

Northern A Health and Disability Ethics Committee

Annual Report
2015

Citation: New Zealand Health and Disability Ethics Committee. 2018. *Northern A Health and Disability Ethics Committee: Annual Report 2015.* Wellington: Ministry of Health.

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

ISBN 978-1-98-856807-2 (online)
HP 6953

This document is available on the New Zealand Health and Disability Ethics Committee website: www.ethicscommittees.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](#_Toc526402532)

[Chairperson’s report 2](#_Toc526402533)

[Membership and attendance 4](#_Toc526402534)

[Membership 4](#_Toc526402535)

[Attendance 6](#_Toc526402536)

[Training and conferences 7](#_Toc526402537)

[Chairpersons’ meetings 7](#_Toc526402538)

[Applications reviewed 8](#_Toc526402539)

[Complaints received 8](#_Toc526402540)

[Overdue review 8](#_Toc526402541)

[Appendix 1: Details of applications reviewed 9](#_Toc526402542)

[Applications reviewed by full committee 9](#_Toc526402543)

[Applications reviewed by expedited review 18](#_Toc526402544)

[Overdue full applications 22](#_Toc526402545)

[Overdue expedited applications 24](#_Toc526402546)

# 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

The year has seen further embedding of the new system and by and large the ethical review is working quite well, both in terms of usability of the site and the quality of information supplied by the researchers.

The Committee meetings have been proficiently supported by the administration staff, we now have quite detailed discussion points in our review document and generally we tend to have a high full approval record of applications.

To some extent ours is an educative process of the researchers. They respond well to committee suggestions and their future applications generally show an improved quality, particularly in the areas of Māori consultation, peer review and future unspecified research and bio banking of tissue. This is helped by improved explanatory documents available to the researchers on our website, which assists in the quality of their submission. Many are now long time users of the application process. This allows the Committee to move on and probe deeper on some ethical issues. Researchers seem to be getting a better grip on the issues surrounding the area of informed consent, delayed consent, consenting of children. There is always a full discussion on enrolment of participants unable to consent, focussing on the issue that enrolment must be considered to be in the best interest of the participant.

The committee has been under pressure with maintaining a full membership (meaning that at times we have had to second members from other committees), but there has been a steady recruitment of new members so that by the start of 2016 the Committee was back to full membership. The Committee is notable for its lack of clinicians and this may need to be addressed when the next appointments are made; it should be noted that there is a distinct lack of clinicians applying when the positions are advertised.

The expedited process through the online system is working well. We make every endeavour to meet the deadlines for review, and in cases where this has not happened it is usually due to other reasons. For example we may have a query of the researcher but the response might still be lacking some detail requested. A timely response is also reliant on the availability of reviewers, who it should be remembered, have fulltime jobs in their own right, and other commitments.

Anecdotally, there appears to be an increase in applications where we are the first in the world to consider the application. We also handle our fair share of First-In-Human trials, but our committee has sufficient maturity and experience to handle the ethical issues. There continues to be applications for new drugs (we are assisted greatly by the independent SCOTT process with regard to these), new uses for existing drugs, and generic drugs, perhaps a reflection of the number of existing drugs coming off patent. Drug trials probably make up about 1/3rd to one half of our applications.

The workload on Chairs remains heavy and issues surrounding the time commitment by Chairs, the change in complexity of the work, have still to be addressed; we have been waiting for a couple of years for a formal process of re-evaluation of the positions to be commenced. There has been considerable goodwill expended by the Chairs and this needs to be formally recognised.

Finally, there still remains a clear and urgent need to increase resource allocation within the HDEC section of the MOH, to address the balance between straight administration support and policy advice. There is now enough accumulated evidence to identify actual workloads (and not the theoretical work estimates prior to the system revamp).

****

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. Three members’ terms expired during 2015. Six members were appointed in 2015.

## Membership

### Lay members

|  |
| --- |
| **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.

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

Ms Buckland is a freelance journalist and editor, specialising in the arts and travel writing. She previously managed public relations for Air New Zealand (1979–1992) and was an independent public relations consultant from 1992–2005. Ms Buckland is an elected member of Auckland District Health Board (2007–present), a Starship Foundation Trustee (2007–present) and is a Professional Conduct Committee member of the Medical Council of New Zealand. She has previously been Chair of New Zealand Travel Communicators (1992–2000) and a Trustee for World Wildlife Fund New Zealand (1997–1998). She completed a Bachelor of Arts at Auckland University (1996) and a Diploma of Italian Language at Perugia University (1967).

|  |
| --- |
| **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.

### Non-lay members

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

Ms Shamim Chagani is working as a Charge Nurse Manager at Counties Manukau Health. She previously worked as a Nurse Educator at Mercy Ascot and Staff Nurse at Tairawhiti District Health Board. She completed Bachelor of Nursing, Post Graduate Diploma in Health Service Management at Massey University and is currently pursuing Master of Management in Health Service Management from Massey University.

|  |
| --- |
| **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.

|  |
| --- |
| **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.

|  |
| --- |
| **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.

### Former Members

|  |
| --- |
| **Mr Kerry Hiini** |
| Membership category: | Community perspectives  |
| Date of appointment: | 1 July 2012 |
| Term expired: | 1 July 2015 |

|  |
| --- |
| **Ms Michèle Stanton** |
| Membership category: | The Law  |
| Date of appointment: | 1 July 2012 |
| Term expired: | 1 July 2015 |
| **Dr Mark Smith** |
| Membership category: | Intervention studies  |
| Date of appointment: | 1 September 2014 |
| Term expired: | 1 September 2015 |

## Attendance

The Northern A HDEC held 13 meetings in 2015.

