

Central Health and Disability Ethics Committee

Annual Report
2021

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**Contents**

[About the committee 1](#_Toc108680448)

[Chairperson’s report 2](#_Toc108680449)

[Membership and attendance 3](#_Toc108680450)

[Membership 3](#_Toc108680451)

[Attendance 5](#_Toc108680452)

[Training and conferences 5](#_Toc108680453)

[Applications reviewed 6](#_Toc108680454)

[Complaints and overdue application summary 7](#_Toc108680455)

[Complaints received 7](#_Toc108680456)

[Overdue review 7](#_Toc108680457)

[Appendix 1: Details of applications reviewed 8](#_Toc108680458)

[Applications reviewed by full committee 8](#_Toc108680459)

[Declaration by Head of Organisation with Primary Responsibility for the EC 29](#_Toc108680460)

[Declaration by EC Chairperson 29](#_Toc108680461)

[Declaration by EC Chairperson 29](#_Toc108680462)

[Declaration by Head of Organisation with Primary Responsibility for the EC 29](#_Toc108680463)

# 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

Each year, I write how the volume of applications for clinical research are increasing and yet again we have exceeded previous years. This Covid World has created so many opportunities for research in New Zealand and we have tried to ensure that approval has occurred in a timely manner. This has created a huge workload for the committee members. It is not only the number of applications but the complexity and detail of each that creates this. There is also now a huge requirement of IT knowledge and experience to assess these applications and we must keep in mind that the members also have day jobs.

The Committees have also stepped in to do extra meetings for Covid research and this has proved to be very interesting and hopefully will provide knowledge to allow the world to move on and cope with the effects.

I would like to thank the Central Committee for their time, dedication and good humour during the past year and it has been a privilege to work with them. Thanks also to our dedicated, hardworking administrative team, you make our lives so much easier.

Helen Walker

Chair, Central HDEC

# Membership and attendance

## Membership

### List of EC members within the reporting period

As long as a member attended at least one meeting they need to be included in this list. This includes both new and retired members.

**Mrs Helen Walker**

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.

**Mrs 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 2022

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 2020

Current term expires: 22nd May 2022

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 Bachelor of Science (BSc) and a Master 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 2022

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 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members**  | ***Membership category*** | **9 Jul 2020** | **13 Aug 2020** | **10 Sep 2020** | **08 Oct 2020** | **12 Nov 2020** | **10 Dec 2020** | **11 Feb 2021** | **10 Mar 2021** | **14 Apr 2021** | **12 May 2021** | **9 Jun 2021** | **Total** |
| Mrs Helen Walker  | L | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Mrs Sandy Gill\* | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Dr Patries Herst  | NL | **Y** | **Y** | **Y** | A | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 9/11 |
| Dr Cordelia Thomas | L | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | 9/11 |
| Dr Peter Gallagher | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Ms Helen Davidson | L | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | 9/11 |
| Ms Julie Jones | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/11 |
| Dr Jillian Wilkinson | NL | **Y** | **Y** | **Y** | A | A | **Y** | / | / | / | / | / | 4/11 |
| Dr Devonie Waaka\* | NL | / | / | / | **Y** | / | / | / | / | / | / | / | 1/11 |
| Mrs Kate O'Connor  | L | / | / | / | / | **Y** | / | / | / | / | / | / | 1/11 |
| **Total no. of members present**  |  | **8** | **7** | **7** | **7** | **6** | **8** | **7** | **7** | **7** | **5** | **7** |  |
| **No. of applications considered**  |  | **12** | **9** | **11** | **11** | **12** | **11** | **12** | **11** | **10** | **6** | **9** |  |

## Training and conferences

### Specify the training undergone by new members

Training was held on the new ethics IT system. An update on ethics and review training is provided in the cover letter.

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

This reporting round did not include any new members or formal training days. Training was scheduled numerous times in anticipation of new members being appointed. Appointments were continually delayed, resulting in the National Ethics Advisory Committee writing to the Minister. Their letter is attached, and once appointments were made in August 2021 training for all members was subsequently provided. An agenda is provided that covers the training topics.

# Applications reviewed

### Summary of applications received by full EC.

|  |  |
| --- | --- |
| No. of applications approved |  3 |
| No. of applications approved subject to conditions  | 31 |
| No. of applications deferred and subsequently approved | 44 |
| No. of applications deferred as at time of report | 19 |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | 3 |
| No. of applications that were declined because of no/insufficient consultation with appropriate cultural group |  |
| No. of applications declined (This excludes those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group)  | 11 |
| No. of applications which do not require ethics committee approval (applications submitted to Committee that were either incomplete or out of scope) | 28 |
| No. of studies withdrawn by researcher | 1 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC  | 0 |
| **Total number of applications received by full EC**  | **140** |

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

|  |  |
| --- | --- |
| No. of applications approved | 10 |
| No. of applications approved subject to conditions  | 10 |
| No. of applications deferred and subsequently approved | 51 |
| No. of applications deferred as at time of report | 16 |
| No. of applications which do not require ethics committee approval (applications submitted to Committee that were incomplete or out of scope) | 22 |
| No. of applications referred for full committee review | ? |
| No. of applications declined | 7 |
| No. of studies withdrawn by researcher | 2 |
| **Total number of applications received under expedited / low risk review** | **118** |

|  |  |
| --- | --- |
| Total number of applications received: | 258 |

#

# Complaints and overdue application summary

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

## Complaints received

**Complaint One**

**Study Reference:** 19/CEN/68/AM01

**Type of Complaint:** Appeal of Decision

**Review Date**: 21 October 2020

**Complaint Received:** 15 April 2020

**Nature of Complaint:**

A researcher appealed the HDEC decision to decline an amendment.

**Actions Taken:**

* Appeal sent to Manager
* Manager acknowledged the appeal
* Chair of Central HDEC Informed.
* HRC EC requested information from HDEC
* HDEC provided information.
* HDEC Chair and Manager attended HRC appeal meeting.
* HRC EC upheld the appeal.

**Outcome:**

The study is ongoing under the review of Central HDEC.

## 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 24 days for expedited applications. Target timeframe for expedited applications is 15 calendar days. The Average time has been skewed by some outliers with significant numbers on the clock due to submission issues from the researcher or technical issues faced by the secretariat as well as statutory holidays (with the clock running during break periods).

(Standard Operating Procedures for Health and Disability Ethics Committees, para 9-102).

Average review time was 25 days for full applications. Target timeframe for full applications is 35 days. (Standard Operating Procedures for Health and Disability Ethics Committees, para 54-59).

