

Central Health and Disability Ethics Committee

Annual Report  
2015

Citation: New Zealand Health and Disability Ethics Committee. 2018. *Central 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 978-1-98-856810-2 (online)  
HP 6956

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](#_Toc526407822)

[Chairperson’s report 2](#_Toc526407823)

[Membership and attendance 3](#_Toc526407824)

[Membership 3](#_Toc526407825)

[Attendance 5](#_Toc526407826)

[Training and conferences 7](#_Toc526407827)

[Chairpersons’ meetings 7](#_Toc526407828)

[Applications reviewed 8](#_Toc526407829)

[Complaints and overdue application summary 8](#_Toc526407830)

[Complaints received 8](#_Toc526407831)

[Overdue review 8](#_Toc526407832)

[Appendix 1: Details of applications reviewed 9](#_Toc526407833)

[Applications reviewed by full committee 9](#_Toc526407834)

[Applications reviewed by expedited review 19](#_Toc526407835)

[Overdue full applications 23](#_Toc526407836)

[Overdue expedited applications 25](#_Toc526407837)

# About the committee

The Central 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 Central 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 Central HDEC is registered (number IRB00008712) 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

2015 has been our busiest year since the inception of the new online system, necessitating additional meetings at the end of the year to satisfy the timelines. Whilst it meant extra workload for all involved, we were pleased because it also proved that research is alive and well in New Zealand. A benefit for all.

It is pleasing to see that the quality of applications are improving and along with almost 100% researcher participation at meetings, it now enables an efficient streamlined approval process. I would however implore researchers to check through their applications before they are submitted and ensure they have answered the questions correctly. As an example, the Central committee is committed to lifting researcher awareness into health disparities by pursuing their knowledge of Maori health statistics in the particular field they are working in to give value to their answers.

It is also important to ensure that all relevant documentation is uploaded into the system for each application and that there is a close relationship between the Chief Investigator and the person making the application.

A move to ensure that Tissue Banks are registered with HDEC has been successful, with more complying, which ensures the protection of samples donated by participants for future research. With more initiatives on data sharing being implemented, it is imperative that an individual’s personal data and its confidentiality is respected. Researchers must ensure thorough training of third parties used for the collection of this data so that all involved comply with the informed consent and confidentiality committed to with the HDEC approval process.

Our ethical process is important and we put our trust in researchers to follow through on what has been committed to in the application for all forms of research.

After a significant period of a committee member deficit it is great to once again have a full complement on the Central HDEC. Welcome back to Angela Ballantyne; it is wonderful to have your Ethics experience at our disposal again, we value it. We have two new members who also have great expertise to share with us, thanks Melissa Cragg and Peter Gallagher for coming on board.

Whilst we were not up to complement on the Central Committee, we worked a secondment system with the other Ethics Committees. This proved to be very worthwhile as it helped to improve the consistency between the committees, which we are always endeavoring to achieve.

As in any year, our committee can’t function without the support from our Secretariat led by Philippa Bascand. They have worked extremely hard for us and the increased workload mentioned above impacts them hugely. Thanks to you all.

To the committee, thank you for your commitment also. You are all dedicated to a wonderful cause and are a great team to work with.

****

Mrs Helen Walker

Chairperson

Central 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 2015.

## Membership

### Lay members

|  |  |
| --- | --- |
| Mrs Helen Walker (Chair) | |
| Membership category: | Community representative |
| Date of appointment: | 27 October 2015 |
| Current term expires: | 27 October 2018 |

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

|  |  |
| --- | --- |
| Ms Sandy Gill | |
| Membership category: | Community perspectives |
| Date of appointment: | 30 July 2015 |
| Current term expires: | 30 July 2018 |

Ms Gill has her own consulting company and also works on a voluntary basis with various community groups assisting with policy and procedure, writing programmes and evaluations, clinical supervision of staff, business plans and strategic planning. Her qualifications include an MA in Management (Massey), a MA in Criminal Justice (Victoria) along with post graduate qualifications in Dispute Resolution (Massey) and Human Resources (Victoria). She was a member of the New Zealand Parole Board from 2002 through to 2008, and has been a guest lecturer at Victoria University in the field of criminology. Prior to that she was Standards Manager at the Medical Council of New Zealand. She has also been involved in counseling and reintegration planning for offenders and youth at risk, and in the area of Māori mental health. She has a lifelong addiction to learning and loves to travel and learn about different cultures and history. She is Ngā Puhi and the proud mother of three and nana of one and an Associate Member of AMINZ.

|  |  |
| --- | --- |
| Dr Cordelia Thomas | |
| Membership category: | The Law / Moral reasoning |
| Date of appointment: | 19 May 2014 |
| Current term expires: | 19 May 2017 |

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

|  |  |
| --- | --- |
| Dr Angela Ballantyne | |
| Membership category: | Ethical and moral reasoning |
| Date of appointment: | 1 July 2015 |
| Current term expires: | 1 July 2018 |

Dr Angela Ballantyne is a Senior Lecturer in Bioethics, Wellington School of Medicine, University of Otago Wellington. She is President of the International Association of Bioethics (2016-2017) and the ethics member of the Central Ethics Committee (HDEC) NZ. In 2016 she received a NZ Marsden Fast Start grant and a UOW Award for Best Emerging Researcher. Her research interests include research ethics, exploitation, vulnerability, ethics of pregnancy and reproductive technologies, and secondary use research with clinical data. She has previously worked at the Human Genetics unit for WHO in Geneva, the Medical School at Flinders University and the Yale University Interdisciplinary Center for Bioethics.

### Non-lay members

|  |
| --- |
| Dr Dean Quinn |
| Membership category: | | Interventional studies |
| Date of appointment: | | 28 October 2015 |
| Current term expires: | | 28 October 2018 |

Dr Dean Quinn is a registered medical practitioner, currently the Manager of the Wellington P3 Research unit (2004-present). He has a particular interest in early phase respiratory clinical trials. Prior to this, he has completed a BSc (Hons) (1988) Victoria University of Wellington and MBChB (1993) at the University of Otago. He was formerly a member of the Central ethics committee (2009-2011) and Multi-region ethics committee (2011-2012).

