to Staphylococcus aureus | Dr Ayesha Verrall | Observational | 17/05/2016 |  |  | 30/05/2016 |
| 16/NTA/68 | Approve | Social perception in Mild Cognitive Impairment | Ms. Sandhya Fernandez | Observational | 18/05/2016 | 30/05/2016 | 5/07/2016 | 8/07/2016 |
| 16/NTA/74 | Approve | AbleX stroke rehab project | Mrs Ruth McLaren | Intervention | 26/05/2016 | 8/06/2016 | 21/06/2016 | 22/06/2016 |
| 16/NTA/77 | Approve | Anaesthesia Stroke Study | Dr Gemma Malpas | Observational | 1/06/2016 |  |  | 16/06/2016 |
| 16/NTA/79 | Approve | Curie Score | Dr Tristan Pettit | Observational | 2/06/2016 | 16/06/2016 | 22/06/2016 | 27/06/2016 |
| 16/NTA/80 | Approve | MRI study of the anatomy of the DRUJ | Mr Wolfgang Heiss-Dunlop | Observational | 2/06/2016 | 16/06/2016 | 5/08/2016 | 26/08/2016 |
| 16/NTA/86 | Approve | SPGeTTI-II | Professor Chris Bullen | Intervention | 10/06/2016 |  |  | 22/06/2016 |
| 16/NTA/87 | Approve | Frequency of manual therapy treament for individuals with knee osteoarthritis: a feasibility study | Dr Cathy Chapple | Intervention | 14/06/2016 |  |  | 29/06/2016 |
| 16/NTA/93 | Approve | Gas narcosis in hyperbaric environments | Mr Xavier Vrijdag | Intervention | 30/06/2016 | 13/07/2016 | 31/08/2016 | 8/09/2016 |
| 16/NTA/101 | Approve | Laser Therapy for Lymphedema: Feasibility Trial | Professor David Baxter | Intervention | 14/07/2016 | 28/07/2016 | 2/09/2016 | 2/09/2016 |
| 16/NTA/102 | Approve | Outcomes following silicone metacarpophalangeal joint implant arthroplasty treated in a dynamic splint | Ms Julie Collis | Observational | 14/07/2016 | 27/07/2016 | 2/08/2016 | 4/08/2016 |
| 16/NTA/106 | Approve | An RCT of mindfulness for colorectal cancer | Dr Andrew McCombie | Intervention | 20/07/2016 | 1/08/2016 | 5/08/2016 | 10/08/2016 |
| 16/NTA/104 | Approve | Comparison of Cough Strength in Patients with dysphagia and healthy participants | Miss Emma Wallace | Observational | 21/07/2016 |  |  | 5/08/2016 |
| 16/NTA/105 | Approve | Voluntary tremor suppression in Parkinson's disease | Dr Rebekah Blakemore | Intervention | 21/07/2016 | 2/08/2016 | 11/08/2016 | 22/08/2016 |
| 16/NTA/107 | Approve | PIPEF - Propofol Pain Study | Ass Prof Dr R Ross Kennedy | Intervention | 21/07/2016 |  |  | 5/08/2016 |
| 16/NTA/115 | Approve | Vaginal prostaglandins for IOL with term PROM | Dr Mei Ling Pearson | Observational | 27/07/2016 | 10/08/2016 | 18/08/2016 | 24/08/2016 |
| 16/NTA/127 | Approve | Multinodular goitre study | Dr Marianne Elston | Observational | 1/08/2016 |  |  | 19/08/2016 |
| 16/NTA/128 | Approve | Defining “normal”: A prospective analysis of synovial fluid from non-septic knees | Dr Rushi chandar Penumarthy | Observational | 3/08/2016 | 24/08/2016 | 2/09/2016 | 6/09/2016 |
| 16/NTA/130 | Approve | Riboflavin prior to cystoscopy | Associate Professor Michael Stitely | Intervention | 25/08/2016 | 7/09/2016 | 25/08/2016 | 19/09/2016 |
| 16/NTA/136 | Approve | Blood test handling and stability study (for i-STAT cardiac troponin I) | Dr Martin Than | Observational | 28/08/2016 | 15/09/2016 | 13/10/2016 | 17/10/2016 |
| 16/NTA/151 | Approve | Achieving healthy weight gain in pregnancy | Dr Kirsten Coppell | Intervention | 7/09/2016 |  |  | 21/09/2016 |
| 16/NTA/152 | Approve | Gram-negative Extreme Resistance at Middlemore 1 - Pilot Study (GERMS-1) | Dr Chris Hopkins | Observational | 8/09/2016 | 22/09/2016 | 18/10/2016 | 21/10/2016 |
| 16/NTA/153 | Approve | Acute mountain sickness and the kidneys | Dr Mickey Fan | Intervention | 9/09/2016 | 23/09/2016 | 13/10/2016 | 17/10/2016 |
| 16/NTA/154 | Approve | Weaning foods, gut bacteria and health | Dr Shanthi Parkar | Observational | 9/09/2016 | 23/09/2016 | 5/10/2016 | 7/10/2016 |