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

## Applications reviewed by full committee

| **Study reference** | **Short Title** | **CI Name** | **Outcome of first review (if date = provisional/Invalid)** | **Study Status** | **Date of final decision** | **CI Organisation (locality not captured)** | **Main sponsor type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 20/CEN/144 | FastFX vs Optifast Meal Replacement For Weight Loss | Dr Cameron Schauer |  | Approve | 8/07/2020 |  | other |
| 20/CEN/146 | ReRAD:Re-Irradiation of Progressive or Recurrent DIPG | Dr Karen Tsui | 19/08/2020 | Approve | 2/12/2020 | Auckland District Health Board | collaborative research |
| 20/CEN/148 | AtTend | Dr Kathryn Chrystal | 19/08/2020 | Approve | 1/02/2021 | Auckland City Hospital | collaborative research |
| 20/CEN/149 | BIOPRO Study | Doctor Meghan Hill |  | Decline | 19/08/2020 | University of Auckland | academic institution, other government agency |
| 20/CEN/150 | A Phase 2, multicenter, single-arm, open-label study to evaluate the efficacy and safety of AK104 in subjects with recurrent or metastatic cervical cancer | Dr Michelle Wilson |  | Approve | 19/08/2020 | Auckland District Health Board | pharmaceutical company |
| 20/CEN/151 | The REEF-D study to investigate the Efficacy, Safety and Pharmacokinetics of JNJ-73763989 for the treatment of Hepatitis B and Hepatitis D co-infection | Prof Edward Gane |  | Approve | 17/08/2020 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 20/CEN/152 | Isatuximab in combination with lenalidomide and dexamethasone in high-risk smouldering multiple myeloma (ITHACA) | Dr Andrew Butler | 19/08/2020 | Approve | 13/11/2020 | Canterbury District Health Board | pharmaceutical company |
| 20/CEN/153 | Seroepidemiological investigation for coronavirus (COVID-19) infection testing DSL’s COVID-19 IVD device | A/Prof Ashton Partridge | 20/08/2020 | Approve | 1/09/2020 | Digital Sensing Limited, Manufacturing Systems Ltd, University of Auckland | other |
| 20/CEN/154 | AIR Algorithm Study | Professor Richard Beasley |  | Approve | 20/08/2020 | Medical Research Institute of New Zealand | academic institution |
| 20/CEN/155 | Bronchial complications after Lung transplantation | Dr Ram Duvuru |  | Invalid Application | 30/07/2020 |  | no sponsor |
| 20/CEN/156 | Rights of children in health data | Dr Yvonne Anderson | 20/08/2020 | Approve | 9/11/2020 | Taranaki District Health Board & University of Auckland | non-governmental organisation (NGO) |
| 20/CEN/157 | Effectiveness of Multistrain Probiotics as an adjuvant treatment in Major depressive disorder | Dr. Venkat Naga |  | Decline | 20/08/2020 |  | non-governmental organisation (NGO) |
| 20/CEN/158 | The impact of deprivation in palliative care | Mrs Jackie Robinson | 20/08/2020 | Approve | 15/09/2020 |  | academic institution |
| 20/CEN/162 | PROGRAM | Dr. Patrick Gladding | 12/08/2020 | Approve | 14/08/2020 | Auckland Bioengineering Institute, University of Auckland | collaborative research |
| 20/CEN/163 | Engagement with Māori whānau on CT screening for lung cancer in Māori | Dr Bernard Kim |  | Invalid Application | 31/07/2020 |  | no sponsor |
| 20/CEN/164 | Exercise Training and the Chemoreflex. | Miss Thalia Babbage |  | Invalid Application | 30/07/2020 | University of Auckland | academic institution |
| 20/CEN/165 | Experiences of telehealth in hospice care at home. | Ms Wendy English | 3/08/2020 | Approve | 9/09/2020 | University of Auckland | academic institution |
| 20/CEN/166 | Opiate substitution during the COVID lockdown | Dr Elizabeth Pollock | 3/08/2020 | Approve | 9/11/2020 | Southern district health board | no sponsor |
| 20/CEN/167 | ABCpro study | Dr Marion Kuper-Hommel | 3/08/2020 | Approve | 18/08/2020 | Waikato District Health Board | non-governmental organisation (NGO) |
| 20/CEN/168 | Breathing and anxiety | Dr Olivia Harrison | 3/08/2020 | Approve | 20/08/2020 | University of Otago | academic institution |
| 20/CEN/169 | SARS-CoV-2 HCQ Prophylaxis Staff Survey | Prof Richard Beasley |  | Approve | 5/08/2020 | Medical Research Institute of New Zealand | academic institution |
| 20/CEN/170 | Views and use of the World Health Organisation Surgical Safety Checklist to improve patient safety: a qualitative study of operating room staff in Auckland, New Zealand. | Ms Anna McGregor |  | Invalid Application | 30/07/2020 |  | no sponsor |
| 20/CEN/171 | An audit to assess the incidence of post-induction hypotension in patients receiving endovascular thrombectomy for large vessel ischaemic stroke under general anaesthesia at Christchurch Hospital | Dr Holly Edmond |  | Invalid Application | 30/07/2020 |  | no sponsor |
| 20/CEN/172 | PBM Retrospective Review | Dr Elizabeth Dunn |  | Approve | 5/08/2020 | Auckland District Health Board | no sponsor |
| 20/CEN/173 | The FiDGIT Study | Mrs Sharon Erdrich |  | Invalid Application | 31/07/2020 | The University of Sydney | academic institution |
| 20/CEN/174 | Anaesthetists' Well-being Study | Dr Susan Nicoll | 20/08/2020 | Approve | 22/09/2020 | CDHB | no sponsor |
| 20/CEN/175 | Colour vision in glaucoma | Dr Jesse Gale |  | Invalid Application | 13/08/2020 | University of Otago Wellington | no sponsor |
| 20/CEN/176 | Exercise Training and the Chemoreflex. | Miss Thalia Babbage |  | Approve | 25/08/2020 | University of Auckland | academic institution |
| 20/CEN/177 | Sleep Quality Quantified by Cardiac Vagal Tone | Dr Andrew George Veale |  | Invalid Application | 13/08/2020 | Sleep & Breathing (NZ) Ltd t/a the NZ Respiratory & Sleep Institute | medical device company |
| 20/CEN/178 | Waikato MND Retrospective Study | Dr Jee-Eun Oh | 25/08/2020 | Approve | 9/09/2020 | Waikato DHB | no sponsor |
| 20/CEN/179 | Hospital based assessment of depression and psoriasis | Dr Karen Koch | 3/09/2020 | Approve | 28/09/2020 | Waikato District Healthboard | no sponsor |
| 20/CEN/180 | Impact of Covid lockdown on ICU admissions and mortality | Mr Tobias Merz |  | Invalid Application | 13/08/2020 | Cardiovascular Intensive Care Unit Auckland City Hospital | no sponsor |
| 20/CEN/181 | Retrospective Assessment of Baseline Sexual function in Men Diagnosed with Prostate Cancer | A/Prof kamran Zargar Shoshtari |  | Invalid Application | 13/08/2020 | Counties Manukau DHB and Univerity of Auckland | no sponsor |
| 20/CEN/182 | Social issues in Down Syndrome | Dr Laura Bridson | 25/08/2020 | Approve | 30/10/2020 | Counties Manukau District Health Board | no sponsor |
| 20/CEN/183 | Wintec Partnership Project for Student- Assisted Community Healthcare in Hamilton, Huntly and Ngāruawāhia – Determining the Need | Prof Sharon Brownie |  | Invalid Application | 13/08/2020 | Wintec | no sponsor |
