

Southern Health and Disability Ethics Committee

Annual Report
2021

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# About the committee

The Southern 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 Southern 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 Southern HDEC is registered (number IRB00008713) 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 has been a privilege to work with the Southern Ethics Committee as Acting Chair for the Last twelve months. It is always good to work with new people to ensure that our Ethics Platform has consistency throughout. We certainly endeavour to achieve that. Like all the committees, Southern has also had a huge workload and the time and commitment displayed by all has been amazing. Along with this is the innovative discussions that also occur as we try to make the Ethics approval system more streamlined and user friendly for both researchers and participants.

Southern members have also given their time to the Emergency Committee as it assesses and approves Covid Research. A beneficial process but it also adds to the time/workload for committee members.

I would like to thank the Southern Committee for their time, dedication and good humour during the past year and it has been a privilege to work with them. Extra thanks to Sarah Gunningham and Devonie Waaka for their support in covering the Expedited Applications, it certainly takes some pressure off the Chair. Thanks, must also go to our dedicated, hardworking administrative team, you make our lives so much easier.

Helen Walker

Acting Chair, Southern HDEC

# Membership and attendance

## Membership

### List of EC members within the reporting period

**Dr Sarah Gunningham**

Membership category: Intervention Studies

Date of appointment: 5th July 2019

Current term expires: 5th July 2022

Dr Sarah Gunningham is currently a Postdoctoral Fellow at the University of Otago (2008-present). Prior to this she was an Assistant Research Fellow and PhD student at the University of Otago (1996-2008). Dr Gunningham completed a PhD at the University of Otago (2008), a Master of Science at the University of Otago (2003) and a Bachelor of Science at the University of West of England (1995). She was registered as a General Nurse at Royal United Hospital (1982) and worked as a nurse 1982-1996 completing a Diploma of Nursing at London University (1986) and Certificates of Teaching and Assessing in Clinical Practice (1989), and General Intensive Care (1987) at the Bristol and Weston School of Nursing. Dr Gunningham has published one book, 15 refereed journal articles and presented papers at six conference proceedings.

**Dr Devonie Waaka\***

Membership category: Intervention Studies

Date of appointment: 18th July 2016

Current term expires: 18th July 2019

Dr Waaka graduated in medicine from the University of Otago in 1996. She worked as a medical registrar for several years, developing an interest in nephrology and rheumatology, before joining an early phase clinical trials unit as a research physician in 2004. Over the past decade she has been involved in the planning and implementation of numerous early phase trials in New Zealand and Australia. In 2011 Devonie completed a Master of Medical Science in Drug Development from the University of New South Wales. In addition to her clinical duties, Dr Waaka has been on the teaching staff for the Pharmaceutical Medicine and Drug Development Master Program, University of New South Wales (2012 – present).

**Dr Pauline Boyles**

Membership category: Consumer/Community Perspectives

Date of appointment: 5th July 2019

Current term expires: 5th July 2022

Dr Pauline Boyles has worked in the health and disability field for over thirty years. Until recently she worked as Director Disability Strategy and Performance for nine years with the three sub regional district health boards in Wellington bringing about major change in the lives of people with disabilities accessing health services regionally and nationally. In addition her own lived experience inspired consistent advocacy at planning and funding and board levels for service and strategic change driven by and with communities of people experiencing mental health distress. While serving the communities of the three Wellington regions she was a member of the Clinical Ethics Committee over a six year period.

**Professor Jean Hay-Smith**

Membership category: Disability, Health Service Provision

Date of appointment: 31st October 2018

Current term expires: 31st October 2021

Professor Jean trained as a physiotherapist, working in a range of clinical roles in the New Zealand and UK health sector. She completed a MSc in the UK, and a PhD at the University of Otago, both in the area of women’s health. Her particular research interest is in the management of bladder problems in adults, with and without neurological disorders. Research methods are another interest, and Jean has experience of a wide range of methods including research synthesis, experimental, observational, qualitative, and mixed methods. Jean is currently a full-time academic in rehabilitation at the University of Otago.

**Mr Dominic Fitchett**

Membership category: Law

Date of appointment: 5th July 2019

Current term expires: 5th July 2022

Dominic qualified from the University of Otago with a BA/LLB and is a solicitor with Anthony Harper Lawyers in Christchurch. He has practised law in both New Zealand and the United Kingdom, primary as a property specialist, since 2004.

**Associate Professor Mira Harrison-Woolryn**

Membership category: Intervention Studies

Date of appointment: 28th June 2019

Current term expires: 28th June 2020

Dr Harrison-Woolrych is the former director of the Intensive Medicines Monitoring Programme for the Department of Preventative and Social Medicine, University of Otago. She has extensive research experience in pharmacovigilance and pharmacoepidemiology and is a former member of the executive of the International Society of Pharmacovigilence (2009-2012) and the Medicines Assessment Advisory Committee (2003-2011). Dr Harrison-Woolrych holds a Bachelor of Medicine (1989), Doctor of Medicine (1995) University of Southhampton, and is a Fellow of the Royal College of Obstetricians and Gynaecologists.

**Dr Patries Herst (Co-Opted)**

Membership category: Intervention Studies

Date of appointment: Co-Opted

Current term expires: Co-Opted

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 Cordelia Thomas**

Membership category: Law

Date of appointment: Co-Opted

Current term expires: Co-Opted

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.