|  |  |  |
| --- | --- | --- |
| **Members** | **Meetings** | **Total** |
| Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct 13 | Oct 21 | Nov | 1 Dec | 18 Dec |  |
| **Lay and No-Lay members** | Cn | Dr Brian Fergus |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | 12/13 |
| Cn | Ms Susan Buckland |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | ***A*** | 11/13 |
| L | Ms Michele Stanton |  | ***A*** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** |  |  |  |  | ***A*** | 6/9 |
| Cm | Mr Kerry Hiini |  | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **X** | **✓** | **✓** | **✓** |  |  | 9/13 |
| HP | Ms Shamim Chagani |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | ***A*** | 11/13 |
| HP | Dr Mark Smith |  | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | ***A*** | ***A*** |  |  |  | 7/10 |
| HR | Dr Karen Bartholomew |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | ***A*** | **✓** | ***A*** | 10/13 |
| HR | Dr Christine Crooks |  | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | 11/13 |
| HP | Dr Nicola Swain(Co-opted from STH HDEC) |  |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |
| E | Ms Kate O’Connor (Co-Opted from NTB HDEC) |  |  |  |  |  |  | **✓** |  |  |  |  | **✓** |  |  | 2/2 |
| Cn | Mrs Helen Walker (Co-Opted from CEN HDEC) |  |  |  |  |  |  |  |  | **✓** |  |  |  |  |  | 1/1 |
| Cm | Mrs Maliaga Erick (Co-Opted from NTB HDEC) |  |  |  |  |  |  |  |  |  | **✓** |  |  |  | **✓** | 2/2 |
| HR | Dr Sarah Gunningham (Co-opted from STH HDEC) |  |  |  |  |  |  |  |  |  |  | **✓** |  |  |  | 1/1 |
| Cm | Miss Tangihaere Macfarlane (Co-opted from NTB HDEC) |  |  |  |  |  |  |  |  |  |  | **✓** |  |  | **✓** | 2/2 |
| HR | Dr Patries Herst (Co-opted from CEN HDEC) |  |  |  |  |  |  |  |  |  |  | **✓** |  |  | **✓** | 2/2 |
| HR | Dr Charis Brown |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | **✓** | 2/2 |
| CM | Dr Kate Parker |  |  |  |  |  |  |  |  |  | **\** |  |  | **✓** | ***A*** | 1/2 |
|  | Cn | Ms Raewyn Idioine(Co-opted from STH HDEC) |  |  |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 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 2015:

* Ethics in Practice - Dunedin
* Māori Health Research Ethics Symposium – Wellington
* Indigenous Approaches to Research and Tissue Banking – Auckland.

There was no new member training held in 2015.

## Chairpersons’ meetings

There were three Chairs’ day meetings in 2015. The meetings were held at the Freyberg Building in Wellington. Dr Fergus attended three meetings.

# Applications reviewed

The Northern A HDEC reviewed 167 applications in 2015. From the 167 applications reviewed, 116 applications were reviewed by the full committee and 51 were reviewed through the expedited pathway.

|  |  |  |
| --- | --- | --- |
| Full | Approved | 103 |
| Declined | 1 |
| Provisional Approval (as at 31 December 2015) | 12 |
| *Total (with a decision at 31 December 2015)* | 116 |
| Expedited | Approved | 47 |
| Declined | 1 |
| Provisional Approval (as at 31 December 2015) | 3 |
| *Total (with a decision at 31 December 2015)* | 51 |
| **Total applications reviewed** | ***167*** |

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 Committee did not receive any complaints about the decision making process in 2016.

## Overdue review

During 2015 there were 22 instances where the review time was over 35 days for full applications and 15 where the review time was over 15 days for expedited applications.

See Appendix 1 for more information.