| 20/CEN/184 | Surgical AVR at Waikato | Dr Sarah Page |  | Invalid Application | 13/08/2020 | Waikato DHB | no sponsor |
| 20/CEN/185 | Trametinib in Neurofibromatosis-associated Tumours (TiNT) | Dr Andrew Dodgshun | 3/09/2020 | Approve | 30/10/2020 | Christchurch Hospital | collaborative research |
| 20/CEN/186 | Choosebetweenamab | Prof Peter Wark | 3/09/2020 | Approve | 10/12/2020 | University of Newcastle | academic institution |
| 20/CEN/187 | YO42137: Stage II/III esophageal squamous cell cancers following concurrent chemotherapy and radiation therapy | Dr Richard North |  | Approve | 3/09/2020 | Tauranga Hospital | pharmaceutical company |
| 20/CEN/188 | A Study Evaluating the Safety, Tolerability, and Pharmacokinetics of HB0017 | Dr Christian Schwabe |  | Approve | 3/09/2020 | Auckland Clinical Studies (ACS) Ltd | pharmaceutical company |
| 20/CEN/189 | Retrospective cohort study of antineutrophil cytoplasmic antibodies (ANCA) associated vasculitis in the Auckland region. | Dr Alina Ali | 25/08/2020 | Approve | 23/11/2020 |  | no sponsor |
| 20/CEN/190 | A Phase 1 Study of mRNA-5671/V941 as Monotherapy and in Combination with Pembrolizumab | Dr Sanjeev Deva | 7/09/2020 | Approve | 5/10/2020 | Auckland City Hospital | pharmaceutical company |
| 20/CEN/191 | PIVOT-12 | Dr Richard North | 3/09/2020 | Approve | 3/11/2020 | Tauranga Hospital | pharmaceutical company |
| 20/CEN/192 | AK119-101: A study assessing single doses of the investigational drug AK119-101, in healthy adults. | Dr Chris Wynne |  | Approve | 25/08/2020 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/CEN/193 | BGB-11417-101 | Dr Henry Chan | 3/09/2020 | Approve | 22/09/2020 | Waitemata District Health Board | pharmaceutical company |
| 20/CEN/194 | Vitamin D and glycaemic control in pre-diabetic patients | Associate Professor Pamela von Hurst | 25/08/2020 | Approve | 9/09/2020 | Massey University | academic institution |
| 20/CEN/195 | Prospective case series comparing patient reported outcomes and anatomical success following fascial sacrocolpopexy/ sacrohysteropexy versus mesh sacrocolpopexy/ sacrohysteropexy | Dr Eva Fong |  | Invalid Application | 13/08/2020 |  | no sponsor |
| 20/CEN/196 | CAMEO-1 | A/Prof Peter Jones |  | Approve | 25/08/2020 | Auckland District Health Board | no sponsor |
| 20/CEN/197 | The FiDGIT Study | Mrs Sharon Erdrich | 25/08/2020 | Approve | 29/10/2020 | The University of Sydney | academic institution |
| 20/CEN/199 | Lymphoma in pregnant patients | Dr Nada Hamad |  | Invalid Application | 4/09/2020 | St Vincent's Health Network | no sponsor |
| 20/CEN/200 | Modifying activity behaviours in people with osteoarthritis | Dr Rebecca Meiring |  | Approve | 11/09/2020 | University of Auckland | academic institution |
| 20/CEN/201 | Testing the Brain Injury Screening Tool (BIST) | Prof Alice Theadom | 7/10/2020 | Approve | 19/11/2020 |  | academic institution |
| 20/CEN/203 | ABP-671-201: Study to Assess the Efficacy, Safety, and Pharmacokinetics of ABP-671 in Patients with Gout or high uric acid level in the blood | Dr. Barnaby Montgomery | 7/10/2020 | Withdrawn by Researcher | 23/11/2020 | Optimal Clinical Trials | pharmaceutical company |
| 20/CEN/204 | The BONANZA trial | Dr Paul Young | 7/10/2020 | Approve | 11/11/2020 | Capital Coast District Health Board | collaborative research |
| 20/CEN/205 | Progesterone loading as a strategy for treating Post-Partum Depression. | Health Research South Yoram Barak | 7/10/2020 | Approve | 13/11/2020 | Otago University School of Medicine | other |
| 20/CEN/206 | FIS 002-2020: A study assessing single and multiple doses of FTX-6058. | Dr Chris Wynne |  | Approve | 29/09/2020 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/CEN/207 | Pharmacogenetics in General Practice | Dr Simran Maggo |  | Decline | 7/10/2020 | University of Otago | no sponsor |
| 20/CEN/208 | Glycaemic suppressing effect of kiwifruit – a mechanistic study | Dr John Monro | 25/09/2020 | Approve | 19/10/2020 | Plant and Food research | other |
| 20/CEN/209 | BO42592: Atezolizumab plus chemotherapy with or without tiragolumab in 1L NSCLC | Dr Jonathan Davis |  | Approve | 29/09/2020 | Bay of Plenty District Health Board | pharmaceutical company |
| 20/CEN/210 | How does peritoneal dialysis affect the removal of oxypurinol in patients with gout | Professor Robert Walker |  | Decline | 7/10/2020 |  | academic institution |
| 20/CEN/211 | Comparison of two iron polymaltose tablets. | Dr Noelyn Hung |  | Approve | 29/09/2020 | Zenith Technology Corporation Limited | pharmaceutical company |
| 20/CEN/212 | Ph1 INBRX-101: Assessment of single and multiple doses of INBRX-101, in adults with alpha-1 antitrypsin deficiency. | Dr Andrew George Veale |  | Approve | 29/09/2020 | Sleep & Breathing (NZ) Ltd t/a the NZ Respiratory & Sleep Institute | pharmaceutical company |
| 20/CEN/214 | Multimorbity as a uniquely disparate population group | Mrs Janine Palmer | 12/10/2020 | Approve | 22/01/2021 |  | academic institution |
| 20/CEN/215 | Postoperative Pain in IBD | Dr Carrie Falling | 12/10/2020 | Approve | 29/10/2020 | University of Otago | academic institution |
| 20/CEN/216 | Bioequivalence of spray-dried versus commercial blackcurrant extract and the effect of caffeine on blackcurrant polyphenol bioavailability. | Dr Dominic Lomiwes | 19/10/2020 | Approve | 30/10/2020 | The New Zealand Institute for Plant and Food Research Ltd. | other government agency |
| 20/CEN/217 | Effective mental health practice with care-involved young people | Mrs Joanna Appleby | 16/10/2020 | Approve | 16/11/2020 | University of Auckland | no sponsor |
| 20/CEN/218 | ROAM (Researching Osteoarthritis and Greenshell Mussels) Study | Associate Professor Pamela von Hurst | 19/10/2020 | Approve | 9/11/2020 | Massey University | academic institution, other |
| 20/CEN/219 | A Study of Nivolumab or Placebo in Combination with Docetaxel in Men with Metastatic Castration-resistant Prostate Cancer (mCRPC). | Dr. Navin Wewala |  | Approve | 2/11/2020 | MidCentral DHB | pharmaceutical company |
| 20/CEN/220 | Retrospective Analysis of the efficacy and safety of the MonaLisa Fractionated CO2 Laser for Genitourinary syndrome of menopause | Dr Anna Hudspith | 12/10/2020 | Approve | 26/01/2021 |  | no sponsor |
| 20/CEN/221 | Vitamin D Level in Children with Cancer | Dr Leonie Naeije | 2/11/2020 | Approve | 22/12/2020 | Auckland District Health Board | no sponsor |
