

Central Health and Disability Ethics Committee

Annual Report
2020

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# 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 Health and Disability Ethics Committee 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 Health and Disability Ethics Committee 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

It is always interesting to go back and read the last years report and see what has changed. Last year I spoke of the digital world and the impact it was having on “consenting and security”. Never did we think that 12 months later we would be so dependent on our digital world in so many ways. As “lockdown” occurred communication, consent and monitoring have all benefited, information security is still foremost in our minds.

As also mentioned last year and the year before, Data repositories and the continued requests for data sharing and linking is a continual problem. Requests for unconsented data are becoming more prevalent, it would be so much better if consent was gained for this data at the onset. The Participant Information Sheet Template is in the process of being reworked with extensive data management processes included. But that is only for data from research, it is data sharing from other avenues to be used in research that is a real issue.

The much awaited NEAC guidelines have arrived and thanks to everyone for their hard work in this avenue. These have been released electronically rather than hardcopy to enable timely changes to be made as necessary, so always head to the online version to be up to date.

Right 7 (4) remains a challenging area for the ethics committees, especially how it relates to the field of the Emergency and Intensive Care research and working with vulnerable participants. More clarity and understanding is required to ensure that researchers know their responsibilities in terms of both ethics and the law when conducting this important research. Other recurring frustrations are the quality of ethics applications in regard to the robustness of peer review, the adequacy of sponsor insurance in commercial trials, and lack of researcher cultural literacy (as evidenced in the Māori responsiveness section of the application form). These have been topics of discussion at our chair-only meetings and something we hope to have some resolution with the new IT system and development of new Standard Operating Procedures for 2021 allowing for a clearer application form and process for researchers.

The Central Committee has successfully managed the meeting challenge via zoom since March and it appears this will be the ongoing mode of communication for the near future. One benefit is that we get to see our Researchers rather than converse with just a voice, there has to be some pluses! The workload for the committee is ever increasing which is positive for Research in New Zealand but hard for members that also have “day jobs”, the preparation reading is enormous. The workload also increased with the appointments process being quite slow, so less people more work. This has been improved for Central in recent months with the appointments of two new members, thank you.

Workload also increased with members making themselves available for the COVID Emergency committee. The SOPs for this have tight timelines around them to enable a faster approval rate to enable the very important Covid research to occur.

Sitting behind all this is the HDEC Secretariat who manages to continually support the committees and who have also been impacted by the changing world around us. Thank you all.

To the Central Committee, thank you for being the team you are. We work well together, and you should be proud of the part we play in the achievements of research in New Zealand.

Helen Walker

Central Health and Disability Ethics Committee

# Membership and attendance

Turnover was low as membership changes were due to members stepping down or not being re-appointed after their term expired by the Minister, resulting in a mixture of long-serving members and new members at any given time. No impact as been observed.

## Membership

### List of EC members within the reporting period

**Mrs Helen Walker (Chair)**

Membership category: Consumer/Community Perspectives

Date of appointment: 22nd May 2020

Current term expires: 22nd May 2023

Mrs Helen Walker is currently the Chairperson Central Health and Disability Ethics Committee, a Member of the Medical Sciences Council, a Trustee of the Cranford Hospice Trust, Chairperson of the New Zealand Singing School and the owner of Kilgaren Farming Partnership. She completed a Bachelor of Science at Massey University, a Certificate in Company Direction through the New Zealand Institute of Directors and is a Chartered member of the Institute. Mrs Walker is previously a Director and Chair of Health Hawkes Bay, Guardian/Kaitiaki of the Turnbull Library, Director of Unison Networks Ltd and Hawke’s Bay District Health Board. Chairman of the Central Hawke’s Bay Consumers Power Trust, Past President of the Waipawa Musical and Dramatic Club and a member of the Waipawa Municipal Theatre Refurbishment Trust. Finance Audit and Risk (FAR) has been a major part all these roles with position of FAR Chair in most.

**Ms Sandy Gill\***

Membership category: Consumer/Community Perspectives

Date of appointment: 22nd May 2020

Current term expires: 22nd May 2023

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

**Dr Patries Herst**

Membership category: Intervention Studies

Date of appointment: 22nd May 2020

Current term expires: 22nd May 2023

Dr Patries Herst is currently an Associate Professor at the Department of Radiation Therapy, University of Otago, Wellington and a Senior Research Fellow at 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 biomedical 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 and overseas. She is the Chair 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 Peter Gallagher**

Membership category: Health/Disability Service Provision

Date of appointment: 22nd May 2020

Current term expires: 22nd May 2023

Dr Peter Gallagher RN PhD was first appointed to the Central HDEC as a non-lay member in July 2015. Before his retirement from full time work in 2018 he held various academic posts in the education of undergraduate and post graduate health professionals. His last post was as an education advisor to the Medical School at the University of Otago Wellington. His key research interest was in investigating how the learning that eventuates from clinical practice may be enhanced

**Mrs Helen Davidson**

Membership category: Ethical/Moral reasoning

Date of appointment: 6th December 2018

Current term expires: 6th December 2021

Helen Davidson has an LLB (Hons) and a Masters of Bioethics and Health Law from the University of Otago. Helen is currently a General Manager at Engineering New Zealand responsible for leading the organisations legal and policy portfolios, including complaints resolution, governance and thought leadership. Helen has over 15 years’ experience in law, complaints management and policy. Prior to Engineering New Zealand, she worked mainly in the health sector, including as Principal Legal Advisor at the Health and Disability Commissioner and Director of Patient Safety at the Ministry of Health Services in British Columbia Canada. Helen has also worked on academic projects at the University of Otago and the University of British Columbia investigating ethical issues associated with preimplantation genetic diagnosis and biobanking, as well as public deliberation methods. In 2017 Helen was awarded the In-house Lawyers’ Association of New Zealand’s Private Sector In-house Lawyer of the Year and Innovation awards, and in 2019 was awarded In-house Legal Team of the Year.

**Dr Cordelia Thomas**

Membership category: Law

Date of appointment: 22nd May 2017

Current term expires: 22nd May 2020

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

**Ms Julie Jones**

Membership category: Intervention Studies

Date of appointment: 22nd May 2017

Current term expires: 22nd May 2020

Ms Julie Jones is currently the president of the New Zealand Association of Clinical Research, and has been a member of the association’s executive committee since 2016. She has previous experience establishing a GMP facility at the Malaghan Institute, project and country portfolio management of clinical trials internationally and in New Zealand, and is currently working with the Medical Research Institute of New Zealand to implement a clinical research quality management system. She has a Bachelors of Science (BSc) and a Masters of Veterinary Studies (MVS) from Massey University and 20 years of experience in vaccine development and clinical trials.

**Dr Jillian Wilkinson**

Membership category: Observational Studies

Date of appointment: 22nd May 2020

Current term expires: 22nd May 2023

Dr Jill Wilkinson has a PhD in nursing and over 30 years’ experience in the health and education sectors as a clinician, policy advisor, academic and researcher. She works as a research fellow with the Diana Unwin Chair of Restorative Justice at Victoria University of Wellington researching in the area of consumer complaint. Previous teaching and research interests have been connected to the nurse practitioner role in New Zealand, advanced practice nursing, and safe prescribing practice. She is on the Board of Te Aro Health Centre, a nurse practitioner-led clinic which provides services to low income and often homeless people in Wellington. Jill is a past member and acting Chair of a research ethics committee at Massey University.