##

## 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** | **09 Feb 2021** | **09 Mar 2021** | **13 Apr 2021** | **12 May 2021** | **08 Jun 2021** | **Total**  |
| Dr Sarah Gunningham  | L | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | A | 9/11 |
| Dr Devonie Waaka  | NL | A | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | 9/11 |
| Assc Prof Mira Harrison-Woolrych  | NL | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 10/11 |
| Dr Paul Chin  | NL | A | **Y** | **Y** | A | **Y** | **Y** | A | **Y** | A | **Y** | **Y** | 7/11 |
| Professor Jean Hay-Smith  | NL | **Y** | **Y** | A | **Y** | A | **Y** | **Y** | **Y** | A | A | / | 7/11 |
| Mrs Helen Walker  | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | 10/11 |
| Mr Dominic Fitchett  | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | 10/11 |
| Dr Pauline Boyles  | L | **Y** | A | Y | A | **Y** | **Y** | **Y** | / | / | / | / | 5/11 |
| Dr Patries Herst (Co-opted) | NL | **Y** | / | / | / | / | / | / | / | **Y** | / | / | 2/11 |
| Dr Cordelia Thomas (Co-opted) | L | / | / | / | / | / | / | / | / | **Y** | / | / | 1/11 |
| **Total no. of members present**  |  | **7** | **6** | **7** | **6** | **7** | **6** | **7** | **6** | **6** | **6** | **5** |  |
| **No. of applications considered**  |  | **11** | **7** | **12** | **12** | **11** | **12** | **12** | **12** | **9** | **10** | **5** |  |

## 3. Training and conferences

### Specify the training undergone by new members

There were no new members appointed during this reporting period.

### Specify the on-going training for EC 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 NEAC 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 | 0 |
| No. of applications approved subject to conditions  | 24 |
| No. of applications deferred and subsequently approved | 56 |
| No. of applications deferred as at time of report | 10 |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | 1 |
| 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 (applications submitted to Committee that were either incomplete or out of scope) | 30 |
| No. of studies withdrawn by researcher | 3 |
| No. of studies terminated by sponsor | 1 |
| No. of studies transferred to another EC  | 0 |
| **Total number of applications received by full EC**  | **139** |

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

|  |  |
| --- | --- |
| No. of applications approved | 1 |
| No. of applications approved subject to conditions  | 18 |
| No. of applications deferred and subsequently approved | 41 |
| No. of applications deferred as at time of report | 14 |
| 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 | 1 |
| No. of applications declined | 9 |
| No. of studies withdrawn by researcher | 1 |
| **Total number of applications received under expedited / low risk review** | **107** |

|  |  |
| --- | --- |
| **Total number of applications received:** | **246** |

#

# Complaints and overdue application summary

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

## Complaints received

**Complaint One**

**Study Reference**: 20/STH/119

**Type of Complaint:** Appeal of Decision

**Review Date:** 31 May 2021 (response to applicant)

**Complaint Received:** 21 December 2021

**Nature of Complaint:**

A researcher appealed the HDEC decision to decline the study on legal grounds.

**Actions Taken:**

* Appeal sent to Manager
* Manager acknowledged the appeal
* Chair of Southern HDEC Informed.
* HRC EC requested information from HDEC
* HDEC provided information.
* HDEC Chair and Manager attended HRC appeal meeting.
* HRC EC did not uphold the appeal.

**Outcome:**

The study does not have ethical approval.

**Complaint Two**

**Study Reference:** 15/STH/70

**Type of Complaint:** A complaint to HDEC regarding the care they have received.

**Review Date:** 22 December 2020

**Complaint Received**: 23 November 2020

**Nature of Complaint:**

Trial Participant stated that they were abruptly discontinued from the trial, that they were not aware of the potential withdrawal symptoms, did not receive adequate care to manage the withdrawal effects and that his concern was dismissed without suitable follow-up, and lastly that they lost wages due to the side effects.

**Actions Taken:**

* Complaint sent to Manager
* Manager acknowledged the complaint.
* Chair of Southern HDEC informed and requested information from the CI.
* CI informed and responded to points.
* Chair of Southern HDEC informed of response and drafted a response to the complainant.
* CI response forwarded to complainant with permission for progression of sponsor claim.

**Outcome:**

The complainant was sent a detailed response to their concerns and complaint and re-engaged with the research team to progress their compensation claim. The HDEC has followed up to seek whether compensation was provided.