**Dr Patries Herst**

|  |  |
| --- | --- |
| Membership category: | Intervention studies |
| Date of appointment: | 28 October 2015 |
| Current term expires: | 28 October 2018 |

Dr Patries Herst is currently a senior lecturer at the Department of Radiation Therapy, University of Otago, Wellington and a visiting scientist at Victoria University and the Malaghan Institute. She completed a PhD in cancer cell biology at the Malaghan Institute of Medical Research/Otago University in Wellington (2006), a Master of Philosophy (microbiology) at Waikato University in Hamilton (1984) and a Master of Science (biology) at Nijmegen University (Netherlands) in 1982. Dr Herst conducts cell based medical research at the Malaghan Institute as well as clinical trials that investigate better management options for acute side effects caused by radiation therapy in various hospitals in New Zealand. She is the secretary of the New Zealand Oncological Society and the immediate past president of the Wellington Health and Biomedical Research Society. She is also a committee member of the Animal Ethics Committee at the University of Otago, Wellington and joined the Central HDEC as a non-lay member in July 2012.

|  |  |
| --- | --- |
| Dr Melissa Cragg | |
| Membership category: | Observational Studies |
| Date of appointment: | 1 July 2015 |
| Current term expires: | 1 July 2018 |

Dr Melissa Cragg B.A (Hons), PhD (Massey). Principal Consultant, Karake Consultancy. Melissa completed a PhD in Māori Studies at Massey University in2010. Dr Cragg undertakes research, evaluation and policy analysis/development within the health and social service sectors with a specific focus on Māori development. Melissa has worked for DHBs, PHOs and Māori Health and Social Service providers and takes a community based approach to project design and implementation. Other areas of interest include vulnerable populations such as children, Pacifika communities, disabilities and mental health. Currently a member of the Whakauae Research Team working the HRC funded research project ‘Preventing Chronic Conditions for Māori’, the Quality and Research Manager for Te Piki Oranga and Research Request Support for Nelson Marlborough District Health Board.

|  |  |
| --- | --- |
| Dr Peter Gallagher | |
| Membership category: | Health/Disability service provision |
| Date of appointment: | 1 July 2015 |
| Current term expires: | 1 July 2018 |

Dr Peter Gallagher is currently the Medical Education Advisor to the University of Otago, Wellington. He holds a registration as a nurse and completed a PhD in education at Victoria University of Wellington. He has been involved in the education of health professionals for over 30 years with a particular interest in how the learning that eventuates from clinical practice may be enhanced. He was appointed to the Central HDEC as a non-lay member in July 2015.

|  |  |  |  |
| --- | --- | --- | --- |
| Former MembersMr Paul Barnett | | | |
| Membership category: | | The Law | |
| Date of appointment: | | 1 July 2012 | |
| Term expired: | | 1 July 2015 | |
| Mrs Gael Donoghue | | | |
| Membership category: | | Pharmacist/Pharmacologist | |
| Date of appointment: | | 1 July 2012 | |
| Term expired: | | 1 July 2015 | |
| Ms Kay de Vries | | |
| Membership category: | Observational studies | |
| Date of appointment: | 19 May 2014 | |
| Term expired: | 19 May 2015 | |

## Attendance

The Central HDEC held 13 meetings in 2015.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | | | Meetings | | | | | | | | | | | | | **Total** |
| Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep 22 | Sep 25 | Oct | Nov | Dec |
| Lay members | Cm | Mrs Helen Walker (Chair) | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 13/13 |
| L | Mr Paul Barnett | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  |  |  |  |  |  | 7/7 |
| E | Dr Cordelia Thomas | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | 11/13 |
| Cm | Ms Sandy Gill | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 12/13 |
| Cm | Ms Raewyn Idoine (co-opted from Southern Committee) |  |  |  |  |  |  |  |  |  | **✓** |  |  |  | 1/1 |
| E | Dr Angela Ballantyne |  |  |  |  |  |  |  | ***A*** | ***A*** | ***A*** | **✓** | **✓** | **✓** | 3/6 |
| Cm | Mrs Maliaga Erick |  |  |  |  |  |  |  |  | **✓** |  |  |  |  | 1/1 |
| Non-lay members | P | Mrs Gael Donoghue | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  |  |  |  |  |  | 7/7 |
| HR | Dr Kay de Vries | **✓** | **✓** | **✓** |  |  |  |  |  |  |  |  |  |  | 3/3 |
| HR | Dr Dean Quinn | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | ***A*** | ***A*** | **✓** | **✓** | 9/13 |
| HR | Dr Patries Herst | **✓** | **✓** | **✓** | **✓** | ***A*** | ***A*** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | 10/13 |
| HR | Dr Melissa Cragg |  |  |  |  |  |  |  | ***A*** | ***A*** | ***A*** | **✓** | **✓** | **✓** | 3/6 |
| HP | Dr Peter Gallagher |  |  |  |  |  |  |  | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | 5/6 |
| HR | Mrs Stephanie Pollard (Co-opted from NTB HDEC) |  |  |  | **✓** | **✓** |  |  |  |  |  |  |  |  | 2/2 |
| E/HR | Ms Kate O’Connor (Co-opted from NTB HDEC) |  |  |  |  |  | **✓** |  |  |  | **✓** |  |  |  | 2/2 |
| HR | Dr Nicola Swain (Co-opted from STH HDEC) |  |  |  |  |  |  | **✓** |  | **✓** |  |  |  |  | 2/2 |
| HR | Dr Devonie Eglinton (Co-opted from STH HDEC) |  |  |  |  |  |  |  |  | **✓** |  |  |  |  | 1/1 |
| HR | Dr Sarah Gunningham (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
* Maori 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. Mrs Walker attended three meetings.

# Applications reviewed

The Central HDEC received 168 applications in 2015. From the 168 applications 116 applications were reviewed by the full committee and 52 were reviewed through the expedited pathway.

|  |  |  |
| --- | --- | --- |
| Full | Approved | 92 |
| Declined | 3 |
| Provisional Approval (as at 31 December 2015) | 21 |
| *Total (with a decision at 31 December 2015)* | 116 |
| Expedited | Approved | 50 |
| Declined | 0 |
| Provisional Approval (as at 31 December 2015) | 2 |
| *Total (with a decision at 31 December 2015)* | 52 |
| **Total applications reviewed** | | **168** |

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 2015.

## Complaints received

The Central Committee did not receive any complaints about the decision making process in 2015.

## Overdue review

During 2015 there were 22 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.