##

## Attendance

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

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | ***Membership category*** ***(L/NL)*** | **Jul** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** | **Jan** | **Feb** | **Ma**r | **Apr** | **May** | **Jun** | **Total** |
| John Smith \* | NL |  |  |  |  |  |  | X  | **Y**  | **Y**  | **Y**  | **Y**  | A  | 7/8 |
| Mrs Helen Walker | L | **Y** | **Y** | A | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Mrs Sandy Gill | L | **Y** | **Y** | **Y** | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Dr Patries Herst | NL | **Y** | **Y** | **Y** | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Dr Peter Gallagher | NL | **Y** | **Y** | **Y** | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Mrs Helen Davidson | L | **Y** | **Y** | **Y** | **Y** | **Y** | X | A | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Dr Cordelia Thomas | L | **Y** | A | **Y** | **Y** | **Y** | X | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Ms Julie Jones | NL | / | / | / | / | / | / | / | / | / | / | / | **Y** | 1/11 |
| Dr Jillian Wilkinson | NL | / | / | / | / | / | / | / | / | / | / | / | **Y** | 1/11 |
| Dr Dean Quinn | NL | **Y** | A | / | / | / | / | / | / | / | / | / | / | 1/11 |

## Training and conferences

### Specify the training undergone by new members

New HDEC member training for 2 members.

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

On 29 & 31 January 2020 there was a day-long training of the National Ethics Standards (6 members).

**If no training was undertaken over the last 12 months, provide reasons below.**

The only training for Central HDEC members over the last 12 months from the end of the reporting period is that above. However, since the reporting period on the 22 September we have held a training for new members, covering research-ethics, the HDEC SOPs and the online members’ portal. Ms Julie Jones, Dr Jillian Wilkinson and the chair of Central attended this training.

# Applications reviewed

### Summary of applications received by full EC

|  |  |
| --- | --- |
| No. of applications approved | 3 |
| No. of applications approved subject to non-standard conditions | 27 |
| No. of applications deferred and subsequently approved | 51 |
| No. of applications deferred as at time of report | 8 |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | 2 |
| No. of applications that were declined because of no/insufficient consultation with appropriate cultural group | 0 |
| No. of applications declined (This excludes those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group)  | 14 |
| No. of applications which do not require ethics committee approval *NB: this number includes applications rejected because they were incomplete* | 17 |
| No. of studies withdrawn by researcher | 2 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC  | 0 |
| **Total number of applications received by full EC**  | **124** |

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

|  |  |
| --- | --- |
| No. of applications approved | 65 |
| No. of applications deferred as at time of report | 2 |
| No. of applications which do not require ethics committee approval *NB: this number includes applications rejected because they were incomplete* | 12 |
| No. of applications referred for full committee review | N/A |
| No. of applications declined | 4 |
| No. of studies withdrawn by researcher | 0 |
| **Total number of applications received under expedited / low risk review** | **83** |

|  |  |
| --- | --- |
| Total number of applications received: | **207** |

#

# Complaints and overdue application summary

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

## Complaints received

### Complaint One

**Study Reference:** 18/CEN/49

**Type of Complaint:** Participant of Research

**Review Date:** 3 May 2018

**Complaint Received:** 17 July 2019

**Nature of Complaint:**

A Dermatologist informed the HDEC that a study participant had developed in late October/early November 2018 a florid rash on his right arm and shoulder area which corresponded to where the topical gel medication being investigated had been applied. In the view of the Dermatologist (based on photo evidence) the rash was either an acute allergic contact eczematous dermatitis or possibly an irritant dermatitis. The patient was treated initially by the study team but did not see a dermatologist until June 2019. The Dermatologist has recommended that patch testing be performed to determine the etiology of the skin eruption. The Dermatologist was concerned that appropriate treatment was not sought and wants to ensure that necessary agencies were contacted and to ensure that the study covers the required patch testing expenses.

**Actions Taken:**

* Complaint sent to Manager
* Manager acknowledged the complaint.
* Chair of Central HDEC Informed.
* Letter sent to CI asking for following information: a) why dermatology treatment was delayed b) what the follow up protocols were for this participant c) confirmation that the cost of patch testing will be covered by the study d) ensuring that other regulators had been notified that a reaction had occurred.

**Outcome:**

The Committee was satisfied that appropriate care and follow up had taken place for the participant. The participant was initially treated by the study team and then referred to their own GP to await Dermatologist appointment. Regulators were notified appropriately, and the research team would cover the costs of patch testing. Complaint closed.

## Overdue review

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

Average review times exclude time taken for researchers to respond to requests for further information. Researchers have up to 90 days to respond.

Average review time was 40 days for full applications. Target timeframe for full applications is 35 calendar days. The delay in this has been caused primarily by COVID-19 challenges to the Secretariat.

Average review time was 23 days for expedited applications. Target timeframe for expedited applications is 15 calendar days. The delay was largely caused by COVID-19 work taking priority, and the strain changes to working arrangements and workloads as a result had on the Secretariat.