# Appendix 1: Details of applications reviewed

## 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 |
| 15/NTA/11 | Approve | Stroke navigator development study | Dr Dianne E Roy | Intervention | 29/01/2015 | 13/02/2015 | 24/02/2015 | 12/03/2015 |
| 15/NTA/2 | Approve | A study of Tiotropium dry powder delivered by the Monohaler device in subjects with COPD | Dr Dean Quinn | Intervention | 29/01/2015 | 13/02/2015 | 25/02/2015 | 18/03/2015 |
| 15/NTA/4 | Approve | Investigating the effect of AIRVO on PaCO2 in patients with stable COPD | Prof Richard Beasley | Intervention | 29/01/2015 | 13/02/2015 | 19/02/2015 | 25/02/2015 |
| 15/NTA/6 | Approve | PINBALL Pilot RCT | Dr Shay McGuinness | Intervention | 29/01/2015 |  |  | 13/02/2015 |
| 15/NTA/7 | Approve | COBALT Open Label Extension (OLE) study | Dr Sunil Kumar | Intervention | 29/01/2015 | 13/02/2015 | 10/03/2015 | 31/03/2015 |
| 15/NTA/8 | Approve | Probenecid to boost flucloxacillin levels in clinical practice | Dr Jared Green | Observational | 29/01/2015 | 13/02/2015 | 24/02/2015 | 13/03/2015 |
| 15/NTA/9 | Approve | Metformin 500 mg bioequivalence study conducted under fed conditions | Dr Noelyn Hung | Intervention | 29/01/2015 |  |  | 13/02/2015 |
| 15/NTA/16 | Approve | The effect of high protein diets on weight loss and lean muscle mass in patients awaiting bariatric surgery | Ms Jessica Robinson-de Wit | Intervention | 26/02/2015 | 13/03/2015 | 26/03/2015 | 13/04/2015 |
| 15/NTA/17 | Approve | Microwave ablation of liver tumours | Dr. Adam Bartlett | Observational | 26/02/2015 | 13/03/2015 | 16/06/2015 | 30/06/2015 |
| 15/NTA/19 | Approve | Study of CTX-4430 in Acne Patients | Assoc Professor Marius Rademaker | Intervention | 26/02/2015 | 13/03/2015 | 20/03/2015 | 2/04/2015 |
| 15/NTA/20 | Approve | M15-310: A study of Ombitasvir/Paritaprevir/Ritonavir, Dasabuvir and Sofosbuvir with or without RBV in patients with chronic Genotype 1 HCV | Prof Edward Gane | Intervention | 26/02/2015 | 13/03/2015 | 31/03/2015 | 22/04/2015 |
| 15/NTA/21 | Approve | NiPPeR | Professor Philip Baker | Intervention | 26/02/2015 | 13/03/2015 | 18/05/2015 | 16/06/2015 |
| 15/NTA/25 | Approve | Observational study of microangiopathy | Dr Mark Smith | Observational | 26/02/2015 | 13/03/2015 | 21/04/2015 | 8/05/2015 |
| 15/NTA/29 | Approve | Evaluation and update of TF-CBT | Miss Olivia Taylor | Intervention | 2/04/2015 | 17/04/2015 | 6/05/2015 | 26/05/2015 |
| 15/NTA/31 | Approve | Implementation of a national guideline in babies on postnatal wards | Dr Jane Alsweiler | Intervention | 2/04/2015 | 17/04/2015 | 29/04/2015 | 11/05/2015 |
| 15/NTA/34 | Approve | DISRUPT PAD | Dr Andrew Holden | Intervention | 2/04/2015 |  | 21/04/2015 | 17/04/2015 |
| 15/NTA/36 | Approve | Ocriplasmin for Vitreomacular Traction/Symptomatic Vitreomacular Adhesion | Dr. Stephen Guest | Intervention | 2/04/2015 | 17/04/2015 | 13/05/2015 | 28/05/2015 |
| 15/NTA/37 | Approve | FAME 3 | Dr Gerard Devlin | Intervention | 2/04/2015 |  |  | 17/04/2015 |
| 15/NTA/38 | Approve | ACH422-004: A study of ACH-0143422 and ACH-0143102 in patients with chronic Hepatitis C | Prof Edward Gane | Intervention | 2/04/2015 |  |  | 17/04/2015 |
| 15/NTA/40 | Approve | BIOFLOW-V | Prof Mark Webster | Intervention | 2/04/2015 |  |  | 17/04/2015 |
| 15/NTA/41 | Approve | Insights into AFOs | Miss Elizabeth Binns | Observational | 2/04/2015 |  |  | 17/04/2015 |
| 15/NTA/42 | Approve | CHiPS study | Miss Joanne Clements | Intervention | 2/04/2015 |  |  | 17/04/2015 |
| 15/NTA/43 | Approve | Impact of Dietary Protein Supplementation Combined with Exercise Training on Diabetic Rehabilitation in Overweight/Obese Adults with Type 2 Diabetes | Dr Lee Stoner | Intervention | 2/04/2015 | 17/04/2015 | 23/04/2015 | 14/05/2015 |
| 15/NTA/44 | Approve | A non-inferiority trial of smartphone-based health applications IBDsmart and IBDoc for IBD patients in NZ | Assoc. Prof Michael Schultz | Intervention | 2/04/2015 | 17/04/2015 | 30/04/2015 | 20/05/2015 |
| 15/NTA/48 | Approve | RCT comparing diagnostic yield between R-EBUS guided cryo-biopsy Vs. CT guided biopsy for PPL. (CT-CROP) | Dr Samantha Herath | Intervention | 30/04/2015 |  |  | 13/05/2015 |
| 15/NTA/49 | Approve | Management of Feeding Decisions | Dr Anna Miles | Intervention | 30/04/2015 | 13/05/2015 | 29/05/2015 | 29/06/2015 |
| 15/NTA/50 | Approve | Oral Antiviral treatment for HCV/HIV coinfected patients: TURQUOISE-I | Prof Edward Gane | Intervention | 30/04/2015 | 13/05/2015 | 28/05/2015 | 22/06/2015 |
| 15/NTA/52 | Approve | Comparison of the blood levels of four forms of isotretinoin 40 mg capsules in healthy male volunteers | Dr Noelyn Hung | Intervention | 30/04/2015 |  |  | 13/05/2015 |
| 15/NTA/53 | Approve | Comparison of the blood levels of two forms of tibolone tablet in healthy female volunteers | Dr Noelyn Hung | Intervention | 30/04/2015 |  |  | 13/05/2015 |