## 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 review 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 26 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 27 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 application)** | **Study Status** | **Date of final decision** | **CI Organisation (locality not captured)** | **Main sponsor type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 20/STH/116 | Study of EP547 in Adult Healthy Volunteers as well as in Patients with or without itch due to Liver or Kidney disease | Prof Edward John Gane |  | Approve | 28/07/2020 | New Zealand Liver Transplant Unit | pharmaceutical company |
| 20/STH/119 | (duplicate) RESOLVE | Dr Mark Marshall |  | Decline | 28/08/2020 | Middlemore Hospital | no sponsor |
| 20/STH/120 | A Mixed Methods Evaluation of a Canterbury Breast Feeding Support Service | Miss Brenna Russell | 20/08/2020 | Approve | 11/09/2020 | University of Canterbury, Child and Family Psychology | no sponsor |
| 20/STH/121 | Gluco-Light: Pulse-glucometery clinical proof of concept study | Dr Jennifer Knopp | 1/09/2020 | Approve | 6/10/2020 | University of Canterbury | academic institution |
| 20/STH/122 | Evaluation of Efficacy and Safety of PLN-74809 in patients with Idiopathic Pulmonary Fibrosis | Prof Lutz Beckert | 1/09/2020 | Approve | 2/12/2020 | Universiy of Otago, Christchurch | pharmaceutical company |
| 20/STH/123 | Morpheus study of new treatment combinations for advanced liver cancer | Professor Edward Gane | 28/08/2020 | Approve | 22/10/2020 | Auckland Clinical Studies Ltd. | pharmaceutical company |
| 20/STH/124 | An effective point-of-care screening pathway for COVID-19 | AP Jo Stanton | 1/09/2020 | Approve | 3/12/2020 | University of Otago | no sponsor |
| 20/STH/125 | A study to test a new rectally administered drug for Ulcerative Colitis Colitis | Dr Richard Stubbs | 1/09/2020 | Approve | 22/09/2020 | P3 Research Ltd | pharmaceutical company |
| 20/STH/126 | Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Novel Rifaximin Formulations in Healthy Volunteers | Mr Christian Schwabe | 24/08/2020 | Approve | 14/09/2020 | Auckland Clinical Studies | pharmaceutical company |
| 20/STH/127 | NATO | Mrs Helen Houston | 4/12/2020 | Approve | 12/02/2021 |  | no sponsor |
| 20/STH/128 | Tele-therapy for mood disorders | Prof Marie Crowe | 8/09/2020 | Approve | 28/09/2020 |  | academic institution |
| 20/STH/129 | Does advanced platelet-rich fibrin (A-PRF) improve healing following wisdom teeth surgery? | Dr Jesslyn Praganta | 28/08/2020 | Approve | 30/09/2020 | University of Otago, Faculty of Dentistry | no sponsor |
| 20/STH/130 | Younger onset dementia diagnosis | Dr Brigid Ryan |  | Approve | 22/09/2020 | University of Auckland | academic institution |
| 20/STH/133 | Melanoma surveillance prospective audit | Dr charlotte blau |  | Invalid Application | 26/08/2020 |  | no sponsor |
| 20/STH/134 | EmQuest | Dr Michelle Wilson |  | Decline | 22/09/2020 |  | no sponsor |
| 20/STH/135 | GWAS of asthma in Niue Islanders | Dr. William Abbott |  | Decline | 22/09/2020 |  | no sponsor |
| 20/STH/136 | CVBT | Mr. Haemish Crawford |  | Approve | 22/09/2020 | ABJS | academic institution |
| 20/STH/137 | LIFE -BTK | Associate Professor Andrew Holden | 22/09/2020 | Approve | 3/12/2020 | Auckland District Health Board | medical device company |
| 20/STH/138 | Dignified Dying, Reality of Human Mortality- the New Zealand context | Mrs Inderpreet Kaur |  | Decline | 22/09/2020 | Massey University | academic institution, other |
| 20/STH/139 | Perispinal Entanercept in post stroke patients with moderate to severe disability | Dr Nigel Gilchrist | 22/09/2020 | Approve | 11/12/2020 | Canterbury Geriatric Medical Research Trust | collaborative research |
| 20/STH/140 | Physiological pain regulation and the buffering effect of social support in patients with chronic pain | Dr Maria Kleinstaeuber |  | Decline | 22/09/2020 |  | academic institution |
| 20/STH/141 | The Interface Between Dialysis and Psychiatry - A Case Report | Dr Luke Sutherland Registrar |  | Withdrawn by Researcher | 22/09/2020 |  | no sponsor |
| 20/STH/142 | Veganism by Proxy: A Novel Case of Elder Abuse | Dr Luke Sutherland Registrar |  | Withdrawn by Researcher | 22/09/2020 |  | no sponsor |
| 20/STH/143 | Morphologic study of the cervical spine | Associate Professor Joseph Baker | 30/09/2020 | Approve | 22/10/2020 |  | no sponsor |
| 20/STH/144 | Clinical Evaluation of the Aatru npSIMS System | Assoc Prof Jon Mathy | 22/09/2020 | Approve | 9/11/2020 | Middlemore Clinical Trials | medical device company |
| 20/STH/145 | Early pregnancy HbA1c and perinatal outcomes | Dr Megan Chatfield | 25/09/2020 | Approve | 14/12/2020 | CCDHB/HVDHB | no sponsor |