#

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

## Applications reviewed by full committee

| **Study reference** | **Short title** | **CI Name** | **Clock Start** | **Date of provisional approval** | **Study status** | **Date of final decision** | **CI Organisation[locality not captured]** | **Main sponsor type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 19/CEN/110 | Post-operative infection rate of hip hemiarthroplasty at Canterbury District Health Board | Dr. Luca Killick | 5/07/2019 | 22/07/2019 | Approve | 13/08/2019 |  | no sponsor |
| 19/CEN/114 | Impact of re-operation within one month on early and long term outcomes after renal transplantation: A single centre experience. | Dr Sam Taylor |  |  | Invalid Application | 10/07/2019 | Auckland District Health Board | no sponsor |
| 19/CEN/115 | Phase 3 Study of Pembrolizumab with or without Maintenance Olaparib in First-line Metastatic Squamous NSCLC | Mr Brendan Luey | 11/07/2019 | 5/08/2019 | Approve | 7/11/2019 | Capital and Coast District Health Board | pharmaceutical company |
| 19/CEN/116 | Eidos AG10-301: A study to measure how effective and safe AG10 is for the treatment of Symptomatic Transthyretin Amyloid Cardiomyopathy | Dr Hugh Goodman | 11/07/2019 | 5/08/2019 | Approve | 23/09/2019 | Waikato District Health Board | pharmaceutical company |
| 19/CEN/117 | Phase 3 Study of Pembrolizumab with Maintenance Olaparib or MaintenancePemetrexed in 1L Metastatic Nonsquamous NSCLC | Mr Brendan Luey | 11/07/2019 | 5/08/2019 | Approve | 8/11/2019 | Capital and Coast District Health Board | pharmaceutical company |
| 19/CEN/118 | Pilot study for determining the prevalence of drug use in trauma patients in the Emergency Department | Professor Ian D Civil | 11/07/2019 | 31/07/2019 | Approve | 5/09/2019 | Auckland District Health Board | no sponsor |
| 19/CEN/119 | Sensitisation in Shoulder Pain Study | Mr Rani Othman | 8/07/2019 |  | Approve | 21/08/2019 | University of Otago | academic institution |
| 19/CEN/120 | AB-506-003: Safety, Tolerability, and Pharmacokinetics of AB-506 in Healthy Subjects for 28 Days | Prof Edward Gane | 11/07/2019 |  | Approve | 5/08/2019 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 19/CEN/121 | Cemiplimab Treatment After Surgery and Radiation Therapy in Patients with High Risk Cutaneous Squamous Cell Carcinoma | Dr Andrew Macann | 11/07/2019 | 31/07/2019 | Approve | 13/09/2019 | Auckland District Health Board | pharmaceutical company |
| 19/CEN/122 | A Randomized, Multicenter, Double-blind, Parallel, Active-control Study of the Effects of Sparsentan, a Dual Endothelin Receptor and Angiotensin Receptor Blocker, on Renal Outcomes in Patients with Pr | Dr Kannaiyan Rabindranath | 11/07/2019 | 5/08/2019 | Approve | 22/10/2019 | Waikato Hospital | pharmaceutical company |
| 19/CEN/123 | (duplicate) CA045-001 | Dr Catherine Barrow | 11/07/2019 | 5/08/2019 | Approve | 14/10/2019 | Capital and Coast District Health Board | pharmaceutical company |
| 19/CEN/124 | ACHieve | Prof Paul Hofman | 11/07/2019 | 5/08/2019 | Approve | 17/09/2019 | Liggins Institute, University of Auckland | pharmaceutical company |
| 19/CEN/125 | Phase 3 study of SBRT ± pembrolizumab for participants with medically inoperable Stage I or IIA NSCLC | Dr Gareth Rivalland | 11/07/2019 | 31/07/2019 | Approve | 8/10/2019 | Auckland City Hospital | pharmaceutical company |
| 19/CEN/126 | Ketamine in anorexia nervosa | Professor Paul Glue | 11/07/2019 | 31/07/2019 | Decline | 13/12/2019 | University of Otago | no sponsor |
| 19/CEN/127 | Transition of care from paediatric to adult renal services | Dr Claudia Vallebella |  |  | Invalid Application | 11/07/2019 |  | no sponsor |
| 19/CEN/128 | Generation of frailty index from electronic data | Dr Himali Wethasinghe | 12/07/2019 |  | Approve | 30/07/2019 | Waitemata District Health Board | district health board (DHB) |
| 19/CEN/129 | Healthy controls as a baseline measure of molecular inflammatory disease processes | Dr Kirsty Danielson | 17/07/2019 |  | Approve | 13/08/2019 | University of Otago | no sponsor |
| 19/CEN/130 | Oculomotor Function in Young Adults with Mild Traumatic Brain Injury. | Ms Alice Cade | 18/07/2019 |  | Approve | 21/08/2019 | University of Auckland | academic institution |
| 19/CEN/131 | Effectiveness of Lee Silverman Voice Treatment (LSVT LOUD) on voice, swallowing and cough function in Parkinson’s Disease: A randomized controlled trial | Ms Fathima Shakeela Abdul Saleem | 23/07/2019 |  | Approve | 21/08/2019 |  | academic institution |
| 19/CEN/132 | Optimising recovery after concussion (Phase Two). | Dr Deborah Snell | 24/07/2019 |  | Approve | 21/08/2019 | Canterbury District Health Board | no sponsor |
| 19/CEN/133 | REACCT Collaborative Study | Prof Ian Bissett | 24/07/2019 |  | Approve | 15/08/2019 | Auckland District Health Board | no sponsor |
| 19/CEN/134 | Sevoflurane Pharmacokinetics and Pharmacodynamics during Anaesthesia | Dr Benjamin van der Griend | 25/07/2019 | 21/08/2019 | Approve | 9/09/2019 | Canterbury District Health Board | no sponsor |
| 19/CEN/135 | A multi-disciplinary approach to diagnose mild traumatic brain injuries | Dr Rachel Fleming | 26/07/2019 |  | Approve | 21/08/2019 | ESR | other government agency |
| 19/CEN/136 | PHITT Trial (COG) | Dr Mark Winstanley | 15/08/2019 |  | Approve | 5/09/2019 | Auckland District Health Board | collaborative research |
| 19/CEN/137 | Closing the Rehabilitation Service Utilization Gaps of Māori People | Miss Ngonidzashe Mpofu | 26/07/2019 | 21/08/2019 | Approve | 24/09/2019 | University of Wisconsin - Madison | other |
| 19/CEN/138 | Head Start 4 | Dr Karen Tsui | 15/08/2019 |  | Approve | 5/09/2019 | Auckland District Health Board | collaborative research |
| 19/CEN/139 | Nox 1 and 4 inhibition in type 1 diabetic kidney disease | Professor Jonathan Shaw | 16/08/2019 | 5/09/2019 | Approve | 11/11/2019 | Baker Heart and Diabetes Institute | collaborative research |
| 19/CEN/141 | Youth Wellbeing Study 3.0: How do adolescents think, feel, and behave? | Professor Marc Wilson | 16/08/2019 | 5/09/2019 | Approve | 2/03/2020 | Victoria University of Wellington | academic institution |
| 19/CEN/142 | tune.in: an app to help young people meet their health behaviour change goals | Associate Professor Sarah Hetrick | 16/08/2019 |  | Approve | 5/09/2019 | The University of Auckland | academic institution |
| 19/CEN/143 | The relationship between spine adipose index and deep infection after posterior fusion of the lumbar spine | Dr Vikesh Gupta | 16/08/2019 |  | Approve | 5/09/2019 |  | no sponsor |
| 19/CEN/144 | Diet and Diabetes | Miss Christina Lampey | 16/08/2019 | 5/09/2019 | Approve | 22/01/2020 |  | no sponsor |
| 19/CEN/145 | Efficacy and Safety of Selonsertib in Participants With Moderate to Advanced Diabetic Kidney Disease | Dr Michael Collins | 16/08/2019 |  | Approve | 5/09/2019 | Auckland District Health Board | pharmaceutical company |