| 20/CEN/222 | Parent coaching in the Early Start Denver Model for parents of young children with Autism Spectrum Disorder. | Ms Lauren van Noorden |  | Decline | 2/11/2020 | Victoria University of Wellington | no sponsor |
| 20/CEN/223 | TWIST3: Validation of the Time to Walking Independently after Stroke Tool | Professor Cathy Stinear | 2/11/2020 | Approve | 10/12/2020 | University of Auckland | academic institution |
| 20/CEN/225 | Follow up study of children conceived following a Lipiodol HSG | Prof Paul Hofman | 2/11/2020 | Approve | 2/02/2021 | Liggins Institute, University of Auckland | academic institution |
| 20/CEN/226 | VIS649-102: A study assessing single doses of VIS649, in healthy adults. | Dr Paul Hamilton |  | Approve | 2/11/2020 | Auckland Clinical Studies (ACS) Ltd | pharmaceutical company |
| 20/CEN/227 | EmQuest | Dr Michelle Wilson | 30/10/2020 | Approve | 10/11/2020 | Auckland District Health Board | no sponsor |
| 20/CEN/228 | BO41932: Tumour-agnostic Precision Immuno-oncology Phase II Platform Trial (TAPISTRY) | Dr Michelle Wilson |  | Approve | 2/11/2020 | Auckland District Health Board | pharmaceutical company |
| 20/CEN/229 | DNLI-F-0002: A study assessing different formulations of DNL343, in healthy adults. | Dr Christian Schwabe |  | Approve | 2/11/2020 | Auckland Clinical Studies (ACS) Ltd | pharmaceutical company |
| 20/CEN/230 | MK3475-U03 | Dr Nicola Lawrence |  | Approve | 2/11/2020 | Auckland City Hospital | pharmaceutical company |
| 20/CEN/231 | Gender match and mismatch in the care of emergency department patients | Dr Paul Bridgman |  | Approve | 10/11/2020 | Christchurch Hospital | no sponsor |
| 20/CEN/232 | MK-3655-001: Assessment of the safety and effectiveness of MK-3655, in adults with non-alcoholic steatohepatitis (NASH). | Professor Edward Gane | 2/11/2020 | Approve | 1/02/2021 | New Zealand Clinical Research and Auckland City Hospital | pharmaceutical company |
| 20/CEN/233 | 73763989HPB2003 Combination of siRNA and Nucleoside analogue with or without Core Inhibitor for chronic hepatitis B | Professor Edward Gane |  | Approve | 2/11/2020 | New Zealand Clinical Research and Auckland City Hospital | pharmaceutical company |
| 20/CEN/238 | Whakapounamu Mana Wāhine | Professor Bev Lawton |  | Approve | 10/11/2020 | Victoria University of Wellington | academic institution |
| 20/CEN/239 | Evaluation of dried blood spot testing for HIV and syphilis | Dr Rose Forster |  | Approve | 10/11/2020 | Waikato DHB | no sponsor |
| 20/CEN/240 | Co-designing hauora-oranga services for rangatahi | Dr Ridvan Firestone |  | Withdrawn by HDEC | 20/11/2020 |  | academic institution, other |
| 20/CEN/242 | AWESSoM: Lifecurve | Professor Ngaire Kerse | 26/11/2020 | Approve | 26/01/2021 | University of Auckland | no sponsor |
| 20/CEN/243 | Reducing Inequities in Well Child Tamariki Ora Developmental Surveillance | Dr Alison Leversha | 24/11/2020 | Approve | 22/01/2021 | Starship Child Health | no sponsor |
| 20/CEN/245 | GEn1E-1124-001: A study assessing single and multiple doses of GEn1E-1124. | Dr Chris Wynne |  | Approve | 30/11/2020 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/CEN/246 | C109-CTD1: A study assessing single and multiple doses of ALP001E, in healthy adults and adults with type 2 diabetes. | Dr Chris Wynne |  | Approve | 30/11/2020 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/CEN/247 | AR882-104: A study assessing single and multiple doses of AR882, in adults with differing levels of kidney function or albumin in the urine. | Dr Richard Robson | 8/12/2020 | Approve | 12/01/2021 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/CEN/248 | GS-US-540-9015: A study comparing how remdesivir is processed and cleared from the body, in adults with normal and reduced kidney function. | Dr Michael Collins |  | Approve | 8/12/2020 | Auckland District Health Board | pharmaceutical company |
| 20/CEN/249 | Review of the SACAT Act | Ms Marnie Carter |  | Decline | 8/12/2020 | Allen + Clarke | other government agency |
| 20/CEN/250 | Effects of thyroid hormone levels on the eye | Dr Stuti Misra |  | Decline | 8/12/2020 | The University of Auckland | academic institution |
| 20/CEN/251 | Effect of air humidification and warming on surgical site temperature during spinal surgery. | Dr Simon Manners |  | Approve | 10/12/2020 | Middlemore Clinical Trials, Middlemore Hospital | medical device company |
| 20/CEN/252 | APOLLO-B: A Study to Evaluate Patisiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy (ATTR Amyloidosis with Cardiomyopathy) | Dr Hugh Goodman | 8/12/2020 | Approve | 11/02/2021 | Waikato District Health Board | pharmaceutical company |
| 20/CEN/253 | Parent coaching for parents of young children with autism. | Ms Lauren van Noorden | 8/12/2020 | Approve | 1/02/2021 | Victoria University of Wellington | no sponsor |
| 20/CEN/254 | BI 1404-0036: A study to test whether different doses of BI 456906 can help people overweight or obese to lose weight | Dr Dean Quinn | 8/12/2020 | Approve | 14/01/2021 | P3 Research | pharmaceutical company |
| 20/CEN/255 | Effect of Ketamine and brain stimulation on tinnitus loudness and distress. | Mr William Pitts | 8/12/2020 | Approve | 12/02/2021 | University of Otago | academic institution |
| 20/CEN/256 | Atrasentan in Patients with IgA Nephropathy (IgAN) | Dr Kalpa Jayanatha | 8/12/2020 | Approve | 11/01/2021 | Middlemore Clinical Trials, Middlemore Hospital, CMDHB | pharmaceutical company |
| 20/CEN/258 | IgA nephropathy audit | Dr Kalpa Jayanatha |  | Invalid Application | 16/11/2020 | Middlemore Clinical Trials, Middlemore Hospital, CMDHB | no sponsor |
| 20/CEN/262 | Osteoporosis therapies within 12 months of IV zoledronic acid in hospital | Mr Rajan Ragupathy |  | Approve | 9/12/2020 |  | no sponsor |
| 20/CEN/263 | Medication safety in resus | SMO Andrew Brainard |  | Invalid Application | 23/11/2020 | Middlemore | no sponsor |
| 20/CEN/264 | Autologous protein solution in the treatment of knee osteoarthritis | Dr. MARLA Ross | 1/12/2020 | Approve | 16/12/2020 | Northland DHB | district health board (DHB) |
| 20/CEN/265 | Prospective observation of ischaemic optic neuropathy | Dr Jesse Gale | 9/12/2020 | Decline | 20/04/2021 | University of Otago Wellington | no sponsor |
| 20/CEN/266 | Inflammation and outcomes of knee replacements. | Mr Simon Young | 11/12/2020 | Approve | 16/12/2020 | Waitemata DHB | no sponsor |
| 20/CEN/268 | Lung cancer outcome study | Dr Amanda Gimblett |  | Approve | 11/12/2020 | CDHB | no sponsor |