| 20/STH/151 | FOURIER LEGACY | Professor Russell Scott | 25/09/2020 | Approve | 16/12/2020 | CDHB | academic institution |
| 20/STH/152 | Prediction of the severity and long-term complications in diarrhoea -associated Haemolytic Uremic Syndrome in children | Dr Claudia Vallebella |  | Invalid Application | 8/09/2020 | ADHB | no sponsor |
| 20/STH/153 | Mussel with fucoidan as a supplemented superfood | Prof Jun Lu | 30/09/2020 | Approve | 19/11/2020 | Auckland University of Technology | other |
| 20/STH/154 | Lifestyle Programme for Pacific Peoples | Dr Ridvan Firestone | 30/09/2020 | Approve | 28/01/2021 |  | academic institution, other |
| 20/STH/155 | Comparing cancer progression rates | Dr Nokuthaba Sibanda |  | Invalid Application | 9/09/2020 | Victoria University of Wellington | no sponsor |
| 20/STH/156 | (duplicate) Lymphoma in pregnant patients | Dr Catherine Tang |  | Decline | 30/09/2020 | Wellington Regional Hospital | no sponsor |
| 20/STH/157 | Sustained well-being benefits of red meat consumption and meat-analogue meals in a 10-week randomised clinical trial | Dr Andrea Braakhuis | 27/10/2020 | Approve | 28/01/2021 |  | no sponsor |
| 20/STH/159 | ARISE | Prof Lutz Beckert |  | Approve | 21/10/2020 | Universiy of Otago, Christchurch | pharmaceutical company |
| 20/STH/160 | ENCORE | Prof Lutz Beckert |  | Approve | 21/10/2020 | Universiy of Otago, Christchurch | pharmaceutical company |
| 20/STH/161 | The relationship between cognition and swallowing in neurological disease | Dr Sarah Perry | 28/10/2020 | Approve | 3/12/2020 | University of Otago/New Zealand Brain Research Institute | no sponsor |
| 20/STH/162 | Residential care staff use of relational and supportive interventions for residents living with dementia who like to walk | Mrs Christianah Adesina | 28/10/2020 | Approve | 28/01/2021 | AUT University | no sponsor |
| 20/STH/163 | Impact of inflammation on the Cxbladder test in detection of urothelial carcinoma | Mr. Tony Lough |  | Decline | 28/10/2020 | Pacific Edge Ltd | medical device company |
| 20/STH/164 | Investigation into the efficacy and safety of a micronutrient formula compared with placebo on mood in teenagers | Prof Julia Rucklidge | 28/10/2020 | Approve | 10/12/2020 |  | no sponsor |
| 20/STH/165 | Persica 002, Phase 1B PP353 vs Placebo in the treatment of chronic low back pain | Dr Nigel Gilchrist | 28/10/2020 | Approve | 7/12/2020 | CGM Research Trust | pharmaceutical company |
| 20/STH/166 | (duplicate) MINOCA-BAT | Dr Jithendra Somaratne | 28/10/2020 | Approve | 9/12/2020 | Auckland District Health Board | no sponsor |
| 20/STH/167 | Non-invasive lung imaging system | Dr Kelly Burrowes | 10/02/2021 | Decline | 22/02/2021 |  | academic institution |
| 20/STH/168 | Effectiveness of Multistrain Probiotics as an adjuvant treatment in Major depressive disorder-a pilot study | Dr. Venkat Naga | 28/10/2020 | Approve | 3/12/2020 | University of Auckland | non-governmental organisation (NGO) |
| 20/STH/169 | ZN-c5-006: A study assessing the effect of food on ZN-c5, in healthy post-menopausal women. | Dr Chris Wynne |  | Approve | 21/10/2020 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 20/STH/170 | A Phase 2 Study to Evaluate Efficacy and Safety of AL002 in Participants With Early Alzheimer's Disease | Dr Nigel Gilchrist | 28/10/2020 | Approve | 4/12/2020 | CGM Research Trust | pharmaceutical company |
| 20/STH/172 | CIPHUR | Dr Guy Stanley |  | Invalid Application | 1/10/2020 |  | no sponsor |
| 20/STH/173 | (duplicate) BIOPRO Study | Doctor Meghan Hill | 28/10/2020 | Approve | 28/01/2021 |  | academic institution, other government agency |
| 20/STH/177 | A retrospective cohort study of the predictive value of urine culture in the initial investigation of bacteraemic adults | Dr Nicholas Young | 29/10/2020 | Approve | 19/11/2020 | Counties Manukau District Health Board | no sponsor |
| 20/STH/178 | Artificial intelligence (AI) diabetic retinopathy grading classifier | Dr. David Squirrell | 2/11/2020 | Approve | 25/11/2020 | Auckland District Health Board | no sponsor |
| 20/STH/179 | Comparing two tests of thinking and memory abilities | Dr Matthew Croucher |  | Approve | 19/11/2020 | Canterbury District Health Board | no sponsor |
| 20/STH/180 | Microbiological findings, treatment and outcomes of patients presenting with epididymo-orchitis | Dr Cindy Nguyen | 19/11/2020 | Approve | 21/12/2020 | Auckland City Hospital | no sponsor |
| 20/STH/181 | Societal Preferences on Breast Cancer Treatment and Care | Professor Carlo Marra | 19/11/2020 | Decline | 28/01/2021 | University of Otago | no sponsor |
| 20/STH/182 | He Wawata Whaanau | Ms Te Hao Apaapa-Timu | 2/11/2020 | Approve | 14/12/2020 | Counties Manukau Health | district health board (DHB) |