| 15/NTA/55 | Approve | The PAMILA Study | Professor Richard Troughton | Observational | 30/04/2015 | 13/05/2015 | 2/06/2015 | 30/06/2015 |
| 15/NTA/56 | Approve | Investigating the effect of Carbon Dioxide and Humidity on Human Peritoneum | Dr Tinte Itinteang | Observational | 30/04/2015 | 13/05/2015 | 21/05/2015 | 11/06/2015 |
| 15/NTA/57 | Approve | INS-212 - Study of Liposomal Amikacin in Adults with Nontuberculous Mycobacterial Lung Infections | Dr Amanda McNaughton | Intervention | 30/04/2015 | 13/05/2015 | 27/05/2015 | 19/06/2015 |
| 15/NTA/65 | Approve | Antibiotics in acute diverticulitis | Associate Professor Ian Bissett | Intervention | 28/05/2015 |  |  | 16/06/2015 |
| 15/NTA/66 | Approve | Effect of warm humidified carbon dioxide on bacteria in a surgical wound | Mrs Jessica Fogarin | Intervention | 28/05/2015 | 16/06/2015 | 22/06/2015 | 15/07/2015 |
| 15/NTA/67 | Approve | The GEM Project | A/Prof Dr Michael Schultz | Observational | 28/05/2015 | 16/06/2015 | 7/08/2015 | 24/08/2015 |
| 15/NTA/68 | Approve | Validation of Test of Masticating and Swallowing Solids (TOMASS) | Ms Wan Tian Ng | Intervention | 28/05/2015 | 16/06/2015 | 26/06/2015 | 13/07/2015 |
| 15/NTA/70 | Approve | SHIELD Trial | Dr Andrew Holden | Intervention | 28/05/2015 |  |  | 16/06/2015 |
| 15/NTA/72 | Approve | BR.31 | Dr David Gibbs | Intervention | 28/05/2015 | 16/06/2015 | 23/06/2015 | 8/07/2015 |
| 15/NTA/73 | Approve | ReLeaf Feasibility Study | Dr Andrew Holden | Intervention | 28/05/2015 |  |  | 16/06/2015 |
| 15/NTA/75 | Approve | A study to investigate pembrolizumab in patients with metastatic triple-negative breast cancer (mTNBC) | Dr David Porter | Intervention | 28/05/2015 | 16/06/2015 | 22/07/2015 | 7/08/2015 |
| 15/NTA/79 | Approve | Clinical outcomes of a cohort of patients presenting to an emergency department with sepsis: relationship to patient, staff and family/whānau understanding of disease | Dr Paul Huggan | Observational | 2/07/2015 | 21/07/2015 | 24/07/2015 | 13/08/2015 |
| 15/NTA/81 | Approve | JPBM / Monarch 3 | Dr Audrey Fenton | Intervention | 2/07/2015 | 21/07/2015 | 26/08/2015 | 16/09/2015 |
| 15/NTA/83 | Approve | Comparison of the blood levels of two forms of isotretinoin 20 mg capsules in healthy male volunteers | Dr Noelyn Hung | Intervention | 2/07/2015 |  |  | 21/07/2015 |
| 15/NTA/84 | Approve | Comparison of the blood levels of two forms of isotretinoin (1 x 40 mg and 2 x 20 mg capsules) in healthy male volunteers | Dr Noelyn Hung | Intervention | 2/07/2015 |  |  | 21/07/2015 |
| 15/NTA/85 | Approve | A study to determine the bioequivalence of two Peginterferon alfa-2a formulations | Dr Chris Wynne | Intervention | 2/07/2015 |  |  | 21/07/2015 |
| 15/NTA/86 | Approve | Isotretinoin in chronic sinusitis | Associate Professor Richard Douglas | Intervention | 2/07/2015 | 21/07/2015 | 20/08/2015 | 7/09/2015 |
| 15/NTA/87 | Approve | PQB 4 FP II | Dr Andrew Holden | Intervention | 2/07/2015 |  |  | 21/07/2015 |
| 15/NTA/88 | Decline | Gastrointestinal motility study | Dr Susanna Every-Palmer | Observational | 2/07/2015 |  |  | 21/07/2015 |
| 15/NTA/89 | Approve | A randomised double blinded placebo controlled study investigating MyriCell for the improvement of skin health in subjects with eczema | Dr Simon Carson | Intervention | 2/07/2015 |  |  | 21/07/2015 |
| 15/NTA/101 | Approve | FILLY | Prof Philip Polkinghorne | Intervention | 30/07/2015 | 12/08/2015 | 2/09/2015 | 23/09/2015 |
| 15/NTA/102 | Approve | Study to Assess the Efficacy and Safety of PT010 Relative to PT003 and PT009 on COPD Exacerbations in Subjects With Moderate to Very Severe COPD | Dr Dean Quinn | Intervention | 30/07/2015 | 12/08/2015 | 11/09/2015 | 5/10/2015 |
| 15/NTA/103 | Approve | GS-US-223-1018: Study Evaluating GS-4997 Pharmacokinetics in Subjects with Normal and Impaired Hepatic Function | Prof Edward Gane | Intervention | 30/07/2015 | 12/08/2015 | 26/08/2015 | 11/09/2015 |
| 15/NTA/104 | Approve | Glucose in Well Babies (GLOW) | Dr Deborah Harris | Observational | 30/07/2015 |  |  | 12/08/2015 |
| 15/NTA/105 | Approve | Tiotropium inhalation powder bioavailability study | Dr Noelyn Hung | Intervention | 30/07/2015 |  |  | 12/08/2015 |
| 15/NTA/106 | Approve | JenaValve AS NZ Study | Prof Mark Webster | Intervention | 30/07/2015 |  | 8/09/2015 | 12/08/2015 |
| 15/NTA/107 | Approve | Improving diabetes outcomes for Māori in Whangaroa | Dr Jennifer Reid | Intervention | 30/07/2015 |  |  | 12/08/2015 |
| 15/NTA/108 | Approve | JenaValve AR NZ Study | Prof Mark Webster | Intervention | 30/07/2015 |  |  | 12/08/2015 |
| 15/NTA/93 | Approve | LAAOS 3 | Dr Shay McGuinness | Intervention | 30/07/2015 |  |  | 12/08/2015 |