| 19/CEN/146 | Investigation of the endometrial cancer genomic profile in New Zealand women | Dr Claire Henry | 16/08/2019 | 5/09/2019 | Approve | 25/10/2019 |  | academic institution |
| 19/CEN/147 | (duplicate) Hyperbaric Oxygen Therapy for the treatment of acute sensorineural hearing loss | Dr Ben Thomson | 16/08/2019 | 5/09/2019 | Approve | 14/11/2019 |  | no sponsor |
| 19/CEN/148 | What do people with arthritis think about their medications? | Professor Keith J. Petrie | 19/08/2019 |  | Approve | 30/08/2019 | University of Auckland | academic institution |
| 19/CEN/149 | The optimal delivery of a Brain Computer Interface intervention for people with stroke. | Mrs Sharon Olsen | 19/08/2019 |  | Approve | 2/09/2019 | AUT University | academic institution |
| 19/CEN/150 | Using a Convolutional Neural Network to aid the detection and characterisation of thyroid nodules | Dr Rachael Bentall | 19/08/2019 |  | Approve | 24/09/2019 | Bay of Plenty District Health Board | no sponsor |
| 19/CEN/151 | Correlation of testicular mass morphology on ultrasound with histopathologic findings | Dr Muthu Muthappan | 19/08/2019 |  | Approve | 24/09/2019 | Waikato DHB | no sponsor |
| 19/CEN/153 | NP40435: Dose Escalation And Expansion Study Of PD-1/TIM-3 Bispecific Antibody In Patients With Advanced And/Or Metastatic Solid Tumours. | Dr Sanjeev Deva | 12/09/2019 |  | Approve | 7/10/2019 | Auckland City Hospital | pharmaceutical company |
| 19/CEN/154 | MK-1308 in combination with Pembrolizumab in Advanced Solid Tumours (MK-1308) | Dr Sanjeev Deva | 12/09/2019 | 7/10/2019 | Approve | 11/11/2019 | Auckland City Hospital | pharmaceutical company |
| 19/CEN/155 | ANBL1821: Testing the addition of Eflornithine (DFMO) to therapy in people with neuroblastoma (NBL) that has come back or has not responded to treatment (COG) | Dr Tristan Pettit | 12/09/2019 | 7/10/2019 | Approve | 8/11/2019 | Canterbury District Health Board | collaborative research |
| 19/CEN/156 | Klippel-Trenaunay Syndrome (KTS) Study | Dr Swee Tan | 12/09/2019 |  | Decline | 7/10/2019 | Hutt Valley DHB | collaborative research , district health board (DHB), non-governmental organisation (NGO) |
| 19/CEN/157 | Understanding the calming effect of passionflower | Assoc. Prof. Pamela von Hurst | 12/09/2019 | 1/10/2019 | Approve | 8/10/2019 | Massey University | academic institution, other |
| 19/CEN/158 | LIBRETTO-201 EAP | Professor Mark McKeage | 12/09/2019 | 7/10/2019 | Approve | 24/06/2020 | Oncology Medical Services and Consulting Ltd | other |
| 19/CEN/159 | Use of non-invasive ventilation in de-novo acute hypoxaemic respiratory failure | Dr Dilip Jayasimhan | 9/09/2019 |  | Decline | 7/10/2019 | Waikato District Health Board | no sponsor |
| 19/CEN/160 | (duplicate) Closed vs open abdomen in severe secondary peritonitis | Dr Li Hsee |  |  | Invalid Application | 13/09/2019 |  | no sponsor |
| 19/CEN/162 | CRP and its use in deciding to perform CTPA in the diagnosis of PE | Dr Christopher Yee |  |  | Invalid Application | 12/09/2019 | Midcentral DHB | no sponsor |
| 19/CEN/163 | Involving Medical Companions in an Explanation about Switching to a Biosimilar. | Professor Keith Petrie | 12/09/2019 |  | Approve | 1/10/2019 | University of Auckland | academic institution |
| 19/CEN/164 | The Effects of Infraslow Neurofeedback on Anxiety and Depression (ISAD) | Tyson Perez | 13/09/2019 |  | Decline | 7/10/2019 | University of Otago | no sponsor |
| 19/CEN/165 | RSV MAT-004 - a research study to vaccinate pregnant women against RSV and assess the incidence of RSV associated events in the children born to these mothers | Dr Thorsten Stanley | 12/09/2019 |  | Decline | 7/10/2019 |  | pharmaceutical company |
| 19/CEN/166 | The eCIMUS study (Use of electronic Cigarettes in Inpatient Mental health service Users who Smoke) | Dr Coni Kalinowski | 13/09/2019 |  | Approve | 1/10/2019 | Counties Manukau Health | district health board (DHB) |
| 19/CEN/167 | (duplicate) REOPEN 2 STUDY. A study of intranasal OPN-375 in participants with chronic sinusitis without nasal polyps | Dr Dean Quinn | 19/09/2019 |  | Approve | 7/10/2019 | P3 Research Wellington | pharmaceutical company |
| 19/CEN/169 | Proof of Principle BCG Trial | Professor Philip Hill | 10/10/2019 |  | Decline | 4/11/2019 | University of Otago | academic institution |
| 19/CEN/170 | COG AALL1731 | Dr Lochie Teague | 10/10/2019 | 4/11/2019 | Approve | 5/12/2019 | Auckland District Health Board | collaborative research |
| 19/CEN/171 | Testing Strategies to Minimise Stress Testing in Patients with Acute Chest Pain and Negative Cardiac Blood Tests in New Zealand (TACTICS-NZ) | Dr MARTIN THAN | 22/10/2019 | 4/11/2019 | Provisionally approve |  | CANTERBURY DISTRICT HEALTH BOARD | no sponsor |
| 19/CEN/172 | ACNS1721: A Study of the Drug Veliparib with Radiation Therapy in Patients with Newly-Diagnosed High-Grade Glioma (COG) | Dr Stephen Laughton | 10/10/2019 |  | Approve | 4/11/2019 | Auckland District Health Board | collaborative research |
| 19/CEN/173 | Cabozantinib with Nivolumab and Ipilimumab in Untreated Metastatic RCC | Dr Alvin Tan | 10/10/2019 | 4/11/2019 | Approve | 20/12/2019 |  | pharmaceutical company |
| 19/CEN/174 | A study to evaluate the safety and tolerability of seladelpar in subjects with primary biliary cholangitis | Dr. Jing Hieng (Jeffrey) Ngu | 10/10/2019 | 4/11/2019 | Withdrawn by Researcher | 13/01/2020 | Canterbury District Health Board | pharmaceutical company |
| 19/CEN/175 | WO41554: Phase III in CDK4/6 inhibitor experienced PIK3CA mutant HR+/HER2- metastatic breast cancer | Dr Sheridan Wilson | 10/10/2019 | 4/11/2019 | Approve | 19/12/2019 | Auckland District Health Board | pharmaceutical company |
| 19/CEN/176 | Study of the Oral Factor D (FD) Inhibitor ACH-0145228 in PNH Patients as Monotherapy and with an Approved C5 Inhibitor as Background Therapy | Dr Peter Browett | 10/10/2019 | 4/11/2019 | Approve | 15/11/2019 | Auckland Clinical Studies | pharmaceutical company |
| 19/CEN/177 | Do latanoprost eye drops alter optic nerve stress signals in eyes with optic disc drusen? | Mr Paul JY Kim | 10/10/2019 | 4/11/2019 | Approve | 10/12/2019 | Eye Clinic, Capital & Coast District Health Board, Wellington | no sponsor |
| 19/CEN/178 | Assessing cerebrovascular function with MRI: A pilot study | Dr James Fisher | 11/10/2019 |  | Approve | 8/11/2019 | University of Auckland | academic institution |
| 19/CEN/179 | The Effects of Infraslow Neurofeedback on Anxiety and Depression (ISAD) | Tyson Perez | 7/10/2019 | 30/10/2019 | Approve | 15/11/2019 | University of Otago | no sponsor |
| 19/CEN/180 | Prevalence of persistent post-surgical pain after mastectomy in Christchurch, New Zealand. | Dr Jenna Donaldson | 14/10/2019 |  | Approve | 31/10/2019 |  | no sponsor |