| 16/NTA/172 | Approve | Gut Microbiome Transfer for Severe Adolescent Obesity | Professor Wayne Cutfield | Intervention | 6/10/2016 | 20/10/2016 | 4/11/2016 | 8/11/2016 |
| 16/NTA/173 | Approve | Developing Diagnostic & Prognostic Tests for Prostate Cancer Using Multiple RNA Biomarker Amplicon Sequencing (RBAS) | Dr Gen Johnston | Observational | 19/10/2016 | 1/11/2016 | 8/11/2016 | 8/11/2016 |
| 16/NTA/174 | Provisionally approve | TVT outcomes in obesity | Dr Nicola Boyd | Observational | 21/10/2016 | 8/11/2016 |  |  |
| 16/NTA/175 | Approve | The effect of different preparation information on side effects following intravenous iron infusion | Professor Keith Petrie | Intervention | 25/10/2016 | 8/11/2016 | 21/11/2016 | 21/11/2016 |
| 16/NTA/189 | Approve | YOD - Waikato | Dr Lochanie Fonseka | Observational | 2/11/2016 |  |  | 17/11/2016 |
| 16/NTA/206 | Approve | Omega-3 fatty acids and mild traumatic brain injury | Ms Brylee Cresswell | Intervention | 18/11/2016 | 5/12/2016 | 14/12/2016 | 19/12/2016 |
| 16/NTA/214 | Approve | 30-day Mortality of Patients Admitted to Intensive Care Unit with Acute Upper Gastrointestinal-Bleed (AUGIB) | Dr Junaid Beig | Observational | 18/11/2016 | 30/11/2016 | 13/12/2016 | 14/12/2016 |
| 16/NTA/217 | Provisionally approve | CROSSFIRE | Dr Ilia Elkinson | Intervention | 22/11/2016 | 30/11/2016 |  |  |
| 16/NTA/220 | Approve | The effect of different preparation information on side effects following colonoscopy | Professor Keith Petrie | Intervention | 23/11/2016 | 7/12/2016 | 14/12/2016 | 19/12/2016 |
| 16/NTA/225 | Approve | Linking days alive and out of hospital with surgical site infection: the ‘LASSI’ feasibility study | Professor Alan Merry | Observational | 25/11/2016 | 8/12/2016 | 13/12/2016 | 14/12/2016 |
| 16/NTA/226 | Provisionally approve | High Dose Rate (HDR) brachytherapy as a salvage treatment for locally recurrent prostate cancer | Mr Dean Paterson | Observational | 29/11/2016 | 9/12/2016 |  |  |
| 16/NTA/239 | Approve | Assessment of productive bioactivation of cyclophosphamide | Dr Nuala Helsby | Observational | 6/12/2016 |  |  | 19/12/2016 |
| 16/NTA/240 | Approve | Myocardial Perfusion Scan (MPS) in CKD 5 | Dr Margaret Fisher | Observational | 6/12/2016 |  |  | 19/12/2016 |
| 16/NTA/241 | Approve | Urinary Biomarkers for Inflammatory Bowel Disease | Dr Sundaram (Sunny) Veerappan | Observational | 14/12/2016 |  |  | 22/12/2016 |

## Overdue full applications

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| --- | --- | --- | --- | --- | --- | --- |
| Reference | Short title | CI name | Review type | Decision | Days overdue | Reason overdue |
| 16/NTA/108 | PROSPER | Dr Michelle Wilson | HDEC-Full Review | Approve | 1 | Secretariat Delay |
| 16/NTA/112 | The NZ PrEP study: A demonstration project | Dr Sunita Azariah | HDEC-Full Review | Approve | 1 | Secretariat Delay |
| 16/NTA/149 | A study of the Relative Oral Bioavailability of AL-3778 Capsules and Tablets and Drug Interaction in healthy subjects | Dr Christian Schwabe | HDEC-Full Review | Approve | 1 | Committee Member Delay |
| 16/NTA/162 | Long term outcomes following Traumatic Brain Injury (TBI) in Childhood | Dr Kelly Jones | HDEC-Full Review | Approve | 1 | Committee Member Delay |
| 16/NTA/10 | AVeNew | Dr Stewart Hawkins | HDEC-Full Review | Approve | 2 | Secretariat Delay |
| 16/NTA/120 | Prediction of a response to treatment during first episode psychosis | Associate Professor Bruce Russell | HDEC-Full Review | Approve | 2 | Secretariat Delay |
| 16/NTA/23 | A Randomised, Double Blind, Placebo Controlled Study of Dysport Intradetrus or Treatments for Urinary Incontinence in Neurogenic Detrusor Overactivity Due to Spinal Cord Injury or Multiple Sclerosis | Professor Peter Gilling | HDEC-Full Review | Approve | 2 | Secretariat Delay |