| 20/CEN/269 | SPR206-103: A study comparing how fast the trial drug SPR206 is processed and cleared from the body, in adults with varying levels of kidney function. | Dr Richard Robson |  | Approve | 11/02/2021 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/CEN/270 | AVT04-GL-101: A study comparing single doses of Stelara® and the trial drug AVT04, in healthy adults. | Dr Chris Wynne |  | Approve | 11/02/2021 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/CEN/271 | ICare-FASTER | Dr MARTIN THAN |  | Invalid Application | 4/12/2020 |  | no sponsor |
| 20/CEN/272 | Pilot study for the National Eye Health Survey | Dr Jacqueline Ramke |  | Invalid Application | 14/12/2020 |  | no sponsor |
| 20/CEN/274 | Factors influencing perioperative opioid use following elective and emergency surgery at Counties Manukau Health | Mr Taehoon Kim |  | Invalid Application | 18/12/2020 |  | no sponsor |
| 20/CEN/275 | Generation 2040 | Dr Rawiri Jansen |  | Invalid Application | 18/12/2020 | National Hauora Coalition | non-governmental organisation (NGO) |
| 20/CEN/276 | Effect of a 3 day course of dexamethasone on acute phase response to zoledronic acid | Distinguished Professor Ian Reid | 21/12/2020 | Approve | 1/02/2021 | University of Auckland | no sponsor |
| 20/CEN/277 | “It’s all in your head” – investigating the prevalence of traumatic brain injury in the adult mental health population | Dr Rebecca Stephanie Westcott | 11/01/2021 | Provisionally approve |  |  | no sponsor |
| 20/CEN/278 | ICAD and Stroke | Dr Martin Punter | 11/01/2021 | Approve | 23/03/2021 |  | no sponsor |
| 20/CEN/280 | Riskometer RCT | Prof Valery Feigin |  | Decline | 12/01/2021 | AUT | academic institution |
| 21/CEN/10 | A Biomarker-directed Study of XPro1595 in Patients With Mild to Moderate Alzheimer's | Dr. Barnaby Montgomery | 11/02/2021 | Approve | 9/06/2021 | Optimal Clinical Trials | pharmaceutical company |
| 21/CEN/100 | Macrolide resistant Mycoplasma pneumoniae | Dr Matthew Blakiston | 29/04/2021 | Approve | 20/07/2021 | Auckland District Health Board | no sponsor |
| 21/CEN/101 | Automated Echocardiography Analysis in Clinical Practise | Ms Hanna Van der Giessen | 29/04/2021 | Approve | 14/06/2021 |  | medical device company |
| 21/CEN/102 | Disparities in dog related injuries within New Zealand | Dr Michael Shepherd |  | Invalid Application | 14/04/2021 | Starship Hospital | no sponsor |
| 21/CEN/103 | RESHAPING Study | Dr Yuxuan Zhou |  | Invalid Application | 14/04/2021 |  | collaborative research |
| 21/CEN/104 | KiwiC and Immunity | Professor Margreet Vissers | 28/04/2021 | Approve | 10/05/2021 | University of Otago, Christchurch | academic institution |
| 21/CEN/105 | Diabetes intervention programme with Pacific families | Dr Ridvan Firestone |  | Decline | 28/04/2021 |  | academic institution, other |
| 21/CEN/106 | Metabolic syndrome in Huntington’s disease: A retrospective study. | Dr Eileen Mc Manus |  | Invalid Application | 14/04/2021 | Waikato DHB | no sponsor |
| 21/CEN/107 | Project Vitality | Prof Marlena Kruger | 23/04/2021 | Approve | 30/06/2021 |  | academic institution, other |
| 21/CEN/108 | HICCUP | Dr Rebecca Slykerman | 12/05/2021 | Approve | 9/06/2021 |  | no sponsor |
| 21/CEN/109 | Computer vision in Surgery | A/Prof Tim Eglinton |  | Decline | 29/04/2021 | University of Otago (Christchurch), Christchurch District Health Board | collaborative research |
| 21/CEN/11 | Efficacy and safety of GMRx2 compared to dual combinations for the treatment of hypertension | Dr Hari Talreja | 11/02/2021 | Approve | 24/03/2021 | Middlemore Clinical Trials, Middlemore Hospital, CMDHB | academic institution |
| 21/CEN/110 | Clinical Trial of efinopegdutide (MK-6024) in people with nonalcoholic fatty liver disease (NAFLD) | Dr John Baker | 12/05/2021 | Approve | 5/07/2021 | Middlemore Clinical Trials | pharmaceutical company |
| 21/CEN/111 | IRIS study | Dr Eileen Mc Manus |  | Invalid Application | 15/04/2021 | Waikato DHB | no sponsor |
| 21/CEN/112 | Methylphenidate OROS dose finding for Methamphetamine Use Disorder | Dr Christopher Gale |  | Decline | 12/05/2021 |  | academic institution |
| 21/CEN/113 | Does the addition of remote patient monitoring to existing care pathways reduce ED visits for frail elderly? A pilot project. | Dr Lik Loh |  | Decline | 12/05/2021 |  | district health board (DHB) |
| 21/CEN/114 | Investigating the effectiveness of machine learning support for emergency | Mr Mack Delany |  | Invalid Application | 19/04/2021 | STAN Technologies Ltd. | no sponsor |
| 21/CEN/115 | Dipeptidyl peptidase-4 inhibitor-associated Bullous pemphigoid in Auckland region, New Zealand | Dr Cheng Huang |  | Invalid Application | 15/04/2021 |  | no sponsor |
| 21/CEN/116 | Improving Health Care for Cook Islands people with Chronic Kidney Disease | Dr Debbie Ryan |  | Decline | 15/06/2021 | Pacific Perspectives Limited | other government agency |
| 21/CEN/117 | Comparison of tioguanine tablets under fasting conditions. | Dr Noelyn Hung |  | Approve | 12/05/2021 | Zenith Technology Corporation Limited | pharmaceutical company |
| 21/CEN/118 | COG AREN1921 | Dr Amanda Lyver | 12/05/2021 | Approve | 9/06/2021 | CDHB | collaborative research |
| 21/CEN/119 | VNRX-9945-101: A Phase 1 Study of VNRX-9945 in Healthy Adult Volunteers | Professor Edward Gane |  | Approve | 12/05/2021 | New Zealand Clinical Research and Auckland City Hospital | pharmaceutical company |
| 21/CEN/12 | WO42633: A Study to look at whether atezolizumab taken together with trastuzumab emtansine works in people with early breast cancer who have already had chemotherapy and surgery - and how safe this me | Dr Michelle Head |  | Approve | 11/02/2021 | Bay of Plenty District Health Board | pharmaceutical company |
| 21/CEN/120 | ASSET | Dr Nicholas Cross |  | Out Of Scope | 15/04/2021 | Canterbury District Health Board | academic institution |
| 21/CEN/121 | Healthy Lungs Study Follow-up | Dr Adrian Trenholme | 12/05/2021 | Approve | 9/06/2021 | Counties Manukau District Health Board | no sponsor |
| 21/CEN/122 | Tamariki/children growing up in financial hardship: Participation, potential and wellbeing | Mr Simon John Leadley |  | Out Of Scope | 15/04/2021 | Otago Polytechnic (WINTEC city campus) | no sponsor |
| 21/CEN/123 | A Phase 2 Study of Galicaftor/Navocaftor/ABBV-119 in Subjects With Cystic Fibrosis Who Are Homozygous or Heterozygous for the F508del Mutation | Dr Michael Epton | 12/05/2021 | Approve | 5/07/2021 | Christchurch Hospital | pharmaceutical company |
| 21/CEN/124 | Prospective observation of ischaemic optic neuropathy | Dr Jesse Gale |  | Approve | 3/05/2021 | University of Otago Wellington | no sponsor |