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/CEN/13 | Approve | Christchurch Heart Institute Tissue Bank | Professor Mark Richards | Intervention |  |  |  | 11/02/2015 |
| 15/CEN/10 | Approve | Nitrate supplementation on health in TIA patients | Dr Shieak YC Tzeng | Intervention | 12/02/2015 | 25/02/2015 | 9/03/2015 | 30/03/2015 |
| 15/CEN/14 | Approve | The Intensive Care Unit Randomised Trial Comparing Two Approaches to OXygen therapy (The ICU-ROX trial) | Dr Paul Young | Intervention | 12/02/2015 |  |  | 25/02/2015 |
| 15/CEN/15 | Approve | The IDENTAKIT-HF Study | Professor Zoltan H Endre | Observational | 12/02/2015 |  |  | 25/02/2015 |
| 15/CEN/16 | Approve | Can we avoid unnecessary hospital admissions for COPD? | Associate Professor Robert Hancox | Observational | 12/02/2015 | 25/02/2015 | 17/04/2015 | 18/05/2015 |
| 15/CEN/18 | Approve | A CIDI (3.0) assessment of the mental health of newly sentenced prisoners in NZ prisons | Dr P Johnston | Observational | 12/02/2015 | 25/02/2015 | 6/03/2015 | 27/03/2015 |
| 15/CEN/19 | Approve | IntReALL SR 2010 | Dr Siobhan Cross | Intervention | 12/02/2015 |  |  | 25/02/2015 |
| 15/CEN/22 | Approve | Assessment of haemodynamic changes following stroke | Dr Shieak Tzeng | Observational | 12/02/2015 |  |  | 25/02/2015 |
| 15/CEN/3 | Approve | AOST1322: Eribulin in Recurrent or Refractory Osteosarcoma | Dr Mark Winstanley | Intervention | 12/02/2015 |  | 1/05/2015 | 25/02/2015 |
| 15/CEN/25 | Approve | Efficacy and safety of riociguat in patients with symptomatic pulmonary hypertension associated with idiopathic interstitial pneumonias (IIP) / RISE-IIP | Prof Lutz Beckert | Intervention | 12/03/2015 | 25/03/2015 | 13/04/2015 | 1/05/2015 |
| 15/CEN/26 | Approve | Pediatric Vasculitis Initiative or PedVas | Dr. Arno Ebner | Observational | 12/03/2015 | 25/03/2015 | 13/04/2015 | 6/05/2015 |
| 15/CEN/27 | Approve | Long term follow-up registry study of subjects with chronic Hepatitis B | Prof Edward Gane | Observational | 12/03/2015 | 25/03/2015 | 22/04/2015 | 30/04/2015 |
| 15/CEN/28 | Approve | Cancer stem cells and receptor signalling in brain and spinal tumours | Mr Agadha Wickremesekera | Observational | 12/03/2015 |  |  | 25/03/2015 |
| 15/CEN/29 | Approve | Study Evaluating GS-6615 Pharmacokinetics in Subjects with Normal and Impaired Hepatic Function | Prof Edward Gane | Intervention | 12/03/2015 | 25/03/2015 | 7/04/2015 | 14/04/2015 |
| 15/CEN/32 | Decline | PLASTIC | DR Julie Reeve | Observational | 12/03/2015 |  |  | 25/03/2015 |
| 15/CEN/33 | Approve | Periostin 9 | Professor Richard Beasley | Observational | 12/03/2015 |  |  | 25/03/2015 |
| 15/CEN/34 | Approve | V89\_18 | Dr Simon Carson | Intervention | 12/03/2015 | 25/03/2015 | 22/05/2015 | 16/06/2015 |
| 15/CEN/39 | Approve | Evaluate the impact of the SWiS initiative on child well-being | prof Rhema Vaithianathan | Observational | 1/04/2015 |  |  | 6/05/2015 |
| 15/CEN/41 | Approve | Phase I Study of MK3475 in Combination with Trametinib and Dabrafenib | Dr Rosalie Fisher | Intervention | 16/04/2015 | 29/04/2015 | 8/06/2015 | 4/08/2015 |
| 15/CEN/43 | Approve | Treatment of Hepatitis C in injecting drug users- SIMPLIFY Study | Prof Edward Gane | Intervention | 16/04/2015 | 29/04/2015 | 1/07/2015 | 24/07/2015 |
| 15/CEN/46 | Approve | New ways to deliver oxygen to children | Dr Stuart R Dalziel | Intervention | 16/04/2015 |  |  | 29/04/2015 |
| 15/CEN/47 | Approve | Risk factors for multi-drug resistant bacterial infections | Dr Jacqueline Benschop | Observational | 16/04/2015 | 29/04/2015 | 25/05/2015 | 16/06/2015 |
| 15/CEN/48 | Approve | Modafinil 100 mg bioequivalence study conducted under fasting conditions | Dr Noelyn Hung | Intervention | 16/04/2015 | 29/04/2015 | 22/05/2015 | 19/06/2015 |
| 15/CEN/50 | Approve | Maxigesic® Oral Suspension PK-PD Study | Professor Brian J Anderson | Intervention | 16/04/2015 | 29/04/2015 | 12/05/2015 | 13/05/2015 |
| 15/CEN/51 | Approve | Can one month of Blis K12 lessen Group A Streptococcal carriage and infection? | Dr John Malcolm | Intervention | 16/04/2015 | 29/04/2015 | 25/05/2015 | 16/06/2015 |
| 15/CEN/52 | Approve | Paediatric Perianaesthesia Questionnaire validation in New Zealand | Dr Victor Birioukov | Observational | 16/04/2015 | 29/04/2015 | 30/06/2015 | 5/08/2015 |
| 15/CEN/61 | Decline | Play and Anxiety in Hospitalised Children | Ms Esther Leauanae | Observational | 14/05/2015 |  |  | 28/05/2015 |
| 15/CEN/62 | Approve | The study of Fulranumab as Adjunctive Therapy in Subjects with Signs and Symptoms of Osteoarthritis of the Hip or Knee | Dr Paul Noonan | Intervention | 14/05/2015 | 28/05/2015 | 24/06/2015 | 9/07/2015 |
| 15/CEN/63 | Approve | Edoxaban in Venous Thromboembolism (VTE)Associated with Cancer (Hokusai VTE Cancer) | Dr Gordon Royle | Intervention | 14/05/2015 |  |  | 28/05/2015 |