| 16/NTA/63 | Behavioural Balloon Dilatation in UES Dysfunction | Ms Seh Ling Kwong | HDEC-Full Review | Approve | 2 | Committee Member Delay |
| 16/NTA/99 | (duplicate) Study to Improve Adherence to Type 2 Diabetes Oral Medications Through Personalised Multi-Channel Interventions | Dr Jodie Main | HDEC-Full Review | Approve | 2 | Committee Member Delay |
| 16/NTA/109 | FAST Feasibility Study | Dr. Seif El-Jack | HDEC-Full Review | Approve | 3 | Committee Member Delay |
| 16/NTA/188 | A study of RO7062931 in healthy subjects and patients chronically infected with hepatitis B virus infection | Professor Ed Gane | HDEC-Full Review | Approve | 3 | Holiday Shut Down Period |
| 16/NTA/55 | The gene related factors that contribute to chronic pain following breast cancer surgery  | Dr Daniel Chiang | HDEC-Full Review | Approve | 4 | Committee Member Delay and Secretariat Delay |
| 16/NTA/60 | Randomized Sitagliptin Withdrawal Study | Dr John Baker | HDEC-Full Review | Approve | 4 | Committee Member Delay |
| 16/NTA/133 | Whare Aroha transition study | Associate Professor Stephen Neville | HDEC-Full Review | Approve | 5 | Committee Member Delay |
| 16/NTA/169 | Pain Free TRUS B | Mr Nicholas Buchan | HDEC-Full Review | Approve | 5 | Committee Member Delay |
| 16/NTA/18 | Evaluating the addition of Regional Analgesia to reduce post-operative delirium in patients having Hip Fracture surgery. (RASAPOD) | Dr Tin Chiu | HDEC-Full Review | Approve | 5 | Secretariat Delay |
| 16/NTA/33 | Top up 4 yr top up. Waikato Rangatahi Rheumatic Heart Disease Secondary Prevention Study  | Prof John Oetzel | HDEC-Full Review | Approve | 5 | Committee Member Delay |
| 16/NTA/110 | Evaluation of the Safety of N1539 Following Major Surgery | Dr John Currie | HDEC-Full Review | Approve | 6 | Committee Member Delay |
| 16/NTA/64 | Targeting Functional Recovery in Mood Disorders | Professor Richard Porter | HDEC-Full Review | Approve | 6 | Committee Member Delay |
| 16/NTA/134 | KEYNOTE-355 for Triple Negative Breast Cancer | Dr Marion Kuper-Hommel | HDEC-Full Review | Approve | 7 | Incomplete Provisional Response |
| 16/NTA/158 | The feasibility of assessing changes in muscle strength in children with Cerebral Palsy following Chiropractic care | Mrs Jenna Salmons | HDEC-Full Review | Approve | 7 | Committee Member Delay |
| 16/NTA/56 | ADHD and eye tracking with chiropractic intervention | Dr Kelly Jones | HDEC-Full Review | Approve | 10 | Committee Member Delay |
| 16/NTA/75 | Adults coping with cancer mindfully | Mrs. Fernanda Fernandez Zimmermann | HDEC-Full Review | Approve | 11 | Committee Member Delay |
| 16/NTA/54 | BLIS Tonsillitis Trial | Dr Tony Walls | HDEC-Full Review | Approve | 13 | Incomplete Provisional Response |
| 16/NTA/98 | A two-arm, randomised, parallel group study to evaluate the effect of fluticasone/formoterol breath actuated inhaler (BAI) or Relvar® Ellipta® DPI on ventilation heterogeneity in asthma | Dr Andrew Veale | HDEC-Full Review | Approve | 21 | Committee Member Delay |

## Overdue expedited applications

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| Reference | Short title | CI name | Review type | Decision | Days overdue | Reason overdue |
| 16/NTA/13 | VTEC Auckland and Northland communities | Dr Arlo Upton | HDEC-Expedited Review | Approve | 1 | Committee Member Delay |
| 16/NTA/154 | Weaning foods, gut bacteria and health | Dr Shanthi Parkar | HDEC-Expedited Review | Approve | 1 | Committee Member Delay |
| 16/NTA/32 | Talking about Health | Dr Claire Budge | HDEC-Expedited Review | Approve | 1 | Committee Member Delay |
| 16/NTA/49 | Exploring the medicines information needs of patients | Ms Amy Chan | HDEC-Expedited Review | Approve | 1 | Committee Member Delay |