| 15/NTA/97 | Approve | CEDAR: Safety and Efficacy of Abicipar Pegol (AGN-150998) in Patients With Neovascular Age-related Macular Degeneration | Prof Philip Polkinghorne | Intervention | 30/07/2015 | 12/08/2015 | 11/09/2015 | 29/09/2015 |
| 15/NTA/98 | Approve | PINTO | Dr Ruth Hughes | Intervention | 30/07/2015 |  |  | 12/08/2015 |
| 15/NTA/117 | Approve | Oxygen in Acute Coronary Syndromes | Prof Ralph Stewart | Intervention | 27/08/2015 |  |  | 11/09/2015 |
| 15/NTA/119 | Approve | A4091058 (Pfizer OA) | Dr Simon Carson | Intervention | 27/08/2015 | 11/09/2015 | 5/10/2015 | 27/10/2015 |
| 15/NTA/120 | Approve | Evaluating the effect of a new drug on exercise tolerance in subjects with angina | Prof Russell Scott | Intervention | 27/08/2015 | 11/09/2015 | 5/10/2015 | 27/10/2015 |
| 15/NTA/121 | Approve | A4091064 (Observation) | Dr Simon Carson | Observational | 27/08/2015 | 11/09/2015 | 29/09/2015 | 19/10/2015 |
| 15/NTA/122 | Approve | Drug Interaction Study between an experimental Hepatitis C treatment and an oral contraceptive drug | Dr Richard Robson | Intervention | 27/08/2015 | 11/09/2015 | 25/09/2015 | 5/10/2015 |
| 15/NTA/123 | Approve | ASCEND-II | Dr Natalie Walker | Intervention | 27/08/2015 |  | 25/09/2015 | 11/09/2015 |
| 15/NTA/126 | Approve | Antibiotics in critically ill children (Part A) | Dr Brian J Anderson | Observational | 27/08/2015 |  |  | 11/09/2015 |
| 15/NTA/129 | Approve | “IntelliFlex™” Study | Dr Andrew Holden | Intervention | 27/08/2015 |  |  | 11/09/2015 |
| 15/NTA/130 | Approve | A study of ABT-414 in combination with radiation and temozolomide, compared to radiation and temozolomide alone, in patients with newly diagnosed GBM | Dr David Hamilton | Intervention | 27/08/2015 |  |  | 11/09/2015 |
| 15/NTA/131 | Approve | Obinutuzumab with Idasanutlin in Lymphoma | Dr William Nigel Patton | Intervention | 27/08/2015 |  |  | 11/09/2015 |
| 15/NTA/132 | Approve | The Tempo™ Study | Prof Mark Webster | Intervention | 28/08/2015 | 11/09/2015 | 8/10/2015 | 28/10/2015 |
| 15/NTA/139 | Approve | Comparison of the blood levels of two forms of anagrelide 0.5 mg capsules in healthy male and female volunteers | Dr Noelyn Hung | Intervention | 1/10/2015 |  |  | 15/10/2015 |
| 15/NTA/140 | Approve | Comparison of the blood levels of four forms of isotretinoin 40 mg capsules in healthy male volunteers | Dr Noelyn Hung | Intervention | 1/10/2015 |  |  | 15/10/2015 |
| 15/NTA/141 | Approve | Comparison of the blood levels of three forms of insulin | Dr Noelyn Hung | Intervention | 1/10/2015 |  |  | 15/10/2015 |
| 15/NTA/142 | Approve | POSNOC - A randomised trial of armpit (axilla) treatment for women with early stage breast cancer | A/Prof Ian Campbell | Intervention | 1/10/2015 | 15/10/2015 | 10/12/2015 | 23/12/2015 |
| 15/NTA/143 | Approve | CLS001-CO-PR-005: Safety and effectiveness of once-daily CLS001 gel in Papulopustular Rosacea with 4 week follow-up | Dr Nicholas Birchall | Intervention | 1/10/2015 | 15/10/2015 | 1/12/2015 | 23/12/2015 |
| 15/NTA/144 | Approve | High dose nicotine substitution study for other-drug addicted smokers | Dr Natalie Walker | Intervention | 1/10/2015 |  |  | 15/10/2015 |
| 15/NTA/146 | Approve | The ABC Study: 'Assisted breathing before cord clamping' | Mrs Elizabeth Nevill | Intervention | 1/10/2015 | 15/10/2015 | 24/11/2015 | 22/12/2015 |
| 15/NTA/149 | Approve | DIBH for Breast Cancer DIBH in Breast Cancer | Dr Melissa James | Intervention | 1/10/2015 | 15/10/2015 | 2/11/2015 | 2/11/2015 |
| 15/NTA/150 | Approve | Modelling LQTS using iPSCMs | Dr Jon Skinner | Observational | 1/10/2015 |  |  | 15/10/2015 |
| 15/NTA/152 | Approve | PADDOCK | Dr Humphrey, W, H Pullon | Intervention | 1/10/2015 |  |  | 15/10/2015 |
| 15/NTA/153 | Approve | BAY 94-9027 paediatric pharmacokinetics, safety, and efficacy trial | Dr Mark Smith | Intervention | 1/10/2015 | 15/10/2015 | 6/11/2015 | 26/11/2015 |
| 15/NTA/156 | Approve | Is Intraoperative tissue oxygenation increased with humidified CO2 | Dr Prathima Chowdary | Intervention | 1/10/2015 | 15/10/2015 | 4/11/2015 | 23/11/2015 |
| 15/NTA/158 | Approve | Cast vs Splint for distal radius fractures | Dr Tarun Ahuja | Intervention | 7/10/2015 | 27/10/2015 | 2/11/2015 | 9/11/2015 |
| 15/NTA/159 | Approve | Heparc-2008:Study of ARC-520 alone and in combination with other drugs in patients with Hepatitis B (MONARCH) | Prof Edward Gane | Intervention | 7/10/2015 | 27/10/2015 | 6/11/2015 | 9/11/2015 |
| 15/NTA/160 | Approve | Regional Anaesthesia and Breast Cancer Recurrence | Dr Elizabeth Maxwell | Intervention | 7/10/2015 | 27/10/2015 | 1/12/2015 | 7/12/2015 |
| 15/NTA/161 | Approve | A study of Nivolumab With or Without GS-4774 for Virally-Suppressed Subjects with Chronic Hepatitis B | Prof Edward Gane | Intervention | 7/10/2015 |  |  | 27/10/2015 |