| 19/CEN/181 | Child and adolescent inpatient mental health care in NZ | Ms Julie Artus | 14/11/2019 | 8/12/2019 | Approve | 6/03/2020 |  | no sponsor |
| 19/CEN/182 | Neurofeedback for Osteoarthritic Knee Pain | Mr. Jerin Mathew | 22/10/2019 | 31/10/2019 | Approve | 25/11/2019 | University of Otago | no sponsor |
| 19/CEN/183 | Concussion Recovery in Children and Adolescents | Dr Nicola Starkey | 14/11/2019 | 8/12/2019 | Approve | 24/01/2020 | University of Waikato | academic institution |
| 19/CEN/184 | Axial Spondyloarthritis: Evaluation of Upadacitinib in Adult Subjects | Dr Douglas White | 14/11/2019 | 8/12/2019 | Approve | 18/03/2020 |  | pharmaceutical company |
| 19/CEN/185 | CO41101: STUDY OF IPATASERTIB IN COMBINATION WITH ATEZOLIZUMAB AND PACLITAXEL AS A TREATMENT FOR PATIENTS WITH LOCALLY ADVANCED UNRESECTABLE OR METASTATIC TRIPLE-NEGATIVE BREAST CANCER | Dr Sheridan Wilson | 14/11/2019 | 8/12/2019 | Approve | 24/02/2020 | Auckland District Health Board | pharmaceutical company |
| 19/CEN/186 | Vaccination rates and Meningitis after Cochlear Implantation | Dr Oliver Rose |  |  | Invalid Application | 14/11/2019 | Auckland DHB | no sponsor |
| 19/CEN/187 | The influence of Low Back Pain (LBP) and chiropractic on the motor control of the trunk muscle | Dr Imran Khan Niazi | 13/11/2019 | 26/11/2019 | Approve | 13/12/2019 | New Zealand College of Chiropractic | academic institution |
| 19/CEN/188 | (duplicate) Phase 3 Study of Pembrolizumab plus Docetaxel in mCRPC | Dr Jim Edwards | 14/11/2019 | 10/12/2019 | Approve | 26/02/2020 | Canterbury District Health Board | pharmaceutical company |
| 19/CEN/189 | NeoGluCO Study | Dr Chris McKinlay | 14/11/2019 |  | Approve | 8/12/2019 | University of Auckland | academic institution |
| 19/CEN/190 | Warm humidified insufflation study in acute surgical unit | Professor John Windsor | 14/11/2019 | 8/12/2019 | Provisionally approve |  | University of Auckland | medical device company, academic institution |
| 19/CEN/192 | Neuroimaging in acute strabisumus | Dr Nancy Wang | 14/11/2019 | 13/12/2019 | Approve | 10/04/2020 | Waikato Hospital | no sponsor |
| 19/CEN/193 | The use of e-cigarettes in mental health inpatient units | Dr Henry Naylor | 16/11/2019 | 27/11/2019 | Approve | 18/03/2020 |  | no sponsor |
| 19/CEN/194 | (duplicate) Proof of Principle BCG Trial | Profesor Philip Hill | 15/11/2019 |  | Approve | 8/12/2019 | University of Otago | academic institution |
| 19/CEN/195 | VIR-2482-3001: A study to assess the safety and effectiveness of VIR-2482, in the prevention of community-acquired influenza A illness. | Dr Chris Wynne | 15/11/2019 | 9/12/2019 | Approve | 18/02/2020 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 19/CEN/196 | Impact of Breast Density On Interval Breast Cancer Risk In New Zealand Screening | Dr Monica Saini | 19/11/2019 |  | Approve | 9/12/2019 | Hutt Valley District Health Board | no sponsor |
| 19/CEN/197 | Lay perspectives of home-based palliative care | Dr Katherine Nelson | 15/11/2019 |  | Approve | 29/11/2019 | Victoria University of Wellington | district health board (DHB) |
| 19/CEN/198 | Isolated Free Fluid in Blunt Abdominal Trauma | Dr Nicholas McIntosh |  |  | Invalid Application | 9/01/2020 | Waikato District Health Board | no sponsor |
| 19/CEN/199 | Use of non-invasive ventilation in de-novo acute hypoxaemic respiratory failure | Dr Dilip Jayasimhan | 15/11/2019 |  | Approve | 19/11/2019 | Waikato District Health Board | no sponsor |
| 19/CEN/201 | Detection Methods for a Patent Foramen Ovale | Dr Gillian Whalley | 25/11/2019 | 13/12/2019 | Approve | 5/02/2020 | University of Otago | no sponsor |
| 19/CEN/202 | Specificity in chiropractic care | Dr Imran Khan Niazi | 23/11/2019 | 13/12/2019 | Approve | 20/12/2019 | New Zealand College of Chiropractic | academic institution |
| 19/CEN/203 | Molecular biomarkers in gynaecological cancer | Dr Claire Henry |  |  | Invalid Application | 2/12/2019 |  | no sponsor |
| 19/CEN/204 | REDUCE-trial | Dr Jocelyne Benatar | 2/12/2019 | 18/12/2019 | Approve | 26/02/2020 |  | district health board (DHB) |
| 19/CEN/205 | TuMMI Trial: Temperature treatment of Milk impacts on MRI digestion rates and nutrient delivery. | Dr Amber Milan | 28/11/2019 |  | Approve | 13/12/2019 |  | academic institution, other |
| 19/CEN/206 | A study to investigate safety and optimal dose of Dahlia Extract in people with pre-diabetes or type 2 diabetes. | Professor Jeremy Krebs | 2/12/2019 | 13/12/2019 | Approve | 20/12/2019 |  | pharmaceutical company |
| 19/CEN/207 | Identifying changes in physiological variables resulting from accentuated eccentric strength training combined with a hypocaloric high protein diet. | Associate Professor James Stinear |  |  | Invalid Application | 3/12/2019 | University of Auckland | no sponsor |
| 19/CEN/208 | Young Māori women's access to LARC in Counties Manukau | Ms Jillian Tipene | 4/12/2019 | 13/12/2019 | Approve | 20/12/2019 | Te Puāwai Tapu - t/a Te Whāriki Takapou | no sponsor |
| 19/CEN/209 | The effect of bile acid malabsorption on function and quality of life in patients with major Low Anterior Resection Syndrome (LARS) | Dr John Woodfield | 9/01/2020 | 13/02/2020 | Approve | 11/04/2020 | University of Otago | no sponsor |
| 19/CEN/210 | Body composition and propofol infusions in neonates infants and children | Professor Brian Anderson | 9/01/2020 | 13/02/2020 | Approve | 23/07/2020 | Auckland District Health Board | academic institution |
| 19/CEN/211 | Meditative drawing for people with dementia and their care partners | Ms Emma Febvre-Richards |  |  | Invalid Application | 10/12/2019 | Massey University | academic institution |
| 19/CEN/212 | Emerging Biomarkers for Monitoring of Congenital Adrenal Hyperplasia | Mrs Lauren Bresnahan |  |  | Invalid Application | 12/12/2019 | LabPlus, Auckland DHB | no sponsor |
| 19/CEN/214 | GO41767 | Dr Laird Cameron | 9/01/2020 |  | Approve | 13/02/2020 | Auckland City Hospital | pharmaceutical company |
| 19/CEN/216 | The effect of HbA1c on patient outcomes following elective and emergency surgery | Dr Mikaela Garland | 16/01/2020 | 5/02/2020 | Approve | 19/02/2020 | Counties Manukau Health | no sponsor |
| 19/CEN/217 | PENGUIN 1 | Dr Ketna Parekh | 9/01/2020 | 13/02/2020 | Approve | 9/03/2020 | CCDHB | pharmaceutical company |
| 19/CEN/218 | WV41073 Phase II Combination Therapies for CHB | Prof Edward John Gane | 9/01/2020 |  | Approve | 13/02/2020 | New Zealand Liver Transplant Unit | pharmaceutical company |
| 19/CEN/219 | The SUN Study | Associate Professor Clare Wall | 9/01/2020 |  | Decline | 17/02/2020 | The University of Auckland | no sponsor |
| 19/CEN/221 | PACE in COPD | Professor Robert Hancox | 9/01/2020 |  | Approve | 17/02/2020 |  | academic institution |
| 19/CEN/222 | What impact has Negative Pressure Wound Therapy had on surgical site infection in endometrial cancer patients undergoing laparotomy? | Dr Lois Eva | 7/12/2019 |  | Approve | 20/12/2019 | National Women's Health | no sponsor |