| 15/CEN/64 | Approve | Ki67 and Mitotic count in endocrine sensitive early breast cancer | Dr Sarah Barton | Observational | 14/05/2015 |  |  | 28/05/2015 |
| 15/CEN/66 | Approve | The effect of lifestyle interventions on non-disabling Stroke and TIA patients. | Mr Vishal Nagar | Intervention | 14/05/2015 | 28/05/2015 | 16/06/2015 | 22/06/2015 |
| 15/CEN/67 | Approve | Splenic Flexure Lymph Node (SFLN) Study | Dr Carolyn Vasey | Intervention | 14/05/2015 | 28/05/2015 | 15/06/2015 | 3/07/2015 |
| 15/CEN/73 | Approve | 0.9% Saline vs. Plasma-Lyte 148® in ED patients | Dr Sumeet Reddy | Intervention | 11/06/2015 |  |  | 24/06/2015 |
| 15/CEN/74 | Approve | Communication in NZ families affected by parental chronic pain | Mrs Catherine Swift | Observational | 11/06/2015 | 25/06/2015 | 10/08/2015 | 8/09/2015 |
| 15/CEN/75 | Approve | The ProBrain Study | Professor Edwin Mitchell | Intervention | 11/06/2015 | 25/06/2015 | 10/07/2015 | 21/07/2015 |
| 15/CEN/76 | Approve | The psychosocial interactions of AYA cancer survivors and the impact on their development | Miss Nicole Cameron | Observational | 11/06/2015 | 25/06/2015 | 10/07/2015 | 3/08/2015 |
| 15/CEN/77 | Approve | UNIFI | Prof Richard Gearry | Intervention | 11/06/2015 | 25/06/2015 | 13/07/2015 | 17/08/2015 |
| 15/CEN/82 | Approve | ENZAMET | Dr Peter Fong | Intervention | 11/06/2015 | 25/06/2015 | 23/07/2015 | 25/08/2015 |
| 15/CEN/83 | Approve | Maia | Dr Andrew Butler | Intervention | 11/06/2015 | 24/06/2015 | 5/08/2015 | 2/09/2015 |
| 15/CEN/84 | Approve | MK 3475062 Phase III Trial of Pembrolizumab (MK3475),pembrolizumab+FP/XP vs. Placebo+FP/XP in Biomarker Select, Advanced Gastric or GEJ Adenocarcinoma | Dr Sanjeev Deva | Intervention | 11/06/2015 |  |  | 25/06/2015 |
| 15/CEN/100 | Approve | 3-DHB Youth AOD Exemplar Project | Dr Jessica Allen | Observational | 9/07/2015 | 30/07/2015 | 17/08/2015 | 24/08/2015 |
| 15/CEN/101 | Approve | ASLAN001-003 | Professor Bridget Robinson | Intervention | 9/07/2015 | 30/07/2015 | 31/08/2015 | 15/09/2015 |
| 15/CEN/102 | Approve | Bariatric Embolization for morbidly obese patients | Dr Martin Krauss | Intervention | 9/07/2015 |  |  | 30/07/2015 |
| 15/CEN/103 | Approve | Incidence and clinical significance of anti-DFS70 in a New Zealand population | Mrs Stacey Lucas | Observational | 9/07/2015 |  |  | 30/07/2015 |
| 15/CEN/104 | Approve | Long-term Investigative Follow-up in Trialnet (Lift) | Professor Russell Scott | Observational | 9/07/2015 | 30/07/2015 | 17/08/2015 | 2/09/2015 |
| 15/CEN/89 | Approve | DSD: Navigating decision making | Professor Sunny Collings | Observational | 9/07/2015 |  |  | 30/07/2015 |
| 15/CEN/93 | Approve | Blinded randomised controlled trial of Oxford Uncemented Unicompartmental Knee Arthroplasty and Total Knee Arthroplasty | Dr Jonathan Manson | Intervention | 9/07/2015 |  |  | 30/07/2015 |
| 15/CEN/95 | Approve | CAMERA2 | Dr Genevieve Walls | Intervention | 9/07/2015 |  |  | 30/07/2015 |
| 15/CEN/96 | Approve | Bowel Cancer Study | Dr Tinte Itinteang | Observational | 9/07/2015 |  |  | 30/07/2015 |
| 15/CEN/97 | Approve | Breast Cancer Study | Dr Tinte Itinteang | Observational | 9/07/2015 |  |  | 30/07/2015 |
| 15/CEN/98 | Approve | DAP-PEDOST-11-03: Study investigating Daptomycin in the treatment of bone infection in children | Dr Tony Walls | Intervention | 9/07/2015 | 30/07/2015 | 3/09/2015 | 17/09/2015 |
| 15/CEN/99 | Approve | Effectiveness of Face-to-Face Problem Gambling Interventions Clinical Trial | Professor Max Abbott | Intervention | 9/07/2015 | 30/07/2015 | 17/08/2015 | 27/08/2015 |
| 15/CEN/106 | Approve | The role of cancer stem cells and receptor signaling in liver and periampullary tumours | Dr. Swee T Tan | Observational | 13/08/2015 |  |  | 28/08/2015 |
| 15/CEN/108 | Decline | Investigating whether a targeted nutrient supplement reduces inflammation in people with Inflammatory Bowel Disease | Ms Bobbi B. Laing | Intervention | 13/08/2015 |  |  | 28/08/2015 |
| 15/CEN/111 | Approve | Living away from home: The views of disabled young adults | Dr Brigit Mirfin-Veitch | Observational | 13/08/2015 |  |  | 28/08/2015 |
| 15/CEN/112 | Approve | Antibiotics during cardiac surgery | Professor Brian J Anderson | Observational | 13/08/2015 | 28/08/2015 | 8/09/2015 | 23/09/2015 |
| 15/CEN/114 | Approve | Gastrointestinal motility study | Dr Susanna Every-Palmer | Observational | 13/08/2015 |  |  | 28/08/2015 |
| 15/CEN/115 | Approve | Self-directed rehabilitation RCT after stroke | Dr Harry McNaughton | Intervention | 13/08/2015 |  |  | 28/08/2015 |
| 15/CEN/116 | Approve | Efficacy and safety of finerenone in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease. FIDELIO - DKD | Professor Russell Scott | Intervention | 13/08/2015 |  |  | 28/08/2015 |