| 15/NTA/162 | Approve | Testing the combination of an experimental agent (Pexa-Vec) with standard of care Sorafenib versus Sorafenib alone in patients with advanced liver cancer | Prof Edward Gane | Intervention | 7/10/2015 | 27/10/2015 | 19/11/2015 | 10/12/2015 |
| 15/NTA/163 | Approve | Standard versus symptom-based antibiotic duration | Dr Richard Everts | Intervention | 7/10/2015 | 27/10/2015 | 2/11/2015 | 13/11/2015 |
| 15/NTA/170 | Provisionally approve | PREVENT Trial | Dr David Smyth | Intervention | 29/10/2015 | 11/11/2015 | 11/12/2015 |  |
| 15/NTA/184 | Provisionally approve | LJPC-501 in Patients with Catecholamine-Resistant Hypotension | Dr Paul Young | Intervention | 29/10/2015 | 11/11/2015 | 16/12/2015 |  |
| 15/NTA/168 | Approve | Pulse oximetry screening feasibility study | Prof Frank Bloomfield | Intervention | 29/10/2015 |  |  | 11/11/2015 |
| 15/NTA/169 | Approve | The LaP Study | Dr Jane Alsweiler | Observational | 29/10/2015 |  |  | 11/11/2015 |
| 15/NTA/171 | Approve | EDP 494-001: A study of EDP-494 in healthy subjects and Hepatitis C patients | Prof Edward Gane | Intervention | 29/10/2015 | 11/11/2015 | 26/11/2015 | 9/12/2015 |
| 15/NTA/172 | Approve | MINI | Ms Ying Jin | Observational | 29/10/2015 | 11/11/2015 | 25/11/2015 | 17/12/2015 |
| 15/NTA/173 | Approve | Medical conditions and traumatic brain injury | Miss Shivanthi Balalla | Observational | 29/10/2015 | 11/11/2015 | 23/11/2015 | 17/12/2015 |
| 15/NTA/174 | Approve | Cytisine pharmacokinetics and dose response (C-DRAKS 3 and C-DRAKS 4) | Miss Soo Hee Jeong | Intervention | 29/10/2015 |  |  | 11/11/2015 |
| 15/NTA/175 | Approve | The “rectosigmoid brake” as a neuromodulation target for faecal incontinence | Associate Professor Ian Bissett | Intervention | 29/10/2015 |  |  | 11/11/2015 |
| 15/NTA/176 | Approve | Radiotherapy or Imiquimod in treatment of complex lentigo maligna | Mr Richard C W Martin | Intervention | 29/10/2015 | 11/11/2015 | 1/12/2015 | 16/12/2015 |
| 15/NTA/183 | Approve | The IMPERIAL Study | Dr Andrew Holden | Intervention | 29/10/2015 | 11/11/2015 | 8/12/2015 | 23/12/2015 |
| 15/NTA/185 | Approve | Management of Refractory Cancer Ascites (MORCA) | Dr Celia Palmer | Intervention | 29/10/2015 |  |  | 11/11/2015 |
| 15/NTA/190 | Provisionally approve | Molecular analysis of squamous cell carcinoma of the vulva and the field of cancerization | Dr Susan Bigby | Observational | 19/11/2015 | 10/12/2015 |  |  |
| 15/NTA/194 | Provisionally approve | Safety and Efficacy of EXE844 Otic Suspension in OMTT | Dr Murali Mahadevan | Intervention | 19/11/2015 | 10/12/2015 |  |  |
| 15/NTA/195 | Provisionally approve | Safety and efficacy of ziv Aflibercept compounding in refractory diabetic macular oedema | Dr Andrew Riley | Intervention | 19/11/2015 | 10/12/2015 | 21/12/2015 |  |
| 15/NTA/197 | Provisionally approve | A Phase IIb Study of NTCELL in Patients with Parkinson's Disease | Dr Barry Snow | Intervention | 19/11/2015 | 10/12/2015 |  |  |
| 15/NTA/198 | Provisionally approve | The Role of Lifestyle Factors in Breast Cancer | Dr Rachael Flanagan | Observational | 19/11/2015 | 10/12/2015 |  |  |
| 15/NTA/199 | Provisionally approve | Starship Hospital wide Investigation of Plasma-Lyte® 148 vs. 0.9% Saline (SHIPS) | Dr Brent McSharry | Intervention | 19/11/2015 | 10/12/2015 |  |  |
| 15/NTA/200 | Approve | TTM-TBI: Feasibility | Dr Paul Young | Intervention | 19/11/2015 |  |  | 10/12/2015 |
| 15/NTA/211 | Provisionally approve | COMMENCE TRIAL | Mr Adam El-Gamel | Intervention | 7/12/2015 | 23/12/2015 |  |  |
| 15/NTA/212 | Provisionally approve | To Investigate the Efficacy and Safety of Mongersen for the Treatment of Subjects with Active Crohn’s Disease | Dr James Brooker | Intervention | 7/12/2015 | 23/12/2015 |  |  |
| 15/NTA/213 | Provisionally approve | A Pilot study of a Probiotic for Eczema Treatment | Dr Kristin Wickens | Intervention | 7/12/2015 | 23/12/2015 |  |  |
| 15/NTA/214 | Provisionally approve | OCR002-HE209: STOP-HE Study | Prof Edward Gane | Intervention | 7/12/2015 | 23/12/2015 |  |  |
| 15/NTA/210 | Approve | Enhancing Engagement in a Stopping Violence Programme | Dr Eileen Britt | Intervention | 7/12/2015 |  |  | 23/12/2015 |
| 15/NTA/215 | Approve | A study of GS-9620 in combination with Tenofovir Disoproxil Fumarate (TDF) for the Treatment of Participants with Chronic Hepatitis B and who are currently not on Treatment | Prof Edward Gane | Intervention | 7/12/2015 |  |  | 23/12/2015 |
| 15/NTA/216 | Approve | M15-410: A study of ABT-493/ABT-530 in chronic Hepatitis C patients who failed Direct-Acting Antiviral (DAA) therapy | Prof Edward Gane | Intervention | 7/12/2015 |  |  | 23/12/2015 |
| 15/NTA/217 | Approve | A study assessing the similarity of Avastin® and the trial drug BAT1706 | Dr Chris Wynne | Intervention | 7/12/2015 |  |  | 23/12/2015 |