| 19/CEN/223 | Asian international students remaking lives | Dr Elsie Ho | 16/12/2019 |  | Approve | 20/12/2019 | Asian Family Services | other government agency |
| 19/CEN/224 | Study to Assess the Efficacy and Safety of Nemolizumab (CD14152)in Subjects with Moderate-to-Severe Atopic Dermatitis | Assoc Prof Marius Rademaker | 9/01/2020 | 17/02/2020 | Approve | 12/04/2020 | Clinical Trials New Zealand Ltd | pharmaceutical company |
| 19/CEN/225 | Immediate v delayed switch study to Doravirine/Islatravir | Dr Alan Pithie | 16/01/2020 | 17/02/2020 | Approve | 17/03/2020 | Canterbury District Health Board | pharmaceutical company |
| 20/CEN/1 | The EDGI study | Prof Martin Kennedy | 9/01/2020 | 17/02/2020 | Approve | 3/03/2020 | University of Otago | no sponsor |
| 20/CEN/10 | EXTRAS | Mr Benjamin Scrivener | 28/01/2020 |  | Approve | 13/02/2020 | ADHB | no sponsor |
| 20/CEN/101 | Endometrial cancer in pre-menopausal women | Dr Niveditha Rajadevan | 30/04/2020 |  | Approve | 1/05/2020 | Auckland District Health Board | no sponsor |
| 20/CEN/102 | Interesting manifestations of intra-abdominal Lymphoma on CT: a case review. | Dr Toby Struthers |  |  | Invalid Application | 30/04/2020 |  | no sponsor |
| 20/CEN/106 | Glomuvenous malformation in the New Zealand population | Dr Swee Tan | 14/05/2020 | 18/06/2020 | Provisionally approve |  | Gillies McIndoe Research Institute | no sponsor |
| 20/CEN/107 | MRI Healthy Volunteer Ethics | Dr Samantha Holdsworth | 7/05/2020 | 14/05/2020 | Approve | 26/06/2020 | Matai | no sponsor |
| 20/CEN/108 | Signal study of lopinavir/ritonavir tablets vaginally in women with CIN 2/3 | Dr Amanda Tristram | 14/05/2020 | 18/06/2020 | Approve | 1/07/2020 | CCDHB | pharmaceutical company |
| 20/CEN/109 | BCT 1902 Neo-N | Dr Marion Kuper-Hommel | 14/05/2020 | 18/06/2020 | Provisionally approve |  | Waikato District Health Board | collaborative research |
| 20/CEN/112 | Listen Up New Zealand | Chief Executive Natasha Gallardo | 14/05/2020 |  | Invalid Application | 15/05/2020 | National Foundation for Deaf & Hard of Hearing | no sponsor |
| 20/CEN/113 | CA209-76U | Dr Peter Fong | 14/05/2020 |  | Approve | 18/06/2020 | Auckland City Hospital | pharmaceutical company |
| 20/CEN/114 | (duplicate) Evaluating a model of care for patients with severe COPD | Dr Amanda Landers | 14/05/2020 | 18/06/2020 | Approve | 20/07/2020 | University of Otago | academic institution |
| 20/CEN/115 | (duplicate) GastroIntestinal dysFunction in criTical illness(GIFT):Gut BiOmarker(BOx)study | Ms Varsha Asrani | 14/05/2020 |  | Decline | 18/06/2020 | ADHB / University of Auckland | academic institution, district health board (DHB) |
| 20/CEN/116 | Effects of Paravertebral blocks vs. Erector Spinae blocks on patients with rib fractures | DR MICHAEL HUGH NG | 11/05/2020 | 18/06/2020 | Approve | 5/08/2020 | Counties Manukau District Health Board | no sponsor |
| 20/CEN/117 | Relevance of metabolic profiles in children with cardiac disease | Mrs Sandra Divanisova | 11/05/2020 |  | Decline | 18/06/2020 | LabPLUS, Auckland City Hospital | no sponsor |
| 20/CEN/118 | ACcomplisH | Prof Paul Hofman | 11/05/2020 |  | Approve | 18/06/2020 | Liggins Institute, University of Auckland | pharmaceutical company |
| 20/CEN/119 | Hookworm therapy for maintenance in ulcerative colitis | Dr Stephen Inns | 14/05/2020 | 18/06/2020 | Approve | 6/07/2020 | Hutt Valley DHB | no sponsor |
| 20/CEN/120 | Comparing weight, nutrition and lifestyle in patients who underwent bariatric surgery. | Miss Sarah Louise Deacon |  |  | Invalid Application | 15/07/2020 | University of the Free State | no sponsor |
| 20/CEN/121 | Tolerability of joint health supplement | Dr Aydin Berenjian | 26/05/2020 |  | Decline | 5/06/2020 |  | no sponsor |
| 20/CEN/122 | Outcomes in diabetic foot disease | Dr Odette Hart | 14/05/2020 | 5/06/2020 | Approve | 17/07/2020 | Waikato DHB | no sponsor |
| 20/CEN/123 | The socioeconomic impact of visual impairment | Dr James McKelvie |  |  | Invalid Application | 25/05/2020 | University of Auckland | no sponsor |
| 20/CEN/124 | Effects of neo-adjuvant chemotherapy in breast cancer | Mr Alec Winder | 25/05/2020 |  | Approve | 25/06/2020 | Canterbury District Health Board | no sponsor |
| 20/CEN/125 | (duplicate) (duplicate) Klippel-Trenaunay Syndrome (KTS) Study | Dr Swee Tan | 11/06/2020 | 6/07/2020 | Provisionally approve |  | Hutt Valley DHB | collaborative research , district health board (DHB), non-governmental organisation (NGO) |
| 20/CEN/128 | 233AS102: Long-Term Evaluation of BIIB067. | Dr Deborah Mason | 11/06/2020 |  | Approve | 25/06/2020 | Christchurch Hospital | pharmaceutical company |
| 20/CEN/129 | Health and social outcomes of Viet Nam veterans’ children and grandchildren. | Dr Andrea Mannetje |  |  | Invalid Application | 12/06/2020 | Massey University | academic institution |
| 20/CEN/131 | Laissez-faire vs direct closure in eyelid repair | Dr Stephen Ng | 11/06/2020 | 6/07/2020 | Approve | 13/08/2020 | Waikato Hospital | no sponsor |
| 20/CEN/132 | A Study of CLS346 in People with Diabetic Kidney Disease | Professor Russell Scott | 11/06/2020 |  | Approve | 6/07/2020 |  | pharmaceutical company |
| 20/CEN/133 | Lenvatinib for Pediatric Patients with Relapsed/Refractory Solid Tumors | Dr Karen Tsui | 11/06/2020 | 6/07/2020 | Provisionally approve |  | Auckland District Health Board | pharmaceutical company |
| 20/CEN/134 | A serological survey of SARS-CoV-2 in the Auckland population | Professor Chris Bullen | 11/06/2020 |  | Decline | 6/07/2020 | University of Auckland | academic institution |
| 20/CEN/135 | STEP II | Dr Matthew Daly | 11/06/2020 | 6/07/2020 | Approve | 10/08/2020 | Canterbury District Health Board | medical device company |
| 20/CEN/136 | CT-P43 1.1: A study comparing the trial drug CT-P43 and Stelara®, in healthy male participants. | Dr Chris Wynne | 11/06/2020 |  | Approve | 6/07/2020 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/CEN/137 | Utilization of immunohistochemistry in the diagnosis of pigmented lesions of the skin. | Dr Tony Chen-Wei Chen |  |  | Invalid Application | 15/06/2020 | Anatomic Pathology Service (APS) | no sponsor |
| 20/CEN/138 | Shape and Growth Modelling in Cerebral Palsy - An MRI Study | Mr Salim Bin Ghouth | 11/06/2020 | 6/07/2020 | Provisionally approve |  | The University of Auckland | academic institution |
| 20/CEN/139 | Efficacy and safety of finerenone in participants with symptomatic heart failure and left ventricular ejection fraction ≥ 40% (LVEF ≥ 40%) | Professor Richard Troughton | 11/06/2020 | 6/07/2020 | Approve | 5/08/2020 | Christchurch Heart Institute, University of Otago, Christchurch | pharmaceutical company |
| 20/CEN/140 | Did Anzac Day holidays reduce hospitalisations or deaths 1988 - 2013? | Dr Lucy Telfar Barnard |  |  | Invalid Application | 30/06/2020 |  | no sponsor |