| 15/CEN/117 | Approve | Efficacy and safety of finerenone in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease. FIGARO-DKD | Professor Russell Scott | Intervention | 13/08/2015 |  |  | 28/08/2015 |
| 15/CEN/118 | Approve | IV ARX788 in advanced breast cancer | Dr Anne O'Donnell | Intervention | 13/08/2015 |  |  | 28/08/2015 |
| 15/CEN/122 | Approve | The effect of alcohol consumption on injury presentations at Auckland City Hospital Adult Emergency Department | Dr Bridget Kool | Observational | 10/09/2015 | 24/09/2015 | 21/10/2015 | 12/11/2015 |
| 15/CEN/123 | Approve | WO29519: Idasanutlin in relapsed/refractory AML | Dr Steven Gibbons | Intervention | 10/09/2015 | 24/09/2015 | 12/10/2015 | 2/11/2015 |
| 15/CEN/124 | Approve | Problem Solving Therapy with Young Stroke Survivors | Ms Charlotte Wainwright | Intervention | 10/09/2015 |  |  | 24/09/2015 |
| 15/CEN/125 | Approve | Venous Ulcer study | Mr Janaka Kesara Wickremesekera | Intervention | 10/09/2015 |  |  | 24/09/2015 |
| 15/CEN/129 | Provisionally approve | Drama Therapy and Dementia | Miss Sophie Buchanan | Intervention | 10/09/2015 | 24/09/2015 | 16/12/2015 |  |
| 15/CEN/132 | Approve | Comparing the satiety and blood glucose effects of formulated beverages in adults | Ms Irene H.H. Ho | Intervention | 10/09/2015 | 24/09/2015 | 9/10/2015 | 4/11/2015 |
| 15/CEN/133 | Approve | A Study of APD334 in Patients with Moderately to Severely Active Ulcerative Colitis | Prof Richard Gearry | Intervention | 10/09/2015 | 24/09/2015 | 21/10/2015 | 12/11/2015 |
| 15/CEN/134 | Approve | Acceptance and Commitment Therapy (ACT) for Alcohol and Drug Populations | Miss Rachel Cotter | Intervention | 10/09/2015 | 24/09/2015 | 19/10/2015 | 5/11/2015 |
| 15/CEN/135 | Approve | Older people in retirement villages: unidentified need & intervention research | Professor Martin Connolly | Intervention | 10/09/2015 | 24/09/2015 | 23/11/2015 | 22/12/2015 |
| 15/CEN/142 | Provisionally approve | Diabetes in Pregnancy effects on subsequent generations | Dr Rosemary Hall | Observational | 10/09/2015 | 24/09/2015 |  |  |
| 15/CEN/143 | Approve | Human tissue bank of surgical cancers | Associate Professor Peter Larsen | Observational | 10/09/2015 |  |  | 24/09/2015 |
| 15/CEN/146 | Approve | Comparison of the blood levels of two forms of fingolimod 0.5 mg tablets in healthy male and female volunteers | Dr Noelyn Hung | Intervention | 10/09/2015 |  |  | 28/09/2015 |
| 15/CEN/147 | Approve | Assessment of an oral influenza B vaccine tablet (VXA-BYW.10), following a single dose in healthy adults | Dr Chris Wynne | Intervention | 10/09/2015 |  |  | 28/09/2015 |
| 15/CEN/148 | Approve | AL-335-604 A Study of AL-335, Odalasvir and Simeprevir in GT1 and GT3, Treatment-Naïve Hep C Subjects | Prof Edward Gane | Intervention | 10/09/2015 |  |  | 28/09/2015 |
| 15/CEN/149 | Approve | GS-US-339-1631: Study Evaluating Entospletinib Pharmacokinetics in Subjects with Normal and Impaired Hepatic Function | Prof Edward Gane | Intervention | 10/09/2015 |  |  | 28/09/2015 |
| 15/CEN/150 | Approve | Strength versus skill deficits in dysphagia | Ms Karen Ng | Observational | 10/09/2015 |  |  | 28/09/2015 |
| 15/CEN/151 | Approve | The effect of chiropractic adjustment on mental rotation in children | Dr Kelly Holt | Intervention | 10/09/2015 | 28/09/2015 | 21/10/2015 | 11/11/2015 |
| 15/CEN/153 | Approve | Investigating whether a targeted nutrient supplement reduces inflammation in peoplewith the Inflammatory Bowel Disease Crohn's disease (CD) | Ms Bobbi B Laing | Intervention | 10/09/2015 | 28/09/2015 | 12/10/2015 | 30/10/2015 |
| 15/CEN/157 | Approve | COG AALL1231: Phase III Randomised Trial of Bortezomib in Newly Diagnosed T-ALL and T-LLy | Dr Siobhan Cross | Intervention | 15/10/2015 | 5/11/2015 | 20/11/2015 | 4/12/2015 |
| 15/CEN/166 | Approve | D3FEAT | Prof Edward Gane | Intervention | 15/10/2015 | 5/11/2015 | 20/11/2015 | 20/11/2015 |
| 15/CEN/167 | Approve | BH29884:Prophylactic Subcutaneous R05534262 in Haemophilia A with inhibitors | Dr Paul Ockelford | Intervention | 15/10/2015 |  |  | 8/11/2015 |
| 15/CEN/169 | Approve | MagLev: Increasing magnesium levels and cognition in women with breast cancer receiving adjuvant endocrine treatment | Dr David Porter | Intervention | 15/10/2015 |  |  | 8/11/2015 |
| 15/CEN/170 | Approve | Comparison of the blood levels of two forms of buprenorphine 20 mcg/hr transdermal patch in healthy male and female volunteers | Dr Noelyn Hung | Intervention | 15/10/2015 |  |  | 8/11/2015 |
| 15/CEN/171 | Approve | Efficacy and safety of finerenone in subjects with chronic heart failure at high risk of recurrent heart failure decompensation | Prof. Richard Troughton | Intervention | 15/10/2015 | 5/11/2015 | 26/11/2015 | 11/12/2015 |