| 20/STH/184 | Hip Abduction Strength in Musculoskeletal Conditions | Dr Samantha Wong | 4/12/2020 | Approve | 10/02/2021 |  | collaborative research |
| 20/STH/185 | The Rakeiora Primary Care Pathfinder Study | Professor Stephen Robertson | 4/12/2020 | Approve | 29/01/2021 | University of Otago | academic institution |
| 20/STH/186 | CaPTO study | Dr. Ramya Nagarajan | 18/12/2020 | Approve | 28/01/2021 | University of Auckland | academic institution |
| 20/STH/187 | The Effect of Recovery Nurses on the Recorded Post-Surgery Patient Recovery Outcomes | Dr Tim Starkie | 19/11/2020 | Approve | 16/02/2021 | Waikato DHB | no sponsor |
| 20/STH/188 | Opioid Prescription following Common General Surgery Procedures in the Bay of Plenty | Dr. Scott McLaughlin |  | Invalid Application | 29/10/2020 |  | no sponsor |
| 20/STH/189 | Tokēke | Dr Peter Carswell | 4/12/2020 | Decline | 28/01/2021 | Synergia Ltd | collaborative research |
| 20/STH/190 | BP02-101: A study comparing Herceptin® and the trial drug BP02 in healthy men. | Mr Christian Schwabe |  | Approve | 25/11/2020 | Auckland Clinical Studies | pharmaceutical company |
| 20/STH/191 | A randomised controlled trial of oral BBT-401-1S in Subjects with Moderate to Severe Ulcerative Colitis | Dr Richard Stubbs |  | Approve | 25/11/2020 | P3 Research Ltd | pharmaceutical company |
| 20/STH/192 | Efficacy and Safety of Guselkumab in Participants with Moderate to Severe Ulcerative Colitis | Dr David Rowbotham | 4/12/2020 | Approve | 1/02/2021 | Auckland City Hospital | pharmaceutical company |
| 20/STH/193 | MINT Trial | Professor Harvey Douglas White |  | Approve | 25/11/2020 | Auckland District Health Board | academic institution |
| 20/STH/194 | (duplicate) Physiological pain regulation and the buffering effect of social support in patients with chronic pain | Dr Maria Kleinstaeuber |  | Approve | 25/11/2020 |  | academic institution |
| 20/STH/195 | DIRECT-SAFE | Dr Teddy WU |  | Approve | 25/11/2020 | Canterbury District Health Board | collaborative research |
| 20/STH/196 | Lymphoma in Pregnant Women: the Australasian Experience | Dr Catherine Tang |  | Approve | 19/11/2020 | Wellington Regional Hospital | no sponsor |
| 20/STH/197 | Study of the effect of functional neurological disease (FND) treatment clinic on patient wellbeing | Dr David Palmer |  | Approve | 19/11/2020 |  | no sponsor |
| 20/STH/198 | Impact of inflammation on the Cxbladder test in detection of urothelial carcinoma | Mr. Tony Lough |  | Approve | 18/11/2020 | Pacific Edge Ltd | medical device company |
| 20/STH/199 | Machine learning to subtype invasive breast cancer | Dr Gavin Harris |  | Approve | 19/11/2020 | Christchurch Breast Cancer Register | no sponsor |
| 20/STH/200 | GN41791 - FENTREPID Study | Dr Deborah Fleur Mason | 4/12/2020 | Approve | 25/03/2021 | Canterbury District Health Board | pharmaceutical company |
| 20/STH/201 | The use of Nutrigenomics in Sport Nutrition | Dr Andrea Braakhuis |  | Invalid Application | 6/11/2020 |  | no sponsor |
| 20/STH/202 | THE EFFECTIVENESS OF A TRAUMA SENSITIVE YOGA INTERVENTION WITH SURVIVORS OF SEXUAL VIOLENCE | Miss Bridget McNamara |  | Decline | 1/12/2020 | Massey University | no sponsor |
| 20/STH/203 | The diagnostic accuracy of ACJ tests | Ms Monique Baigent | 20/11/2020 | Approve | 3/12/2020 | CMDHB | no sponsor |
| 20/STH/204 | Rapid Paediatric Chronic Pain Program | Dr Ross Drake |  | Approve | 23/11/2020 | Auckalnd District Health Board | no sponsor |
| 20/STH/205 | Follow-up of a gout randomized controlled trial | Dr George Coleman | 23/11/2020 | Approve | 14/12/2020 | CDHB | no sponsor |
| 20/STH/206 | Ngā Pou o Rongo: A Kaupapa Maori approach to healthy ageing | Dr Anna Rolleston | 23/11/2020 | Approve | 27/11/2020 | University of Auckland | no sponsor |
| 20/STH/207 | TROG 18.01 - NINJA | Dr Roger Yang-Chun Huang | 18/12/2020 | Approve | 10/02/2021 | Waiakto District Health Board | collaborative research |
| 20/STH/208 | MINOCA-BAT | Dr Jithendra Somaratne |  | Withdrawn by HDEC | 25/11/2020 | Auckland District Health Board | no sponsor |
| 20/STH/209 | A Phase 3 Study of darolutamide in addition to ADT versus placebo plus ADT in men with mHSPC | Mr Kevin Bax | 18/12/2020 | Approve | 15/02/2021 | Canterbury Urology Research Trust | pharmaceutical company |
| 20/STH/210 | V201\_01 | Michael Williams |  | Approve | 17/12/2020 | Lakeland Clinical Trials Rotorua | pharmaceutical company |
| 20/STH/211 | 0171 - Phase 3 Extension Study of TD-9855 for Treating snOH in Subjects with Primary Autonomic Failure | Prof Tim Anderson | 18/12/2020 | Approve | 18/02/2021 | University of Otago | pharmaceutical company |