| 21/CEN/125 | Vaping cue reactivity in VR | Dr Simon Hoermann | 18/05/2021 | Approve | 27/05/2021 | University of Canterbury | district health board (DHB) |
| 21/CEN/127 | The DESyne BDS Plus Randomised Clinical Trial | Dr Mark Webster | 16/06/2021 | Provisionally approve |  | Auckland District Health Board | medical device company |
| 21/CEN/128 | ECHO: Examining congenital heart outcomes | Dr Simone Watkins | 16/06/2021 | Approve | 5/07/2021 | The University of Auckland | academic institution |
| 21/CEN/129 | BTX.1702.111- A trial of BTX 1702 in patients with Papulopustular Rosacea | Professor Marius Rademaker | 16/06/2021 | Approve | 19/07/2021 | Clinical Trials New Zealand | pharmaceutical company |
| 21/CEN/13 | Assisting lifestyle change: A case study. | Dr Clare Harvey |  | Invalid Application | 14/01/2021 | Massey University | academic institution |
| 21/CEN/130 | Remote Patient Monitoring Study | Mrs Ruth Kibble | 16/06/2021 | Provisionally approve |  | South Canterbury District Health Board | district health board (DHB) |
| 21/CEN/131 | The PACE Trial | Dr Giuseppe Sasso |  | Approve | 16/06/2021 | Auckland City Hospital | collaborative research |
| 21/CEN/132 | Do micronutrients cause micronutrient-drug interaction? | Dr Ben Beaglehole | 17/06/2021 | Approve | 1/07/2021 | University of Otago | academic institution |
| 21/CEN/133 | ‘Round Ligament Pain’ in pregnancy – A prevalent theory? | Dr Emily Twidale | 25/05/2021 | Approve | 9/06/2021 | Waikato DHB | no sponsor |
| 21/CEN/134 | OSCAR: Optimal selenium for bowel polyps | Assoc. Professor Michael Jameson |  | Approve | 25/05/2021 | University of Auckland | academic institution |
| 21/CEN/136 | Long term outcome of biopsy proven Henoch Schoenlein nephritis | Dr William Wong | 31/05/2021 | Provisionally approve |  |  | no sponsor |
| 21/CEN/137 | BEST sunscreen study | Dr Sharad Paul |  | Decline | 3/06/2021 | Skin Surgery Clinic | collaborative research |
| 21/CEN/138 | Telerehabilitation for people with mild traumatic brain injury | Dr Denise Taylor |  | Approve | 9/06/2021 | AUT University | academic institution |
| 21/CEN/139 | A RCT comparing prehabilitative exercise in home, hospital and community | Dr John Woodfield | 9/06/2021 | Approve | 19/07/2021 | Otago Medical School | academic institution, district health board (DHB) |
| 21/CEN/140 | Validation of Quality of Life Questionnaire in locally recurrent rectal cancer | Dr Tamara Glyn | 17/06/2021 | Approve | 19/07/2021 |  | academic institution |
| 21/CEN/141 | Association between intraoperative oxygen exposure and postoperative morbidity: A retrospective database study | Dr Daniel Frei | 9/06/2021 | Approve | 1/07/2021 | Capital and Coast District Health Board | no sponsor |
| 21/CEN/142 | PRECISE Study | Dr Claire Henry | 9/06/2021 | Approve | 1/07/2021 |  | academic institution |
| 21/CEN/143 | The efficacy of a brief mindset intervention on side effect reporting and experience of the COVID-19 vaccination | Professor Keith J. Petrie | 11/06/2021 | Approve | 1/07/2021 | University of Auckland | no sponsor |
| 21/CEN/144 | Feasibility of APT | Dr Marion Roberts | 11/06/2021 | Approve | 1/07/2021 | University of Auckland | academic institution |
| 21/CEN/145 | Retrospective cohort review of radiotherapy for head and neck cancer in New Zealand | Miss Rebekah Sizer |  | Invalid Application | 3/06/2021 | CCDHB | no sponsor |
| 21/CEN/146 | Aneurysmal SAH in Māori and European Zealanders | Doctor Ben Smith |  | Invalid Application | 3/06/2021 |  | no sponsor |
| 21/CEN/147 | Australian & New Zealand Thyroid Cancer Registry (ANZTCR) | Dr Goswin Meyer-Rochow | 17/06/2021 | Approve | 19/07/2021 | Waikato District Health Board | no sponsor |
| 21/CEN/148 | rNHF tolerability | Dr Karen Oldfield |  | Approve | 17/06/2021 | Medical Research Institute of New Zealand | medical device company |
| 21/CEN/149 | NIV masks for COPD | Dr Alex Semprini |  | Approve | 11/06/2021 |  | medical device company |
| 21/CEN/15 | Progression of aortic valve stenosis | Dr Sean Coffey | 12/02/2021 | Approve | 23/03/2021 | University of Otago | academic institution |
| 21/CEN/150 | Ongoing HIV cascade of care surveillance | Dr Sue McAllister | 14/06/2021 | Approve | 28/06/2021 | University of Otago | academic institution |
| 21/CEN/151 | Regional anaesthesia for Above and Below knee amputations - Retrospective review | Dr Will Tomkins | 30/06/2021 | Provisionally approve |  | Auckland District Health Board | collaborative research |
| 21/CEN/152 | Te Puna Rongoā : Achieving Medicines Access Equity for Māori - Pharmacists' role | Ms Joanna Hikaka | 30/06/2021 | Approve | 19/07/2021 |  | non-governmental organisation (NGO) |
| 21/CEN/153 |  |  |  | Invalid Application | 9/06/2021 |  |  |
| 21/CEN/154 | Stubbs Tissue Bank | Dr Richard Stubbs |  | Approve | 6/07/2021 | P3 Research Ltd |  |
| 21/CEN/155 | Embrace: ExPEC9V Vaccination to Prevent Invasive Extraintestinal Pathogenic Escherichia coli Disease in Adults Aged 60 Years And Older | Dr Ian Rosen | 6/07/2021 | Provisionally approve |  | Middlemore Hospital | pharmaceutical company |
| 21/CEN/156 | TRANSFORM. RF ablation of the trigone for the treatment of urinary urge incontinence. | Associate Professor Michael Stitely | 6/07/2021 | Provisionally approve |  | University of Otago | medical device company |
| 21/CEN/157 | Days Alive and Out of Hospital (DAOH) as a measure of stroke outcome in patients receiving hyperacute stroke intervention | Dr Jae Beom Hong | 28/06/2021 | Provisionally approve |  | University of Auckland | district health board (DHB) |
| 21/CEN/158 | ONC201 single ascending dose and food effect study in healthy adults | Dr. Chris Wynne |  | Approve | 6/07/2021 | New Zealand Clinical Research | pharmaceutical company |
| 21/CEN/159 | Computer vision in Surgery | A/Prof Tim Eglinton |  | Approve | 28/06/2021 | University of Otago (Christchurch), Christchurch District Health Board | academic institution |
| 21/CEN/16 | MRI Upgrading Project | mr Joshua Tiro |  | Invalid Application | 21/01/2021 |  | no sponsor |
| 21/CEN/161 | WHIRI: Pandemic system redesign to maximise Māori health gains | Dr Nina Scott | 28/06/2021 | Approve | 19/07/2021 | Waikato District Health Board | no sponsor |
| 21/CEN/163 | 2102CLI: A Study to Evaluate CDX-7108 in Healthy Adults and in Patients with Exocrine Pancreatic Insufficiency | Dr. Chris Wynne |  | Approve | 6/07/2021 | New Zealand Clinical Research | pharmaceutical company |
| 21/CEN/164 | BETTER-B Better Treatments for Chronic Breathlessness | Dr Michael Epton | 6/07/2021 | Provisionally approve |  | Canterbury District Health Board | academic institution, collaborative research |