| 15/CEN/172 | Approve | A phase III study of Lenalidomide and low-dose Dexamethasone with or without Pembrolizumab (MK3475) in newly diagnosed and treatment naïve Multiple Myeloma(KEYNOTE 185) | Dr Anupkumar George | Intervention | 15/10/2015 | 8/11/2015 | 13/11/2015 | 20/11/2015 |
| 15/CEN/173 | Approve | Comparison of symptoms and signs of two forms of the drug budesonide nasal spray in participants with a history of seasonal allergic rhinitis | Dr Noelyn Hung | Intervention | 15/10/2015 | 8/11/2015 | 4/12/2015 | 18/12/2015 |
| 15/CEN/175 | Approve | Mobile single sided NMR sensor for brain oxygenation monitoring | Dr Shieak YC Tzeng | Observational | 15/10/2015 |  |  | 8/11/2015 |
| 15/CEN/179 | Approve | BGB-A317 given in increasing dose levels to participants with advanced tumors | Dr Michael Jameson | Intervention | 15/10/2015 | 8/11/2015 | 24/11/2015 | 4/12/2015 |
| 15/CEN/181 | Approve | The Nest Study | Prof Julian Crane | Intervention | 15/10/2015 |  |  | 8/11/2015 |
| 15/CEN/182 | Approve | The RESTORE feasibility study | Dr Dougal McClean | Intervention | 15/10/2015 |  |  | 8/11/2015 |
| 15/CEN/136 | Approve | Epidemiology of Trichomoniasis in the Auckland and Northland Communities | Dr Arlo Upton | Observational | 9/11/2015 |  |  | 13/11/2015 |
| 15/CEN/190 | Provisionally approve | RSV Vaccine in Pregnancy | Dr Adrian Trenholme | Intervention | 12/11/2015 | 1/12/2015 | 17/12/2015 |  |
| 15/CEN/192 | Provisionally approve | EuroNet-PHL-C2 | Dr Tim Prestidge | Intervention | 12/11/2015 | 1/12/2015 | 14/12/2015 |  |
| 15/CEN/193 | Provisionally approve | STARRT-AKI | Dr Shay McGuinness | Intervention | 12/11/2015 | 3/12/2015 |  |  |
| 15/CEN/194 | Provisionally approve | Effects of irrigation fluid temperature on body temperature during TURP | Dr Kimberley Sent-Doux | Intervention | 12/11/2015 | 3/12/2015 | 7/12/2015 |  |
| 15/CEN/195 | Provisionally approve | JAVELIN Lung 100 | Dr Archana Srivastava | Intervention | 12/11/2015 | 3/12/2015 |  |  |
| 15/CEN/196 | Approve | A study assessing an investigational injectable gel formulation of dexamethasone, developed for the treatment of sciatica | Dr Richard Robson | Intervention | 12/11/2015 |  |  | 3/12/2015 |
| 15/CEN/198 | Approve | A study to evaluate the safety, antiviral activity and PK of ARB-001467 in subjects with CHB | Prof Edward Gane | Intervention | 12/11/2015 |  |  | 3/12/2015 |
| 15/CEN/199 | Provisionally approve | MAC-V | Dr Douglas Campbell | Intervention | 12/11/2015 | 7/12/2015 |  |  |
| 15/CEN/200 | Provisionally approve | Carrageenan Asthma Study | Prof Julian Crane | Intervention | 12/11/2015 | 7/12/2015 |  |  |
| 15/CEN/202 | Provisionally approve | APD334-005: Extension Study of APD334-003 | Prof Richard Gearry | Intervention | 12/11/2015 | 7/12/2015 | 14/12/2015 |  |
| 15/CEN/206 | Provisionally approve | Segmentation Towards Enabling Pathways (STEP) | Professor Matthew Parsons | Observational | 12/11/2015 | 1/12/2015 | 14/12/2015 |  |
| 15/CEN/207 | Approve | Gut microbiota and influenza vaccine | Dr Irene Braithwaite | Intervention | 12/11/2015 |  |  | 7/12/2015 |
| 15/CEN/212 | Provisionally approve | AAML1331: Acute Promyelocytic Leukaemia | Dr Siobhan Cross | Intervention | 3/12/2015 | 18/12/2015 |  |  |
| 15/CEN/213 | Provisionally approve | AALL1331: Blinatumomab in First Relapse of Childhood B-ALL | Dr Peter Bradbeer | Intervention | 3/12/2015 | 18/12/2015 |  |  |
| 15/CEN/214 | Provisionally approve | M13-545 Rheumatoid Arthritis | Dr Daniel Ching | Intervention | 3/12/2015 | 18/12/2015 |  |  |
| 15/CEN/215 | Provisionally approve | M14-465 Rheumatoid Arthritis | Dr Daniel Ching | Intervention | 3/12/2015 | 18/12/2015 |  |  |
| 15/CEN/216 | Approve | The CRISP study | Associate Professor Anne Camille La Flamme | Intervention | 3/12/2015 |  |  | 18/12/2015 |
| 15/CEN/217 | Approve | T Cell Receptor Therapy of Liver Cancer | Dr. William Abbott | Intervention | 3/12/2015 |  |  | 18/12/2015 |
| 15/CEN/218 | Provisionally approve | My Baby’s Movements | Dr Katie Groom | Intervention | 3/12/2015 | 18/12/2015 |  |  |
| 15/CEN/219 | Provisionally approve | A Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ACH-0144471 in Healthy Volunteers | Dr Rod Ellis-Pegler | Intervention | 3/12/2015 | 18/12/2015 |  |  |
| 15/CEN/222 | Provisionally approve | A Phase I/II trial of MK3475(pembrolizumab) in children’s solid tumours and lymphoma | Dr Timothy Prestidge | Intervention | 3/12/2015 | 18/12/2015 |  |  |
| 15/CEN/224 | Provisionally approve | School readiness | Dr Alison Leversha | Intervention | 3/12/2015 | 18/12/2015 | 21/12/2015 |  |
| 15/CEN/230 | Provisionally approve | ARROW | Dr Hilary Blacklock | Intervention | 3/12/2015 | 18/12/2015 |  |  |
| 15/CEN/231 | Provisionally approve | Investigation of the antibody Sirukumab in patients with Giant Cell Arteritis | Dr Ketna Parekh | Intervention | 3/12/2015 | 18/12/2015 |  |  |