| 20/STH/212 | ALXN1830-HV-108: A study assessing single and multiple doses of ALXN1830 in healthy adults. | Dr Mark Marshall |  | Approve | 17/12/2020 | Auckland Clinical Studies (ACS) Ltd | pharmaceutical company |
| 20/STH/213 | The New Zealand Indigo naturalis dose-escalation study (NZ-INDES) | Dr. Olivier Gasser |  | Approve | 18/12/2020 | Malaghan Institute of Medical Research | collaborative research , district health board (DHB) |
| 20/STH/214 | Real World Advanced Hybrid Closed loop in children and adults with type 1 diabetes | A/Prof Benjamin J Wheeler | 18/12/2020 | Approve | 20/01/2021 |  | academic institution |
| 20/STH/215 | ICAD and Stroke | Dr Martin Punter |  | Invalid Application | 26/11/2020 | Capital and Coast District Health Board | no sponsor |
| 20/STH/216 | Effect of carbonic anhydrase inhibitor eye drops on visual outcomes after macular hole surgery | Dr Thiyagaraj Krishnan | 18/12/2020 | Approve | 29/01/2021 |  | no sponsor |
| 20/STH/218 | Comparison of two lidocaine patches. | Dr Noelyn Hung |  | Approve | 18/12/2020 | Zenith Technology Corporation Limited | pharmaceutical company |
| 20/STH/219 | BRII-179-835-001: Safety and efficacy of BRII-835 (VIR-2218) and BRII-179 (VBI-2601)in CHB | Dr Tien Huey Lim |  | Approve | 18/12/2020 | Middlemore Clinical Trials | pharmaceutical company |
| 20/STH/220 | A feasibility study to investigate individualised exercise prescription for cancer patients | Ms Jessica Allan |  | Decline | 18/12/2020 | University of Canterbury | academic institution |
| 20/STH/221 | Audit of thyroid cancer diagnosis, pre and post TIRADS | dr tom cawood |  | Invalid Application | 26/11/2020 |  | no sponsor |
| 20/STH/223 | Immunity to measles in immunised young adults – is it waning and does it matter? | Professor Peter McIntyre |  | Invalid Application | 8/12/2020 |  | no sponsor |
| 20/STH/230 | FASD Hui | Dr Joanna Chu |  | Approve | 22/12/2020 | University of Auckland | academic institution |
| 20/STH/231 | 4-item SRQ Validation | Dr Holly Foot |  | Invalid Application | 11/12/2020 | The University of Auckland | no sponsor |
| 20/STH/232 | Paediatric Fever and Paracetamol/Ibuprofen Use in NZ EDs | Dr Eunicia Tan |  | Invalid Application | 14/12/2020 | Middlemore Hospital and University of Auckland | no sponsor |
| 20/STH/233 | Kia Mataara. | ms anne fraser |  | Decline | 13/01/2021 | ADHB | academic institution, district health board (DHB) |
| 20/STH/234 | (duplicate) Learning from Adverse Events and Consumer, Family and Whaanau Experience | Nurse Director Carole Kennedy | 25/02/2021 | Approve | 30/04/2021 |  | district health board (DHB), other government agency |
| 20/STH/235 | Korero i te tuatahi | Dr Rachel Roskvist | 12/01/2021 | Approve | 10/03/2021 | University of Auckland | academic institution |
| 20/STH/236 | Impact of acute kawakawa tea ingestion on postprandial glucose metabolism in healthy human volunteers | Prof Richard Mithen | 1/02/2021 | Approve | 12/02/2021 | The University of Auckland | academic institution |
| 20/STH/237 | Is a digital knee brace helpful for patients with osteoarthritis? | Mr Aidan Messenger | 22/12/2020 | Approve | 12/02/2021 | The University of Auckland | academic institution |
| 20/STH/238 | Development and Evaluation of a Pharmacist-Led Intervention to Reduce Polypharmacy for Older Adults | Mr Lisheng Liu |  | Approve | 12/01/2021 | The University of Auckland/MidCentral District Health Board | no sponsor |
| 20/STH/239 | i-Mirror: Modifiable readmission risk factors | Dr Amy Chan | 12/01/2021 | Approve | 25/03/2021 | ADHB | no sponsor |
| 20/STH/241 | Optimising pre-operative malnutrition | Mr Rocco P. Pitto | 19/01/2021 | Decline | 30/04/2021 |  | no sponsor |
| 20/STH/242 | Lifestyle in HAE study | Dr Karen Lindsay | 12/01/2021 | Approve | 15/02/2021 | Auckland District Health Board | academic institution |
| 21/STH/1 | oVRcome - self guided virtual reality for specific phobias |  | 10/02/2021 | Approve | 1/04/2021 |  | other |
| 21/STH/10 | THE EFFECTIVENESS OF A TRAUMA SENSITIVE YOGA INTERVENTION WITH SURVIVORS OF SEXUAL VIOLENCE | Miss Bridget McNamara |  | Approve | 10/02/2021 | Massey University | no sponsor |
| 21/STH/100 | RETAINER Study 1 New Zealand | Dr Christopher Harmston |  | Invalid Application | 29/04/2021 | Whangarei Hospital | collaborative research |
| 21/STH/101 | Respiration data obtained from pacemakers | Dr Martin Stiles |  | Approve | 25/05/2021 | Waikato Hospital | no sponsor |
| 21/STH/102 | Game for Health Level 3 | Dr Hiran Thabrew | 25/05/2021 | Approve | 17/06/2021 |  | non-governmental organisation (NGO) |
| 21/STH/103 | COVID pandemic effects recurrent stroke rate | Prof Anna Ranta |  | Invalid Application | 28/04/2021 | University of Otago | no sponsor |