| 21/CEN/166 | Comparison of dihydrocodeine oral liquid. | Dr Noelyn Hung |  | Approve | 6/07/2021 | Zenith Technology Corporation Limited | pharmaceutical company |
| 21/CEN/167 | EEG, MRI and Parkinson's disease | Prof. John Dalrymple-Alford | 6/07/2021 | Provisionally approve |  | New Zealand Brain Research Institute / University of Canterbury | no sponsor |
| 21/CEN/176 | Family Diabetes Intervention Programme (F-DIP) | Dr Ridvan Firestone | 12/07/2021 | Approve | 19/07/2021 |  | academic institution, other |
| 21/CEN/178 | (duplicate) BEST sunscreen study | Dr Sharad Paul | 19/07/2021 | Provisionally approve |  | Skin Surgery Clinic | collaborative research |
| 21/CEN/18 | Prediction of uncorrected-visual-acuity outliers using refractive data | Dr James McKelvie |  | Invalid Application | 21/01/2021 |  | no sponsor |
| 21/CEN/19 | Post Discharge Phone Follow up Pilot – A Review | Dr Rosemary Chellet |  | Invalid Application | 21/01/2021 | Counties Manakau District Health | no sponsor |
| 21/CEN/2 | Raman markers for photodamage in skin | Mr Ira Mautner |  | Decline | 11/02/2021 |  | academic institution |
| 21/CEN/20 | Quality of TURBT | Dr Cynthia O'Sullivan |  | Invalid Application | 21/01/2021 |  | no sponsor |
| 21/CEN/21 | Seroprevalence Survey of SARS-CoV-2 | Dr Richard Charlewood |  | Invalid Application | 21/01/2021 | New Zealand Blood Service | academic institution |
| 21/CEN/24 | A Case control study of milk curd obstruction in newborn infants in a tertiary surgical NICU. | Professor Frank Bloomfield | 12/02/2021 | Approve | 23/03/2021 | Liggins Institute | academic institution |
| 21/CEN/3 | Neonate Stoma Refeeding Device Study | Dr Greg O'Grady |  | Decline | 11/02/2021 | University of Auckland | academic institution |
| 21/CEN/32 | (duplicate) Dignified Dying, Reality of Human Mortality- the New Zealand context | Mrs Inderpreet Kaur |  | Decline | 29/01/2021 | Massey University | academic institution, other |
| 21/CEN/35 | Paediatric Induction and Maintenance Gas Flows | Dr Ben Van Der Griend |  | Approve | 9/02/2021 | CDHB | no sponsor |
| 21/CEN/36 | Diverticulitis Management: A Snapshot Collaborative Audit | Dr Deborah Wright | 1/02/2021 | Approve | 12/02/2021 | Otago Medical School, Dunedin Campus | no sponsor |
| 21/CEN/37 | Restoring elbow flexion using ulnar fascicle as donors | Dr Richard Tee | 1/02/2021 | Approve | 7/04/2021 |  | no sponsor |
| 21/CEN/38 | Hearing loss and CMV | Dr Holly Teagle |  | Invalid Application | 27/01/2021 | The University of Auckland | no sponsor |
| 21/CEN/39 | Melanoma in BOPDHB: A regional hospital experience | Doctor Tea Williams |  | Invalid Application | 27/01/2021 |  | no sponsor |
| 21/CEN/4 | A Phase 2, Long-Term Extension (LTE) Study in Subjects with Moderately to Severely Active Systemic Lupus Erythematosus A phase 2, long-term extension (LTE) Study in Subject with Moderately to severel | Dr Douglas White | 11/02/2021 | Approve | 25/03/2021 | Waikato District Health Board | pharmaceutical company |
| 21/CEN/40 | Pre-emptive analgesia | Dr Monique Mahadik |  | Invalid Application | 29/01/2021 |  | no sponsor |
| 21/CEN/41 | Emotional stress and physiological tremor | Dr Rebekah Blakemore | 1/02/2021 | Approve | 10/02/2021 | University of Otago | no sponsor |
| 21/CEN/46 | Objective 2: Why do Māori have low notified rates of yersinosis? | Ms Maria Hepi | 16/02/2021 | Approve |  | ESR | no sponsor |
| 21/CEN/47 | Does weather influence presentation rates to the emergency department? and mental health services? | Dr Emily Dickinson |  | Approve | 16/02/2021 | CCDHB | no sponsor |
| 21/CEN/48 | COPES (COmbination of Physical Exercise and Synbiotics) 4 Bones | Dr. Bolaji Lilian Ilesanmi-Oyelere |  | Invalid Application | 4/02/2021 | Massey University | academic institution, other government agency |
| 21/CEN/49 | AB-836-001: Safety, Tolerability, and Pharmacokinetics of AB-836 in Healthy Subjects and Subjects with Chronic HBV Infection | Professor Edward Gane |  | Approve | 10/03/2021 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 21/CEN/5 | Access to Pirfenidone Solution for Inhalation (AP01) for Treatment of Progressive, Fibrosing Interstitial Lung Diseases, including Idiopathic Pulmonary Fibrosis | Dr Margaret Wilsher | 11/02/2021 | Approve | 10/03/2021 | Greenlane Clinical Centre | pharmaceutical company |
| 21/CEN/50 | What does it take to stop hitting home? | Dr Emily Cooney |  | Decline | 10/03/2021 |  | no sponsor |
| 21/CEN/51 | Investigation of Yersiniosis in New Zealand | Dr Brent Gilpin |  | Decline | 10/03/2021 | ESR | no sponsor |
| 21/CEN/52 | (duplicate) Tokēke | Dr Peter Carswell | 10/03/2021 | Provisionally approve |  | Synergia Ltd | collaborative research |
| 21/CEN/53 | Efficacy & safety of CHF6001 DPI vs placebo added to COPD therapy | Dr Simon Carson | 10/03/2021 | Approve | 7/04/2021 | Southern Clinical Trials | pharmaceutical company |
| 21/CEN/54 | Efficacy & safety of CHF6001 DPI vs double-dummy added to COPD therapy | Dr Simon Carson | 10/03/2021 | Approve | 7/04/2021 | Southern Clinical Trials | pharmaceutical company |
| 21/CEN/55 | GC42880: A study assessing single and multiple doses of GDC-2394 in healthy adults. | Dr Chris Wynne |  | Approve | 10/03/2021 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 21/CEN/56 | Effects of BI685509 on kidney function in people with diabetic kidney disease. | Professor Robert Walker |  | Approve | 10/03/2021 |  | pharmaceutical company |
| 21/CEN/57 | Effect of BI 685509 on kidney function in people with chronic kidney disease | Professor Robert Walker |  | Approve | 10/03/2021 |  | pharmaceutical company |
| 21/CEN/58 | BGB-15025 and Tislelizumab in advanced solid tumours | Dr Sanjeev Deva |  | Approve | 10/03/2021 | Auckland City Hospital | pharmaceutical company |
| 21/CEN/59 | (duplicate) Baby’s SOS message in a bottle | Associate professor Mhoyra Fraser | 10/03/2021 | Approve | 5/07/2021 | University of Auckland | academic institution, district health board (DHB) |
| 21/CEN/6 | Kiwifruit and exercise performance study | Dr Kerry Bentley-Hewitt | 1/02/2021 | Withdrawn by Researcher | 24/02/2021 | Plant and Food research | no sponsor |
| 21/CEN/60 | Phase 2/3 Study of MK-5475 in Adults with Pulmonary Arterial Hypertension | Dr Sasiharan Sithamparanathan | 10/03/2021 | Approve | 27/04/2021 | Auckland District Health Board, Greenlane Clinical Centre | pharmaceutical company |
| 21/CEN/61 | Mirror image study | Dr Marella Bedggood | 3/03/2021 | Approve | 29/03/2021 |  | no sponsor |
| 21/CEN/62 | Device Development Study | Mr Shane Leath | 10/03/2021 | Approve | 27/04/2021 |  | medical device company |