| 20/CEN/143 | Anatomically designed pressure dressing after mastectomy and axillary surgery. | Dr Abby Walsh | 1/07/2020 | 9/07/2020 | Provisionally approve |  |  | no sponsor |
| 20/CEN/147 | CIBMTR Registries | Dr Andrew Butler | 16/07/2020 |  | Decline | 17/08/2020 | Canterbury District Health Board | other |
| 20/CEN/16 | Assessment of the Sensitivity of Malarial Antibody Screening in Deceased Plasma | Dr Lauren Child | 16/01/2020 | 5/02/2020 | Provisionally approve |  | New Zealand Blood Service | non-governmental organisation (NGO) |
| 20/CEN/2 | Study of ARO-HSD in Adult Healthy Volunteers as well as in Patients with NASH or suspected NASH | Prof Ed Gane | 16/01/2020 |  | Approve | 13/02/2020 | Auckland District Health Board | pharmaceutical company |
| 20/CEN/20 | Pilot study of Hepatitis C testing and treatment in a community alcohol and drug service. | Dr Vicki Macfarlane | 20/01/2020 | 5/02/2020 | Approve | 26/02/2020 |  | pharmaceutical company |
| 20/CEN/21 | Observational review of referrals and triage of referrals to Hutt Hospital Cardiology Department. | miss Colleen Dunne |  |  | Invalid Application | 28/01/2020 |  | no sponsor |
| 20/CEN/27 | ACLR Outcomes in NZ | Dr Sarah Ward | 31/01/2020 |  | Approve | 2/03/2020 | University of Otago | academic institution |
| 20/CEN/28 | Effect of kiwifruit consumption on gastric emptying | Dr John Monro | 6/02/2020 |  | Approve | 9/03/2020 | New Zealand Institute for Plant & Food Research | other |
| 20/CEN/30 | Brain health in atrial fibrillation | Dr James Fisher | 4/02/2020 |  | Approve | 5/03/2020 | University of Auckland | academic institution |
| 20/CEN/31 | EASY-AS | Professor Ralph A H Stewart | 13/02/2020 | 13/03/2020 | Approve | 26/06/2020 | Auckland City Hospital | district health board (DHB) |
| 20/CEN/32 | (duplicate) Ideal Timing of Subconjunctival Anaesthesia before lntravitreal Injection Treatment | Dr Jiyeon Kim | 14/02/2020 | 9/03/2020 | Approve | 20/08/2020 | CDHB | no sponsor |
| 20/CEN/33 | Treatable traits for the management of asthma: a feasibility study | Dr James Fingleton | 22/01/2020 |  | Approve | 12/03/2020 |  | academic institution |
| 20/CEN/34 | A study of trial drug BTX 1702 in patients with Papulopustular Rosacea | Dr Dean Quinn | 13/02/2020 | 13/03/2020 | Approve | 11/04/2020 | P3 Research Wellington | pharmaceutical company |
| 20/CEN/35 | Hamstring Avulsions and Measuring surgical Management against Early Rehabilitation: the HAMMER trial; a randomised controlled trial | Dr Matthew D'Arcy | 13/02/2020 |  | Decline | 13/03/2020 | Canterbury DHB | no sponsor |
| 20/CEN/36 | Evaluating a model of care for patients with COPD in their last year of life | Dr Amanda Landers | 13/02/2020 |  | Decline | 13/03/2020 | University of Otago | academic institution |
| 20/CEN/37 | IM011075: Long-Term Safety and Efficacy of BMS-986165 in Subjects with Psoriasis | Dr Dean Quinn | 13/02/2020 | 13/03/2020 | Approve | 20/04/2020 | P3 Research Wellington | pharmaceutical company |
| 20/CEN/38 | OLIE Study | Dr Mark Winstanley | 13/02/2020 |  | Approve | 13/03/2020 | Auckland District Health Board | pharmaceutical company |
| 20/CEN/4 | Meditative drawing for people with dementia and their care partners | Ms Emma Febvre-Richards | 13/02/2020 | 13/03/2020 | Approve | 27/05/2020 | Massey University | academic institution |
| 20/CEN/40 | Cochlear implants in variable intralabyrinthine pressure conditions; large vestibular aqueduct and Meniere's disease | Dr Tanja Jelicic | 14/02/2020 |  | Decline | 9/03/2020 | ADHB | no sponsor |
| 20/CEN/41 | CT19649 - A clinical research study that will look at whether SCO-792 is tolerated, how safe it is and whether it works for people with impaired kidney function due to type 2 diabetes. | Professor Russell Scott | 13/02/2020 | 13/03/2020 | Approve | 7/05/2020 |  | pharmaceutical company |
| 20/CEN/42 | Hypertriglyceridaemia | Dr Minesh Prakash | 13/02/2020 |  | Decline | 13/03/2020 |  | no sponsor |
| 20/CEN/44 | Multiple primary melanomas in Waikato | Dr Ken Ip | 14/02/2020 |  | Approve | 9/03/2020 |  | no sponsor |
| 20/CEN/46 | Exceptional trajectories | Professor Kevin Dew | 19/02/2020 | 18/03/2020 | Approve | 8/04/2020 | Victoria University of Wellington | academic institution |
| 20/CEN/47 | Pepi Splint Project | Dr Deborah Harris | 12/03/2020 | 15/04/2020 | Approve | 23/06/2020 | Victoria Univeristy of Wellington, Faculty of Health | academic institution |
| 20/CEN/48 | Proposal to start collecting and storing video of laparoscopic cholecystectomy for future analysis by computer vision and machine learning | Saxon Connor |  |  | Invalid Application | 11/03/2020 | cdhb | collaborative research |
| 20/CEN/49 | Evaluation of the efficacy of broad-spectrum light therapy in treating fatigue following mild traumatic brain injury. | Mrs Kathryn Connolly | 10/03/2020 | 30/03/2020 | Approve | 22/04/2020 | Massey University Wellington | no sponsor |
| 20/CEN/5 | Clinical biomarkers for brain injury | Dr Alice Rogan | 16/01/2020 |  | Approve | 5/02/2020 | Univesity of Otago | academic institution |
| 20/CEN/50 | COG AALL1732 HR-B-ALL | Dr Siobhan Cross | 12/03/2020 |  | Approve | 15/04/2020 | Canterbury District Health Board | collaborative research |
| 20/CEN/51 | SQUEEZE | Dr Andrew Wilson | 12/03/2020 |  | Approve | 15/04/2020 | Auckland District Health Board | collaborative research |
| 20/CEN/52 | Survival Outcome Study of Patients with Metastatic Melanoma in NZ | Dr Ahmad Sufian bin Ab Rahman |  |  | Invalid Application | 11/03/2020 |  | district health board (DHB) |
| 20/CEN/53 | Correlation of cytogenetic data with overall survival in uveal melanoma patients | Dr Peter Hadden |  |  | Invalid Application | 11/03/2020 | University of Auckland | no sponsor |
| 20/CEN/54 | Understanding the impact of mixed meals on insulin response curves. | Dr Catherine Crofts |  |  | Invalid Application | 11/03/2020 | Auckland University of Technology | no sponsor |
| 20/CEN/57 | The effect of Music on the Operating Surgeon | Dr Anantha Narayanan | 17/03/2020 | 10/04/2020 | Approve | 12/05/2020 | Auckland University | no sponsor |
| 20/CEN/59 | TIPS | Associate Professor Peter H Sykes | 12/03/2020 |  | Approve | 15/04/2020 | University of Otago - Christchurch | academic institution |
| 20/CEN/6 | Driving in an upper limb cast | Dr Keith Lee |  |  | Invalid Application | 21/01/2020 |  | no sponsor |
| 20/CEN/60 | Neurofeedback for chronic low back pain. | Dr Divya Adhia | 13/03/2020 |  | Approve | 31/03/2020 | University of Otago | no sponsor |
| 20/CEN/61 | IMG-7289-CTP-201 Phase 2 Essential Thrombocythemia study | Dr James Liang | 12/03/2020 |  | Approve | 15/04/2020 | Counties Manukau District Health Board | pharmaceutical company |
| 20/CEN/63 | Genetics of Stuttering Study | Professor Lynette Sadleir | 12/03/2020 | 15/04/2020 | Approve | 1/07/2020 | Department of Paediatrics and Child Health, University of Otago | no sponsor |