| 21/STH/104 | Impact of COVID-19 on stroke services and presentations | Prof Anna Ranta |  | Invalid Application | 29/04/2021 | University of Otago | no sponsor |
| 21/STH/105 | Impairment-based rehabilitation for dysphagia post-stroke | Mrs Marion VALLET | 25/05/2021 | Provisionally approve |  | University of Canterbury - Rose Centre for Stroke Recovery and Research | academic institution |
| 21/STH/107 | Varicella Vaccine Study | Dr Michael-John Fay |  | Invalid Application | 29/04/2021 | Starship Hospital | no sponsor |
| 21/STH/108 | ACTION-TBI | Prof Alice Theadom |  | Invalid Application | 30/04/2021 |  | academic institution |
| 21/STH/109 | HDClarity study | Dr Richard Roxburgh |  | Invalid Application | 29/04/2021 | Auckland City Hospital | academic institution |
| 21/STH/11 | POSTVenTT | Prof Ian Bissett |  | Invalid Application | 26/01/2021 | The University of Auckland | no sponsor |
| 21/STH/110 | DigiFale: Strengthening digital health litearcy among Pacific populations | Mrs Amio Matenga Ikihele |  | Approve | 10/05/2021 | Moana Research | other government agency |
| 21/STH/111 | Long COVID Study | Dr Nethmi Kearns |  | Approve | 25/05/2021 |  | academic institution, non-governmental organisation (NGO), other |
| 21/STH/112 | NKT-203: Study of the efficacy and safety of norketotifen (NKT) in patients with acute uncomplicated influenza-like illness (ILI) | Dr Claire Thurlow | 25/05/2021 | Approve | 11/06/2021 | Southern Clinical Trials Tasman | pharmaceutical company |
| 21/STH/113 | Parmacokinetics of Dexmedetomidine administered by Jet Injection- The DexJet Trial | Dr Nicola Whittle |  | Decline | 25/05/2021 |  | no sponsor |
| 21/STH/114 | AROANG3-2001: A Study to Investigate the Clinical Effectiveness and Safety of ARO-ANG3 in Adults with Mixed Dyslipidemia | Dr Michael Williams | 25/05/2021 | Provisionally approve |  | Lakeland Clinical Trials Group | pharmaceutical company |
| 21/STH/117 | ACTION-TBI | Prof Alice Theadom |  | Approve | 17/05/2021 |  | academic institution |
| 21/STH/12 | The CANTATA Study | Professor Richard Troughton | 26/02/2021 | Approve | 10/05/2021 | University of Otago | academic institution |
| 21/STH/121 | Noise at Induction | Ms Margie McKellow | 25/05/2021 | Approve | 31/05/2021 |  | no sponsor |
| 21/STH/122 | Evaluating BBM: a community approach to health | Dr Faasisila Savila | 18/05/2021 | Approve | 30/06/2021 | The University of Auckland | academic institution |
| 21/STH/123 | NZ Paediatric Anaesthesia Audit | Dr James Dalby-Ball | 26/05/2021 | Approve | 24/06/2021 | CDHB | no sponsor |
| 21/STH/124 | International Cryptococcus Audit | Dr Rebekah Lane |  | Approve | 26/05/2021 | Auckland District Health Board | no sponsor |
| 21/STH/125 | Air sampling | Dr. Julie Bennett |  | Invalid Application | 21/05/2021 |  | no sponsor |
| 21/STH/126 | Prospective Interventional Cohort Study examining the impact of HPI algorithms on duration of hypotension and associated perioperative outcomes in the emergency general surgical population. | Dr Patrick McKendry |  | Decline | 29/06/2021 |  | no sponsor |
| 21/STH/127 | Evaluation of Dried Blood Spot Testing for hepatitis B and C | Dr Gary McAuliffe | 26/05/2021 | Provisionally approve |  | Auckland District Health Board | no sponsor |
| 21/STH/128 | Can non-invasive brain stimulation enhance the effect of exercise on knee OA pain? | Mr David Toomey | 27/05/2021 | Approve | 14/06/2021 | Auckland Universtity of Technology | no sponsor |
| 21/STH/129 | The effects of a single exercise session on osteoarthritis pain. | Mr David Toomey | 27/05/2021 | Approve | 14/06/2021 | Auckland Universtity of Technology | no sponsor |
| 21/STH/13 | Using the InterRAI DIVERT score to prevent unplanned admissions | Dr Helen Kenealy |  | Invalid Application | 26/01/2021 |  | district health board (DHB) |
| 21/STH/130 | IRIS study | Dr Jan Schepel |  | Approve | 29/06/2021 | Waikato District Health Board | no sponsor |
| 21/STH/131 | (duplicate) Metabolic syndrome in Huntington’s disease: A retrospective study. | Dr Eileen Mc Manus | 31/05/2021 | Decline | 17/06/2021 |  | no sponsor |
| 21/STH/132 | Direct saliva assay for Covid testing | Dr Ross Boswell |  | Invalid Application | 25/05/2021 | None | no sponsor |
| 21/STH/133 | A prospective study of non-technical skills in the medical emergency team | Dr Emma Carlin | 31/05/2021 | Approve | 15/06/2021 | University of Otago - Wellington | no sponsor |
| 21/STH/134 | COVID 19 impact on Stroke numbers | Prof Anna Ranta | 15/06/2021 | Provisionally approve |  | University of Otago | no sponsor |
| 21/STH/135 | COVID pandemic effects TIA Clinic recurrent stroke (Project 1) | Prof Anna Ranta | 15/06/2021 | Provisionally approve |  | University of Otago | no sponsor |