| 21/CEN/63 | Brain Signature of Pain In Knee Osteoarthritis | Mr. Jerin Mathew | 2/03/2021 | Approve | 22/03/2021 | University of Otago | no sponsor |
| 21/CEN/64 | Expanding Media Smart-Targeted | Dr Simon Wilksch |  | Approve | 23/03/2021 |  | no sponsor |
| 21/CEN/65 | Home-based monitoring of visual function of age-related macular degeneration | Mr Tony Han |  | Decline | 3/03/2021 | The University of Auckland | no sponsor |
| 21/CEN/66 | Pharmacogenetics in Primary Practice | Dr Simran Maggo |  | Approve | 9/04/2021 |  | no sponsor |
| 21/CEN/67 | Ethics application for retrospective follow-up of new-onset atrial fibrillation in isolated AVR with/without CABG | Mr Isaac Teng |  | Invalid Application | 27/05/2021 |  | no sponsor |
| 21/CEN/68 | A breath test for bowel cancer | Dr Kirsty Danielson | 10/03/2021 | Approve | 19/05/2021 | University of Otago | no sponsor |
| 21/CEN/69 | Emoqol validation study | Professor Bruce Arroll | 2/03/2021 | Approve | 23/03/2021 |  | academic institution |
| 21/CEN/7 | How does body mass index impact on vaginal pressures? | Dr Xiamin Liang |  | Invalid Application | 13/01/2021 | Middlemore Hospital, Auckland | no sponsor |
| 21/CEN/70 | The efficacy of platelet-rich fibrin clots in the use of third molar surgery |  |  | Invalid Application | 25/02/2021 |  | no sponsor |
| 21/CEN/71 | Atomic force microscopy assessment for early diagnosis of oral cancer | Dr Simon Guan | 3/03/2021 | Approve | 23/03/2021 | University of Otago | no sponsor |
| 21/CEN/72 | The effect of the auto-immune protocol diet in people with rheumatoid arthritis | Ms Julianne McNeill (nee Taylor) |  | Invalid Application | 25/02/2021 | Auckland University of Technology | no sponsor |
| 21/CEN/73 | Te Kuiti Equity of Access to Cardiology | Dr Mark Davis | 3/03/2021 | Approve | 27/04/2021 | Waikato District Health Board | no sponsor |
| 21/CEN/74 | Wearing your Continuous Glucose Monitor on your sleeve | Dr Shekhar Sehgal | 9/04/2021 | Approve | 30/04/2021 | Hawkesbay DHB | academic institution |
| 21/CEN/75 | The 2GO-CGM study | Dr Martin de Bock |  | Approve | 9/04/2021 | University of Otago | academic institution |
| 21/CEN/76 | A Study to Evaluate the Effectiveness and Safety of Vedolizumab Research Medicine in Young People with Ulcerative Colitis | Dr Stephen Mouat | 9/04/2021 | Provisionally approve |  | Starship Children's Health | pharmaceutical company |
| 21/CEN/77 | A Study to Evaluate the Effectiveness and Safety of Vedolizumab Research Medicine in Young People with Crohn's Disease | Dr Stephen Mouat | 9/04/2021 | Provisionally approve |  | Starship Children's Health | pharmaceutical company |
| 21/CEN/78 | Tripalma™ for the Topical Treatment of Impetigo (MBS01) | Dr Alex Semprini |  | Approve | 9/04/2021 |  | other |
| 21/CEN/79 | TAVBTS | Mr Robert Rowan | 9/04/2021 | Approve | 10/06/2021 | Capital & Coast District Health Board | no sponsor |
| 21/CEN/8 | Amplitude | Dr Peter Fong | 11/02/2021 | Approve | 16/03/2021 | Auckland District Health Board | pharmaceutical company |
| 21/CEN/80 | Telehealth-delivered sleep treatment for children with Autism Spectrum Disorder | Dr Laurie McLay | 9/04/2021 | Approve | 14/06/2021 | University of Canterbury | no sponsor |
| 21/CEN/81 | Tell me about you | Associate Professor Brigit Mirfin-Veitch | 9/04/2021 | Approve | 25/05/2021 | Donald Beasley Institute | other |
| 21/CEN/82 | FaR-RMS | Dr Tristan Pettit | 9/04/2021 | Approve | 25/05/2021 | Canterbury District Health Board | collaborative research |
| 21/CEN/83 | Salivary Gland Pathology | Dr Mckenzie Jamie |  | Invalid Application | 11/03/2021 |  | no sponsor |
| 21/CEN/84 | (duplicate) What does it take to stop hitting home? | Dr Emily Cooney | 25/03/2021 | Approve | 20/04/2021 | Otago University | no sponsor |
| 21/CEN/86 | A retrospective review of the delays in recognition, diagnosis and treatment of adults with metastatic spinal cord compression. | Dr Evelyn Gerrish |  | Invalid Application | 25/03/2021 | BOPDHB | no sponsor |
| 21/CEN/87 | Usefulness of the digital knee for rehabilitation post knee Surgery | Miss Anja van Gulden |  | Invalid Application | 25/03/2021 | Auckland university of Technology | academic institution |
| 21/CEN/88 | (duplicate) Home-based monitoring of visual function of age-related macular degeneration | Mr Tony Han | 7/04/2021 | Approve | 20/04/2021 | The University of Auckland | no sponsor |
| 21/CEN/89 | Understanding Knee Osteoarthritis Pain Experiences (U-KOPE) | Mr Mark Overton | 7/04/2021 | Approve | 20/04/2021 | University of Otago | academic institution |
| 21/CEN/9 | "Novel transcranial electrical modulation for Major Depressive Disorder." | Mr Nathaniel Hutchinson-Wong | 11/02/2021 | Approve | 29/04/2021 | University of Otago | academic institution |
| 21/CEN/90 | Evaluating the use of the WHO Surgical Safety Checklist | Professor Alan Merry |  | Invalid Application | 31/03/2021 | The University of Auckland | no sponsor |
| 21/CEN/92 | A Female Specific Anterior Cruciate Ligament Rehab Programme | Ms Emma O'Loughlin | 7/04/2021 | Approve | 28/05/2021 |  | no sponsor |
| 21/CEN/93 | CORI.2019.06 | Mr Simon Young |  | Invalid Application | 31/03/2021 | Waikato District Health Board | medical device company |
| 21/CEN/94 | (duplicate) Riskometer RCT | Prof Valery Feigin | 8/04/2021 | Approve | 18/05/2021 | AUT | academic institution |
| 21/CEN/96 | Skin cancer risk in renal transplant patients | Dr Xiaoyu Zhu | 23/04/2021 | Approve | 3/05/2021 |  | no sponsor |
| 21/CEN/97 | Raman markers for photodamage in skin | Mr Ira Mautner | 12/05/2021 | Approve | 3/06/2021 |  | academic institution |
| 21/CEN/98 | Axon for Pain Clinical Trial | Dr David Rice | 23/04/2021 | Approve | 17/05/2021 | Auckland University of Technology | medical device company |
| 21/CEN/99 | Acoustic therapy study | Mr Jim Bartley | 27/04/2021 | Approve | 18/05/2021 | Counties Manukau District Health Board | academic institution |

# 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:** Brian Fergus \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature: Date:**

## Declaration by EC Chairperson

**Name of EC: Central 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:** Helen Walker \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature: Date:** 24 September 2021

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

**Name of EC: Central 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 :** Manager - Ethics

**E-mail :** hdecs@moh.govt.nz nz



**Signature: Date:** 24 September 2021

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)