## Applications reviewed by expedited review

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 |
| 15/NTA/1 | Approve | EPIC | Dr Helen Petousis-Harris | Observational | 20/01/2015 |  |  | 10/02/2015 |
| 15/NTA/3 | Approve | PERS Evaluation | Ms Gayl Humphrey | Observational | 26/01/2015 |  |  | 10/02/2015 |
| 15/NTA/14 | Approve | 5-FU Uptake into Healthy Cells | Dr Kathryn Burns | Observational | 3/02/2015 |  | 17/03/2015 | 18/02/2015 |
| 15/NTA/15 | Approve | Natural History of TFCC Tears | Dr. MARLA Bennett | Observational | 17/02/2015 |  | 8/04/2015 | 2/03/2015 |
| 15/NTA/24 | Approve | Pressure wave propagation in sigmoid diverticular disease | Associate Professor Ian Bissett | Observational | 27/02/2015 |  | 13/03/2015 | 11/03/2015 |
| 15/NTA/28 | Approve | Effect of exercise and support on postnatal diastasis | Ms Jill Depledge | Intervention | 23/03/2015 | 7/04/2015 | 20/04/2015 | 29/04/2015 |
| 15/NTA/45 | Approve | iMCD | Dr Wenfei Ou | Observational | 1/04/2015 |  | 15/04/2015 | 13/04/2015 |
| 15/NTA/46 | Approve | Profiling bioavailable berry polyphenols in humans | Mr Jeffry Tang | Intervention | 1/04/2015 |  | 11/05/2015 | 13/04/2015 |
| 15/NTA/47 | Approve | The LIVE DONATE NZ study | Dr Michael Collins | Observational | 8/04/2015 |  |  | 21/04/2015 |
| 15/NTA/59 | Approve | The use of mobile devices amongst inpatients | Miss Aryanah Paul | Observational | 1/05/2015 |  |  | 15/05/2015 |
| 15/NTA/60 | Approve | Emotion regulatory skills in pain | Mr Duncan Edwards | Intervention | 4/05/2015 | 15/05/2015 | 22/05/2015 | 26/05/2015 |
| 15/NTA/61 | Approve | HBA1c and dental/oro-facial infections | Dr Lanit Anand | Observational | 5/05/2015 | 18/05/2015 | 29/10/2015 | 2/11/2015 |
| 15/NTA/62 | Approve | Natural History Of Children with Borderline Normal Newborn Screening Metabolites | Dr Callum Wilson | Observational | 5/05/2015 |  |  | 20/05/2015 |
| 15/NTA/63 | Approve | Utilising telehealth to promote oral health | Professor Anita Nolan | Observational | 13/05/2015 |  | 10/06/2015 | 26/05/2015 |
| 15/NTA/76 | Approve | Risk prediction in acute diverticulitis | Associate Professor Ian Bissett | Observational | 3/06/2015 |  |  | 23/06/2015 |
| 15/NTA/77 | Approve | Carboplatin Dosing In the Obese | Dr. Robert Matthew Strother | Observational | 4/06/2015 | 23/06/2015 | 13/08/2015 | 17/08/2015 |
| 15/NTA/78 | Approve | Post mastectomy recurrence project | A/Prof Ian Campbell | Observational | 5/06/2015 |  |  | 23/06/2015 |
| 15/NTA/80 | Approve | A pilot study aimed at establishing whether patient reported outcome measures are acceptable, can be completed reliably and are sensitive to the effects of Parkinson’s disease | Mr Robin Martin Matthews | Observational | 18/06/2015 |  |  | 30/06/2015 |
| 15/NTA/91 | Approve | Non-invasive antenatal screening in New Zealand | Dr Sara Filoche | Observational | 26/06/2015 | 8/07/2015 | 28/10/2015 | 2/11/2015 |
| 15/NTA/92 | Approve | Prostate Cancer Registry | Mr Stephen Mark | Observational | 29/06/2015 | 13/07/2015 | 15/07/2015 | 16/07/2015 |
| 15/NTA/94 | Approve | Effect of berryfruits on appetite and food intake | Prof Sally D Poppitt | Intervention | 24/07/2015 | 31/07/2015 | 17/08/2015 | 20/08/2015 |
| 15/NTA/109 | Decline | International study of volumetric breast composition and mammographic compression | Dr Ariane Chan | Observational | 30/07/2015 | 7/08/2015 | 20/08/2015 | 31/08/2015 |
| 15/NTA/111 | Approve | F&P Saturn In-home NZ 2015 | Miss Irene Cheung | Intervention | 7/08/2015 | 18/08/2015 | 25/08/2015 | 3/09/2015 |
| 15/NTA/112 | Approve | Metabolic Syndrome Parameters and AMY1 Gene Copy Number | Proferssor Grant Schofield | Observational | 11/08/2015 | 18/08/2015 | 7/09/2015 | 14/09/2015 |
| 15/NTA/113 | Approve | F&P Jupiter In-Home NZ 2015 | Mrs Bhavi Ogra | Intervention | 14/08/2015 | 26/08/2015 | 3/09/2015 | 3/09/2015 |
| 15/NTA/115 | Approve | Prebiotic effect of Manuka Health with Cyclopower TM(trade mark) | DR Christiene Butts | Intervention | 17/08/2015 |  |  | 26/08/2015 |
| 15/NTA/116 | Approve | PDOPPS | Dr Mark Marshall | Observational | 18/08/2015 |  |  | 28/08/2015 |
| 15/NTA/114 | Approve | Fetal Fibronectin and Partosure: an observational study | Dr Hayley Smith | Observational | 20/08/2015 |  |  | 28/08/2015 |
| 15/NTA/118 | Approve | Pain at home after daycase surgery in children | Dr Indu Kapoor | Observational | 20/08/2015 | 31/08/2015 | 5/10/2015 | 12/10/2015 |
| 15/NTA/127 | Approve | Adjuvant endocrine therapy for early breast cancer | Professor Bridget Robinson | Observational | 25/08/2015 |  |  | 4/09/2015 |
| 15/NTA/135 | Approve | Audit of oral dextrose gel use in New Zealand maternity hospitals | Dr Jane Alsweiler | Observational | 2/09/2015 | 14/09/2015 | 14/10/2015 | 17/10/2015 |
| 15/NTA/137 | Approve | PKAP Study | Mr Eamon Duffy | Observational | 4/09/2015 |  |  | 17/09/2015 |
| 15/NTA/138 | Approve | Subtypes of stage IV ovarian cancer: response to treatment and patterns of disease recurrence | Dr Amy Jamieson | Observational | 22/09/2015 | 5/10/2015 | 8/10/2015 | 13/10/2015 |
| 15/NTA/166 | Approve | Auckland Central Liver Clinic pilot | Mrs Victoria Oliver | Intervention | 13/10/2015 |  |  | 27/10/2015 |
| 15/NTA/164 | Approve | Patient centred experience of interscalene nerve block analgesia for shoulder surgery | Dr Tin Lun Chiu | Observational | 14/10/2015 | 28/10/2015 | 19/11/2015 | 20/11/2015 |
| 15/NTA/145 | Approve | Ischaemic heart disease in breast cancer radiation | Dr Melissa James | Observational | 19/10/2015 | 2/11/2015 | 13/11/2015 | 20/11/2015 |
| 15/NTA/167 | Approve | Epidemiology of nephrolithiasis | Miss Stephanie Loeff | Observational | 20/10/2015 | 30/10/2015 | 2/11/2015 | 4/11/2015 |
| 15/NTA/178 | Approve | PBMCs and glycolipids | Dr Kristel Kodar | Observational | 21/10/2015 |  |  | 4/11/2015 |
| 15/NTA/179 | Approve | Feasibility of a walking programme in persons with symptoms of osteoarthritis | Dr Prasath Jayakaran | Intervention | 23/10/2015 | 4/11/2015 | 6/11/2015 | 10/11/2015 |
| 15/NTA/177 | Approve | Posterior entry point for percutaneous pinning of the supracondylar fracture of the distal humerus and early loss of reduction | Dr Timothy Roberts | Observational | 27/10/2015 |  |  | 5/11/2015 |
| 15/NTA/188 | Approve | Establishing a database of anaesthetic records | Dr David Cumin | Observational | 29/10/2015 |  |  | 5/11/2015 |
| 15/NTA/189 | Approve | Housing Needs of Mental Health Clients | Ms Jude Woolston | Observational | 29/10/2015 | 9/11/2015 | 13/11/2015 | 17/11/2015 |
| 15/NTA/191 | Provisionally approve | Women’s experiences of antenatal screening tests in New Zealand | Dr Alison McEwen | Observational | 10/11/2015 | 24/11/2015 |  |  |
| 15/NTA/192 | Approve | Catalysts of Health | Dr Tanya Allport | Observational | 10/11/2015 | 24/11/2015 | 14/12/2015 | 18/12/2015 |
| 15/NTA/201 | Approve | He Pikinga Waiora | Mr Maui Hudson | Observational | 19/11/2015 |  |  | 1/12/2015 |
| 15/NTA/202 | Approve | VCCMA | Dr Christopher Wong | Observational | 20/11/2015 |  |  | 2/12/2015 |
| 15/NTA/205 | Provisionally approve | Text4Heart Partnership | Dr Ralph Maddison | Intervention | 23/11/2015 | 30/11/2015 |  |  |
| 15/NTA/207 | Approve | The utility of alternative pulmonary function parameters for assessing reversibility of airway obstruction | Miss Laura Ploen | Observational | 1/12/2015 |  |  | 14/12/2015 |
| 15/NTA/208 | Approve | Blackcurrant phenolic compounds bioavailability and energy metabolism | Dr Suzanne Hurst | Intervention | 1/12/2015 |  |  | 14/12/2015 |
| 15/NTA/209 | Provisionally approve | PELICANZ | Ms Tracey Woulfe | Observational | 3/12/2015 | 17/12/2015 |  |  |
| 15/NTA/218 | Approve | REDDS Study | Dr Robert Weinkove | Intervention | 7/12/2015 |  |  | 23/12/2015 |