| 16/NTA/65 | Effects of human gut microbiome encapsulation, storage, and digestion on microbial populations | Professor Wayne Cutfield | HDEC-Expedited Review | Approve | 1 | Secretariat delay |
| 16/NTA/106 | An RCT of mindfulness for colorectal cancer  | Dr Andrew McCombie | HDEC-Expedited Review | Approve | 2 | Committee Member Delay |
| 16/NTA/130 | Riboflavin prior to cystoscopy | Associate Professor Michael Stitely | HDEC-Expedited Review | Approve | 2 | Secretariat delay |
| 16/NTA/152 | Gram-negative Extreme Resistance at Middlemore 1 - Pilot Study (GERMS-1) | Dr Chris Hopkins | HDEC-Expedited Review | Approve | 2 | Committee Member Delay |
| 16/NTA/127 | Multinodular goitre study | Dr Marianne Elston | HDEC-Expedited Review | Approve | 3 | Secretariat delay |
| 16/NTA/153 | Acute mountain sickness and the kidneys | Dr Mickey Fan | HDEC-Expedited Review | Approve | 3 | Secretariat delay |
| 16/NTA/17 | MTR Sub-Study: MT in Liver Transplant Patients | Dr Kerry Gunn | HDEC-Expedited Review | Approve | 3 | Committee Member Delay |
| 16/NTA/172 | Gut Microbiome Transfer for Severe Adolescent Obesity | Professor Wayne Cutfield | HDEC-Expedited Review | Approve | 3 | Committee Member Delay |
| 16/NTA/19 | Genetics in children with unilateral hearing loss | Dr. Maayan Gruber | HDEC-Expedited Review | Approve | 3 | Committee Member Delay |
| 16/NTA/43 | HPV vaccination status and delivery outcomes | Dr Beverley Lawton | HDEC-Expedited Review | Approve | 3 | Committee Member Delay |
| 16/NTA/220 | The effect of different preparation information on side effects following colonoscopy | Professor Keith Petrie | HDEC-Expedited Review | Approve | 4 | Committee Member Delay and Secretariat delay |
| 16/NTA/51 | Laparoscopic Silastic Ring Omega Loop Gastric Bypass (SR-OLGBP): 10 year results from a single centre | Mr Michael Booth | HDEC-Expedited Review | Approve | 4 | Secretariat delay |
| 16/NTA/53 | Parkinson’s disease: A voice, singing and music Study | Mr Robin Martin Matthews | HDEC-Expedited Review | Approve | 4 | Secretariat delay |
| 16/NTA/79 | Curie Score | Dr Tristan Pettit | HDEC-Expedited Review | Approve | 4 | Committee Member Delay |
| 16/NTA/115 | Vaginal prostaglandins for IOL with term PROM | Dr Mei Ling Pearson | HDEC-Expedited Review | Approve | 5 | Committee Member Delay |
| 16/NTA/26 | A large increase in cases of infectious syphilis presenting to Auckland A large increase in cases of infectious syphilis presenting to Auckland Sexual Health Service in 2015 Sexual Health Service | Dr Sunita Azariah | HDEC-Expedited Review | Approve | 5 | Committee Member Delay |
| 16/NTA/93 | Gas narcosis in hyperbaric environments | Mr Xavier Vrijdag | HDEC-Expedited Review | Approve | 6 | Committee Member Delay |
| 16/NTA/136 | Blood test handling and stability study (for i-STAT cardiac troponin I) | Dr MARTIN THAN | HDEC-Expedited Review | Approve | 7 | Secretariat delay |
| 16/NTA/206 | Omega-3 fatty acids and mild traumatic brain injury | Ms Brylee Cresswell | HDEC-Expedited Review | Approve | 7 | Committee Member Delay and Secretariat delay |
| 16/NTA/105 | Voluntary tremor suppression in Parkinson's disease | Dr Rebekah Blakemore | HDEC-Expedited Review | Approve | 8 | Committee Member Delay |
| 16/NTA/128 | Defining “normal”: A prospective analysis of synovial fluid from non-septic knees | Dr Rushi chandar Penumarthy | HDEC-Expedited Review | Approve | 10 | Committee Member Delay |
| 16/NTA/62 | Historical incidence of earthquake-related fatalities in New Zealand | Ms Shannon Abeling | HDEC-Expedited Review | Approve | 13 | Incomplete provisional approval response |
| 16/NTA/80 | MRI study of the anatomy of the DRUJ | Mr Wolfgang Heiss-Dunlop | HDEC-Expedited Review | Approve | 20 | Incomplete provisional approval response |

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)