## 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/CEN/105 | Approve | The impact of vaccinations on preventing invasive bacterial disease in children | Dr Tony Walls | Observational | 29/07/2015 |  |  | 10/08/2015 | | 15/CEN/109 | Approve | Benefits and burdens of hospital admissions and their impact on preferences for place of care from the perspectives of patients with palliative care needs | Mrs Jackie Robinson | Observational | 7/08/2015 |  |  | 21/08/2015 | | 15/CEN/11 | Approve | Ethnic patterns of hypospadias in New Zealand | Dr Jason Gurney | Observational | 2/03/2015 |  |  | 19/03/2015 | | 15/CEN/113 | Approve | Biodymanic Excisional Skin Tension (BEST) Lines for Cutaneous Surgery | Dr Sharad Paul | Observational | 7/08/2015 |  |  | 21/08/2015 | | 15/CEN/137 | Approve | Pacific youth obesity program | Dr Ridvan Firestone | Intervention | 10/09/2015 |  |  | 25/09/2015 | | 15/CEN/138 | Approve | Second cancers in chronic lymphocytic leukaemia patients | Dr Sean A MacPherson | Observational | 10/09/2015 |  |  | 24/09/2015 | | 15/CEN/141 | Approve | Monitoring O2 Saturation for Extraction: The MOOSE Study | Professor Geoffrey Shaw | Intervention | 10/09/2015 |  |  | 25/09/2015 | | 15/CEN/158 | Approve | FENO and FEV1 in Asthma | Dr Jack Dummer | Intervention | 29/09/2015 |  |  | 14/10/2015 | | 15/CEN/159 | Approve | Mindfulness group for health conditions | Dr Philippa Seaton | Intervention | 29/09/2015 |  |  | 14/10/2015 | | 15/CEN/164 | Approve | Pemberton's Sign Study | Dr Win Meyer-Rochow | Observational | 12/10/2015 |  |  | 28/10/2015 | | 15/CEN/165 | Approve | Hypoxia and the baroreflex | Miss Lydia Hingston | Intervention | 7/10/2015 | 19/10/2015 | 4/11/2015 | 8/11/2015 | | 15/CEN/17 | Approve | Developing a method for assessing bladder motility using two dimensional spatiotemporal analysis of video films taken at cystoscopy or during open bladder surgery. | Prof Roger Lentle | Observational | 12/02/2015 |  |  | 27/02/2015 | | 15/CEN/177 | Approve | Effect of short term temperature changes on energy expenditure | Mr Terrence O'Donnell | Intervention | 9/10/2015 | 28/10/2015 | 4/12/2015 | 11/12/2015 | | 15/CEN/178 | Approve | The Kiwi-COPE Model | Dr David Tripp | Observational | 12/10/2015 |  |  | 28/10/2015 | | 15/CEN/187 | Approve | Assessment of immediate post-insertion migration of Percutaneous Intravenous Central Catheter tips dependant on arm position | Dr Bruno De Carvalho | Observational | 20/10/2015 | 8/11/2015 | 10/11/2015 | 19/11/2015 | | 15/CEN/188 | Approve | The patient experience of musculoskeletal imaging | Professor Nicola Dalbeth | Observational | 29/10/2015 | 10/11/2015 | 18/11/2015 | 23/11/2015 | | 15/CEN/189 | Approve | Impact of the MeNZB Vaccine on Gonorrhoea | Dr Helen Petousis\_Harris | Observational | 28/10/2015 |  |  | 10/11/2015 | | 15/CEN/208 | Approve | Review of Impact of Life Questionnaire in Primary Care | Mr David Todd | Observational | 12/11/2015 | 1/12/2015 | 14/12/2015 | 15/12/2015 | | 15/CEN/21 | Approve | Designing for Adherence | Ms Gillian McCarthy | Observational | 17/02/2015 |  |  | 5/03/2015 | | 15/CEN/210 | Approve | TextMATCH Feedback Study | Ms Rosie Dobson | Observational | 26/11/2015 |  |  | 11/12/2015 | | 15/CEN/211 | Provisionally approve | BIO-LIFT procedure for anal fistulas, a prospective review | Dr Kirsten de Burlet | Observational | 3/12/2015 | 21/12/2015 |  |  | | 15/CEN/227 | Provisionally approve | Transplant-acquired allergies | Dr Alicia Lim | Observational | 3/12/2015 | 21/12/2015 |  |  | | 15/CEN/23 | Approve | Juvenile Fitness to Stand Trial in Auckland | Dr Davin Tan | Observational | 5/03/2015 | 19/03/2015 | 20/03/2015 | 26/03/2015 | | 15/CEN/30 | Approve | Sustained lignocaine intraperitoneal drug delivery following surgery | Professor Andrew Hill | Observational | 12/03/2015 |  |  | 27/03/2015 | | 15/CEN/31 | Approve | MiCBT for PTSD: A pilot study | Mr Nicholas Laurence | Intervention | 13/03/2015 |  |  | 27/03/2015 | | 15/CEN/35 | Approve | Gut peptide responses following bariatric surgery | Dr Brian Corley | Observational | 17/03/2015 |  |  | 27/03/2015 | | 15/CEN/36 | Approve | Shift work, gut bacteria and health | Dr Shanthi Parkar | Observational | 20/03/2015 |  |  | 7/04/2015 | | 15/CEN/37 | Approve | Whānau Health Literacy - Pilot Programme | Ms Carolyn Watts | Intervention | 24/03/2015 | 9/04/2015 | 16/04/2015 | 22/04/2015 | | 15/CEN/38 | Approve | ACL saphenous nerve block study | Dr Ritwik Kejriwal | Intervention | 31/03/2015 | 17/04/2015 | 22/04/2015 | 28/04/2015 | | 15/CEN/4 | Approve | Peri-prosthetic Joint Infections (PJI): Joint washouts and debridements are associated with a risk of acquired poly-microbial infection | Dr Liam Dunbar | Observational | 20/01/2015 |  |  | 3/02/2015 | | 15/CEN/40 | Approve | Distal biceps tendon repair outcomes | Dr. Shiran Zhang | Observational | 8/04/2015 |  |  | 22/04/2015 | | 15/CEN/42 | Approve | ICU Deaths - Assessment and Classification of Reason (ICU-DECLARE) | Dr Elliott Ridgeon | Observational | 13/04/2015 |  |  | 30/04/2015 | | 15/CEN/45 | Approve | Inappropriate prescribing in older people | Dr Shiva Nishtala | Observational | 16/04/2015 |  |  | 1/05/2015 | | 15/CEN/5 | Approve | Feasibility study of cryo-biopsy use in the diagnosis of suspected lung cancer | Dr Samantha Herath | Intervention | 20/01/2015 | 3/02/2015 | 20/02/2015 | 26/02/2015 | | 15/CEN/53 | Approve | Nerve Ultrasound in CANVAS | Dr luciana pelosi | Observational | 22/04/2015 |  |  | 6/05/2015 | | 15/CEN/54 | Approve | Publically funded vs private vasectomy services | Dr Sara Filoche | Observational | 22/04/2015 |  |  | 6/05/2015 | | 15/CEN/55 | Approve | Water for labour and birth | Ms Verity O'Connor | Observational | 28/04/2015 |  |  | 11/05/2015 | | 15/CEN/58 | Approve | Device-Therapy and Heart Failure Management | Dr Khang-Li Looi | Observational | 11/05/2015 |  |  | 25/05/2015 | | 15/CEN/59 | Approve | Bowen Therapy and chronic pain | Dr Gwyn Lewis | Intervention | 13/05/2015 | 27/05/2015 | 17/12/2015 | 21/12/2015 | | 15/CEN/6 | Approve | Olecranon Fracture Management in the Elderly | Dr Ilia Elkinson | Intervention | 22/01/2015 | 3/02/2015 | 9/02/2015 | 13/02/2015 | | 15/CEN/60 | Approve | AT RISC 2 | Dr Paula Barlow | Observational | 13/05/2015 |  |  | 29/05/2015 | | 15/CEN/65 | Approve | MALDI-TOF identified non-toxigenic C.diphtheriae: a case series of skin lesions | Dr James Taylor | Observational | 21/05/2015 |  |  | 5/06/2015 | | 15/CEN/69 | Approve | Silicone oil: a medium for hand rehabilitation following Dupuytrens Surgery | Ms Gail L Donaldson | Intervention | 21/05/2015 | 5/06/2015 | 6/07/2015 | 17/07/2015 | | 15/CEN/7 | Approve | LOTUS | Assoc Prof Vernon Harvey | Intervention | 28/01/2015 | 17/02/2015 | 23/02/2015 | 26/02/2015 | | 15/CEN/71 | Approve | Satiation by carbohydrate foods | Dr John Monro | Intervention | 25/05/2015 |  |  | 11/06/2015 | | 15/CEN/72 | Approve | When to eat kiwifruit | Dr John Monro | Intervention | 26/05/2015 |  |  | 11/06/2015 | | 15/CEN/8 | Approve | Home Insulation and General Health Study (HIGHS) | Associate Professor Barry Borman | Observational | 3/02/2015 |  |  | 17/02/2015 | | 15/CEN/87 | Approve | Beta-lactam Allergy Management Service | Miss Tanya du Plessis | Intervention | 22/06/2015 |  |  | 10/07/2015 | | 15/CEN/88 | Approve | Recovery for South Asian people accessing mental health services in New Zealand | Ms Kaberi Rajendra | Observational | 22/06/2015 |  |  | 10/07/2015 | | 15/CEN/9 | Approve | Long term safety and efficacy of intrapleural tPA and DNase | Dr Nicola Smith | Observational | 4/02/2015 | 17/02/2015 | 18/02/2015 | 26/02/2015 | | 15/CEN/90 | Approve | Exploring the role of primary healthcare clinicians in the detection and diagnosis of mouth cancer in New Zealand | Dr Donna T Kennedy Langley | Observational | 3/07/2015 | 5/08/2015 | 24/08/2015 | 2/09/2015 | | 15/CEN/92 | Approve | Effect of gestational weight gain on vaginal birth after caesarean delivery | Dr Michelle Wise | Observational | 8/07/2015 |  |  | 31/07/2015 | |  |  |  |  |  |  |