## Overdue full applications

|  |  |  |  |
| --- | --- | --- | --- |
| Reference | Short title | Days overdue | Reason |
| 15/NTA/143 | CLS001-CO-PR-005: Safety and effectiveness of once-daily CLS001 gel in Papulopustular Rosacea with 4 week follow-up | 1 | Secretariat Failed to Action Decision |
| 15/NTA/2 | A study of Tiotropium dry powder delivered by the Monohaler device in subjects with COPD | 1 | Secretariat Failed to Action Decision |
| 15/NTA/43 | Impact of Dietary Protein Supplementation Combined with Exercise Training on Diabetic Rehabilitation in Overweight/Obese Adults with Type 2 Diabetes | 1 | Committee member delay in Response |
| 15/NTA/57 | INS-212 - Study of Liposomal Amikacin in Adults with Nontuberculous Mycobacterial Lung Infections | 1 | Committee member delay in Response |
| 15/NTA/67 | The GEM Project | 1 | Committee member delay in Response |
| 15/NTA/68 | Validation of Test of Masticating and Swallowing Solids (TOMASS) | 1 | Committee / Secretariat Failed to Action Decision |
| 15/NTA/7 | COBALT Open Label Extension (OLE) study | 1 | Committee member delay in Response |
| 15/NTA/102 | Study to Assess the Efficacy and Safety of PT010 Relative to PT003 and PT009 on COPD Exacerbations in Subjects With Moderate to Very Severe COPD | 2 | Committee member delay in Response |
| 15/NTA/119 | A4091058 (Pfizer OA) | 2 | Committee / Secretariat Failed to Action Decision |
| 15/NTA/120 | Evaluating the effect of a new drug on exercise tolerance in subjects with angina | 2 | Committee / Secretariat Failed to Action Decision |
| 15/NTA/173 | Medical conditions and traumatic brain injury | 2 | Secretariat Failed to Action Decision |
| 15/NTA/20 | M15-310: A study of Ombitasvir/Paritaprevir/Ritonavir, Dasabuvir and Sofosbuvir with or without RBV in patients with chronic Genotype 1 HCV | 2 | Committee member delay in Response |
| 15/NTA/86 | Isotretinoin in chronic sinusitis | 2 | Committee member delay in Response |
| 15/NTA/50 | Oral Antiviral treatment for HCV/HIV coinfected patients: TURQUOISE-I | 3 | Committee member delay in Response |
| 15/NTA/79 | Clinical outcomes of a cohort of patients presenting to an emergency department with sepsis: relationship to patient, staff and family/whānau understanding of disease | 4 | Committee member delay in Response |
| 15/NTA/81 | JPBM / Monarch 3 | 5 | Committee member delay in Response |
| 15/NTA/162 | Testing the combination of an experimental agent (Pexa-Vec) with standard of care Sorafenib versus Sorafenib alone in patients with advanced liver cancer | 6 | Committee member delay in Response |
| 15/NTA/55 | The PAMILA Study | 6 | Committee member delay in Response |
| 15/NTA/146 | The ABC Study: 'Assisted breathing before cord clamping' | 7 | Committee member delay in Response |
| 15/NTA/66 | Effect of warm humidified carbon dioxide on bacteria in a surgical wound | 7 | Incomplete provisional Response |
| 15/NTA/21 | NiPPeR | 9 | Committee member delay in Response |
| 15/NTA/49 | Management of Feeding Decisions | 9 | Committee member delay in Response |

## Overdue expedited applications

|  |  |  |  |
| --- | --- | --- | --- |
| Reference | Short title | Days overdue | Reason |
| 15/NTA/179 | Feasibility of a walking programme in persons with symptoms of osteoarthritis | 1 | Committee member delay in Response |
| 15/NTA/218 | REDDS Study | 1 | Incomplete provisional Response |
| 15/NTA/61 | HBA1c and dental/oro-facial infections | 2 | Secretariat Failed to Action Decision |
| 15/NTA/91 | Non-invasive antenatal screening in New Zealand | 2 | Secretariat Failed to Action Decision |
| 15/NTA/118 | Pain at home after daycase surgery in children | 3 | Committee member delay in Response |
| 15/NTA/138 | Subtypes of stage IV ovarian cancer: response to treatment and patterns of disease recurrence | 3 | Committee member delay in Response |
| 15/NTA/192 | Catalysts of Health | 3 | Committee member delay in Response |
| 15/NTA/78 | Post mastectomy recurrence project | 3 | Secretariat Failed to Action Decision |
| 15/NTA/109 | International study of volumetric breast composition and mammographic compression | 4 | Committee member delay in Response |
| 15/NTA/111 | F&P Saturn In-home NZ 2015 | 5 | Committee member delay in Response |
| 15/NTA/76 | Risk prediction in acute diverticulitis | 5 | Secretariat Failed to Action Decision |
| 15/NTA/1 | EPIC | 6 | Committee member delay in Response |
| 15/NTA/145 | Ischaemic heart disease in breast cancer radiation | 6 | Committee member delay in Response |
| 15/NTA/77 | Carboplatin Dosing In the Obese | 8 | Committee member delay in Response |
| 15/NTA/28 | Effect of exercise and support on postnatal diastasis | 9 | Committee member delay in Response |