| 20/CEN/64 | COG AAML18P1 | Dr Andrew Dodgshun | 16/04/2020 | 13/05/2020 | Approve | 24/06/2020 | Canterbury District Health Board | collaborative research |
| 20/CEN/65 | FAMILY GROUP EDUCATION INTERVENTION STUDY FOR MOOD DISORDERS | Dr Maree Inder | 16/04/2020 |  | Decline | 13/05/2020 | University of Otago, Christchurch | academic institution |
| 20/CEN/66 | Oral resveratrol supplementation in bronchiectasis | Dr Benjamin Diggins | 1/05/2020 |  | Approve | 12/05/2020 | Counties Manukau DHB | no sponsor |
| 20/CEN/67 | Immune cells in blood and fat tissue in healthy Men and Women | Miss Hannah van der Woude | 13/03/2020 |  | Approve | 30/03/2020 | University of Otago Wellington | academic institution |
| 20/CEN/68 | (duplicate) Klippel-Trenaunay Syndrome (KTS) Study | Dr Swee Tan | 16/04/2020 |  | Decline | 13/05/2020 | Hutt Valley DHB | collaborative research , district health board (DHB), non-governmental organisation (NGO) |
| 20/CEN/69 | Bioavailability Of Kawakawa Tea metabolites in human volunteers (BOKA-T) | Prof Richard Mithen | 16/03/2020 | 10/04/2020 | Approve | 14/05/2020 | University of Auckland | academic institution |
| 20/CEN/7 | Antibiotics in the first years of life | A/Prof Andrea 't Mannetje |  |  | Invalid Application | 22/01/2020 | Massey University | academic institution |
| 20/CEN/70 | Proposal to start collecting and storing video of laparoscopic cholecystectomy for future analysis by computer vision and machine learning | Dr Saxon Connor | 16/03/2020 | 10/04/2020 | Approve | 28/04/2020 | CDHB | collaborative research |
| 20/CEN/71 | Te Pāpākainga o Tāne Whakapiripiri - A Kaupapa Māori Forensic Mental Health Model of Care | Professor Brian McKenna | 20/03/2020 | 10/04/2020 | Approve | 6/07/2020 | AUT | academic institution |
| 20/CEN/72 | Risk factors for positive colonoscopy for symptomatic Northland patients | Dr Rachel Robertson | 25/03/2020 | 11/04/2020 | Approve | 23/04/2020 |  | no sponsor |
| 20/CEN/73 | Interbleed | Dr Matt Wheeler | 31/03/2020 |  | Decline | 14/05/2020 | The Population Health Research Institute | non-governmental organisation (NGO) |
| 20/CEN/74 | MACH: Methoxyflurane analgesia for conscious hysteroscopy | Dr Emily Twidale | 16/04/2020 | 14/05/2020 | Approve | 18/06/2020 | Hamilton Hospital | no sponsor |
| 20/CEN/75 | Coping in Lockdown Study |  |  |  | Invalid Application | 16/04/2020 |  | no sponsor |
| 20/CEN/77 | Rheumatology COVID-19 Study | Dr Rebecca Grainger |  |  | Invalid Application | 16/04/2020 |  | academic institution |
| 20/CEN/78 | Prothrombinex Use in Cardiac Surgery | Dr Charles Allen | 24/06/2020 |  | Approve | 2/07/2020 | Auckland District Health Board | other |
| 20/CEN/79 | IBD inpatient audit Inflammatory Bowel Disease Inpatient Audit | Dr Heidi Su |  |  | Invalid Application | 17/04/2020 | CDHB | no sponsor |
| 20/CEN/8 | Prevalence, predictors, diagnosis and treatment of PTSD, anxiety and depression in traumatic injury patients. | Dr Andrew McCombie | 16/01/2020 | 5/02/2020 | Approve | 18/03/2020 | Canterbury District Health Board | academic institution |
| 20/CEN/82 | Exploration of the impact of Obsessive-Compulsive Disorder in Chronic Pain and associated rehabilitation through a mixed-method design. | Mr Chad Sloley | 6/04/2020 |  | Approve | 20/04/2020 | University of Otago | academic institution |
| 20/CEN/83 | FastFX vs Optifast Meal Replacement For Weight Loss | Dr Alasdair Patrick | 14/04/2020 | 28/04/2020 | Decline | 8/06/2020 | MacMurray Centre | other |
| 20/CEN/84 | MS ABLE T Program | Dr Lynette Hodges | 7/04/2020 | 20/04/2020 | Approve | 15/05/2020 | Massey University | no sponsor |
| 20/CEN/85 | (duplicate) Dietary sodium and potassium intakes in children | Dr Helen Eyles | 16/04/2020 | 14/05/2020 | Approve | 5/08/2020 | The University of Auckland | no sponsor |
| 20/CEN/86 | Ethnicity and ICU outcome in Aotearoa New Zealand | Dr Alice Reid |  |  | Invalid Application | 20/04/2020 | Medical Research Institute of New Zealand | collaborative research |
| 20/CEN/87 | A study of ARO-ENaC in Normal Healthy Volunteers and Patients with Cystic Fibrosis | Dr John Kolbe | 16/04/2020 |  | Approve | 14/05/2020 | Auckland Clinical Studies Trust Ltd and Auckland City Hospital | pharmaceutical company |
| 20/CEN/88 | Physical activity study in Bronchiectasis | Mrs Laura Rensford | 16/04/2020 |  | Approve | 14/05/2020 | Kidz First, Counties Manukau District Health Board | no sponsor |
| 20/CEN/89 | A Pilot study assessing QST testing on PENS therapy | Dr Saad Anis | 16/04/2020 | 14/05/2020 | Provisionally approve |  |  | no sponsor |
| 20/CEN/9 | PORT CF: NZ | Associate Professor Catherine Byrnes |  |  | Invalid Application | 22/01/2020 | University of Auckland/Starship Children's Health | non-governmental organisation (NGO) |
| 20/CEN/90 | PROMIS II\_A clinical study of inhaled CMS by i-Neb in patients with NCFB | Dr Dean Quinn | 16/04/2020 |  | Approve | 14/05/2020 | P3 Research Wellington | pharmaceutical company |
| 20/CEN/91 | Oral Glial Choristoma: A Case Study | Dr Ryan Smit | 15/04/2020 |  | Approve | 30/04/2020 | CDHB | no sponsor |
| 20/CEN/92 | Effect of MDMA and matched sound therapy on Tinnitus | Professor Dirk De Ridder | 16/04/2020 | 14/05/2020 | Withdrawn by Researcher | 23/07/2020 |  | no sponsor |
| 20/CEN/93 | AFIB-ICU | Dr Paul Young | 16/04/2020 | 1/05/2020 | Approve | 11/05/2020 | Capital and Coast District Health Board | no sponsor |
| 20/CEN/94 | KER-050\_A Phase 2, Open-Label, Ascending Dose Study of KER-050 for the Treatment of Anemia in Patients with Very Low, Low or Intermediate Risk Myelodysplastic Syndromes (MDS) | Dr James Liang | 16/04/2020 |  | Approve | 13/05/2020 | Counties Manukau District Health Board | pharmaceutical company |

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

## Declaration by EC Chairperson

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

**I declare for the above named EC:**

* that the information supplied on this form and any attachment(s) is true and correct; and
* that, for the period to which this form relates, the EC has operated in accordance with relevant Guidelines and Legislation.

**Name:** Mrs Helen Walker \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature: Date:** 7 October 2020

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

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

**Name of organisation:** Ministry of Health

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

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

**Name:** Mr Nic Aagaard

 Title First Name Last Name

**Position :** Acting Manager – Ethics, Quality Assurance and Safety, Health System Improvement and Innovation, Ministry of Health

**E-mail :** hdecs@moh.govt.nz nz



**Signature: Date:** 7 October 2020

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