## Overdue full applications

|  |  |  |  |
| --- | --- | --- | --- |
| Reference | Short title | Days overdue | Reason |
| 15/CEN/101 | ASLAN001-003 | 1 | Secretariat Failed to Action Decision |
| 15/CEN/122 | The effect of alcohol consumption on injury presentations at Auckland City Hospital Adult Emergency Department | 1 | Committee member delay in Response |
| 15/CEN/133 | A Study of APD334 in Patients with Moderately to Severely Active Ulcerative Colitis | 1 | Committee member delay in Response |
| 15/CEN/153 | Investigating whether a targeted nutrient supplement reduces inflammation in peoplewith the Inflammatory Bowel Disease Crohn's disease (CD) | 1 | Committee member delay in Response |
| 15/CEN/171 | Efficacy and safety of finerenone in subjects with chronic heart failure at high risk of recurrent heart failure decompensation | 1 | Committee member delay in Response |
| 15/CEN/26 | Pediatric Vasculitis Initiative or PedVas | 1 | Committee member delay in Response |
| 15/CEN/43 | Treatment of Hepatitis C in injecting drug users- SIMPLIFY Study | 1 | Committee member delay in Response |
| 15/CEN/104 | Long-term Investigative Follow-up in Trialnet (Lift) | 2 | Committee member delay in Response |
| 15/CEN/173 | Comparison of symptoms and signs of two forms of the drug budesonide nasal spray in participants with a history of seasonal allergic rhinitis | 3 | Committee member delay in Response |
| 15/CEN/34 | V89\_18 | 3 | Committee member delay in Response |
| 15/CEN/76 | The psychosocial interactions of AYA cancer survivors and the impact on their development | 3 | Committee member delay in Response |
| 15/CEN/151 | The effect of chiropractic adjustment on mental rotation in children | 4 | Committee member delay in Response |
| 15/CEN/132 | Comparing the satiety and blood glucose effects of formulated beverages in adults | 5 | Committee member delay in Response |
| 15/CEN/48 | Modafinil 100 mg bioequivalence study conducted under fasting conditions | 6 | Committee member delay in Response |
| 15/CEN/83 | Maia | 6 | Committee member delay in Response |
| 15/CEN/135 | Older people in retirement villages: unidentified need & intervention research | 8 | Incomplete provisional Response |
| 15/CEN/74 | Communication in NZ families affected by parental chronic pain | 8 | Committee member delay in Response |
| 15/CEN/16 | Can we avoid unnecessary hospital admissions for COPD? | 9 | Committee member delay in Response |
| 15/CEN/82 | ENZAMET | 12 | Incomplete provisional Response |
| 15/CEN/52 | Paediatric Perianaesthesia Questionnaire validation in New Zealand | 14 | Committee member delay in Response |
| 15/CEN/77 | UNIFI | 14 | Incomplete provisional Response |
| 15/CEN/41 | Phase I Study of MK3475 in Combination with Trametinib and Dabrafenib | 35 | Incomplete provisional Response |

## Overdue expedited applications

|  |  |  |  |
| --- | --- | --- | --- |
| Reference | Short title | Days overdue | Reason |
| 15/CEN/164 | Pemberton's Sign Study | 1 | Committee member delay in Response |
| 15/CEN/165 | Hypoxia and the baroreflex | 1 | Secretariat Failed to Action Decision |
| 15/CEN/178 | The Kiwi-COPE Model | 1 | Committee member delay in Response |
| 15/CEN/21 | Designing for Adherence | 1 | Committee member delay in Response |
| 15/CEN/6 | Olecranon Fracture Management in the Elderly | 1 | Secretariat Failed to Action Decision |
| 15/CEN/60 | AT RISC 2 | 1 | Committee member delay in Response |
| 15/CEN/72 | When to eat kiwifruit | 1 | Committee member delay in Response |
| 15/CEN/11 | Ethnic patterns of hypospadias in New Zealand | 2 | Secretariat Failed to Action Decision |
| 15/CEN/188 | The patient experience of musculoskeletal imaging | 2 | Committee member delay in Response |
| 15/CEN/42 | ICU Deaths - Assessment and Classification of Reason (ICU-DECLARE) | 2 | Committee member delay in Response |
| 15/CEN/71 | Satiation by carbohydrate foods | 2 | Committee member delay in Response |
| 15/CEN/36 | Shift work, gut bacteria and health | 3 | Committee member delay in Response |
| 15/CEN/59 | Bowen Therapy and chronic pain | 3 | Committee member delay in Response |
| 15/CEN/87 | Beta-lactam Allergy Management Service | 3 | Committee member delay in Response |
| 15/CEN/88 | Recovery for South Asian people accessing mental health services in New Zealand | 3 | Committee member delay in Response |
| 15/CEN/208 | Review of Impact of Life Questionnaire in Primary Care | 5 | Committee member delay in Response |
| 15/CEN/23 | Juvenile Fitness to Stand Trial in Auckland | 5 | Incomplete provisional Response |
| 15/CEN/5 | Feasibility study of cryo-biopsy use in the diagnosis of suspected lung cancer | 5 | Committee member delay in Response |
| 15/CEN/9 | Long term safety and efficacy of intrapleural tPA and DNase | 6 | Committee member delay in Response |
| 15/CEN/37 | Whānau Health Literacy - Pilot Programme | 7 | Committee member delay in Response |
| 15/CEN/38 | ACL saphenous nerve block study | 8 | Committee member delay in Response |
| 15/CEN/7 | LOTUS | 8 | Committee member delay in Response |
| 15/CEN/92 | Effect of Gestational weight gain on vaginal birth after caesarean delivery | 8 | Committee member delay in Response |
| 15/CEN/177 | Effect of short term temperature changes on energy expenditure | 11 | Committee member delay in Response |
| 15/CEN/69 | Silicone oil: a medium for hand rehabilitation following Dupuytrens Surgery | 11 | Incomplete provisional Response |
| 15/CEN/187 | Assessment of immediate post-insertion migration of Percutaneous Intravenous Central Catheter tips dependant on arm position | 13 | Incomplete provisional Response |
| 15/CEN/90 | Exploring the role of primary healthcare clinicians in the detection and diagnosis of mouth cancer in New Zealand | 27 | Incomplete provisional Response |