| 21/STH/136 | Functional Assessment in the Anaesthetic Assessment Clinic: Introduction of the DASI questionnaire . | Dr John Shepherd |  | Invalid Application | 27/05/2021 |  | no sponsor |
| 21/STH/137 | EDP 721-001: A Study to Evaluate EDP-721 in Healthy Subjects and in Combination with EDP-514 in Patients with Chronic Hepatitis B Virus Infection | Prof Edward Gane | 29/06/2021 | Approve | 13/07/2021 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 21/STH/138 | Ocular Prosthetic Dynamics and Influences | Dr Robert Jacobs |  | Invalid Application | 27/05/2021 | The University of Auckland | no sponsor |
| 21/STH/139 | HDClarity study | Dr Richard Roxburgh | 29/06/2021 | Provisionally approve |  | Auckland City Hospital | academic institution |
| 21/STH/14 | Investigation into Adrenalectomies and paraganglioma operations at an ethnically diverse tertiary centre | Miss Brittany Park | 19/02/2021 | Approve | 18/03/2021 |  | no sponsor |
| 21/STH/140 | HPV self-test for women at high clinical risk of cervical abnormalities | Dr Rachel Mackie | 15/06/2021 | Provisionally approve |  |  | district health board (DHB) |
| 21/STH/141 | Primary Care Cervical Screening Self-test Study | Dr Karen Bartholomew | 15/06/2021 | Provisionally approve |  | Waitemata DHB | collaborative research , district health board (DHB), other |
| 21/STH/142 | Routine Swallow Screening of Hospitalised At-risk Patients | Dr Anna Miles | 15/06/2021 | Approve | 23/06/2021 |  | academic institution |
| 21/STH/143 | The psychological impacts of housing affordability on the youths | Dr Edward Yiu |  | Out Of Scope | 31/05/2021 | University of Auckland Business School | no sponsor |
| 21/STH/144 | Direct saliva assay for Covid testing | Dr Ross Boswell | 15/06/2021 | Provisionally approve |  | None | no sponsor |
| 21/STH/145 | Endometriosis Research Consortium | Professor Cristin Print | 17/06/2021 | Provisionally approve |  | The University of Auckland | academic institution |
| 21/STH/146 | Comparison of two materials used for repair of orbital fracture defects | Dr Darren Wang |  | Invalid Application | 4/06/2021 |  | no sponsor |
| 21/STH/147 | Evaluating a peer-led acute community residential servic | Dr Jenni Manuel |  | Approve | 16/06/2021 | University of Otago | no sponsor |
| 21/STH/148 | Comparison of two materials used for repair of orbital fracture defects | Dr Darren Wang | 24/06/2021 | Provisionally approve |  |  | no sponsor |
| 21/STH/149 | Community-based intensive activation for major depression | Prof Marie Crowe | 24/06/2021 | Provisionally approve |  | University of Otago, Christchurch | academic institution |
| 21/STH/15 | M.E.K.E in Maraenui | Dr Rachel Forrest |  | Decline | 10/02/2021 | Te Aho a Māui - Eastern Institute of Technology Ltd | academic institution |
| 21/STH/150 | Bladder Neuromodulation for Chronic SCI | Dr Sam Paritt |  | Invalid Application | 18/06/2021 | University of Auckland | academic institution |
| 21/STH/151 | Long term failure rates and outcomes of arthroscopic shoulder stabilization | Dr Rachel Price | 28/06/2021 | Provisionally approve |  | Capital and Coast district health board | no sponsor |
| 21/STH/153 | Impact of parental brain injury on their children’s quality of life | Mrs Audrey McKinlay |  | Invalid Application | 28/06/2021 | University of Canterbury | academic institution |
| 21/STH/154 | Inflammatory markers in dry eye disease and uveitis | Dr Stuti Misra | 15/07/2021 | Provisionally approve |  | The University of Auckland | academic institution |
| 21/STH/159 | Meningitis and Sensorineural Hearing Loss | Dr Ben Thomson |  | Out Of Scope | 1/07/2021 |  | no sponsor |
| 21/STH/16 | Department of Medicine Tissue Bank | Ms Fiona Hood | 25/02/2021 | Approve | 14/06/2021 | Otago University | academic institution |
| 21/STH/160 | CAMERA2 case-control retrospective study | A/Prof David Lye Chien Boon |  | Invalid Application | 1/07/2021 | National Centre for Infectious Diseases | academic institution, collaborative research |
| 21/STH/161 | Te Hao Nui: A Longitudinal Research Method for Māori using Administrative Data | Mr Andrew Sporle |  | Out Of Scope | 1/07/2021 |  | no sponsor |
| 21/STH/163 | Assessing Parkinson's disease using Artificial Intelligence (AI) | Prof Tim Anderson |  | Out Of Scope | 1/07/2021 | University of Otago | no sponsor |
| 21/STH/167 | RECLAIM - a Digital Type 2 Diabetes Intervention to Improve Self-Management | Ms. Nikita Karulkar |  | Out Of Scope | 1/07/2021 | Atlantis Healthcare | pharmaceutical company, medical device company, collaborative research |
| 21/STH/17 | Patients' perception and understanding of postoperative neurological complications | Dr Carolyn Deng |  | Decline | 25/03/2021 | ADHB | no sponsor |
| 21/STH/171 | Bladder Neuromodulation for Chronic SCI | Dr Sam Paritt | 6/07/2021 | Provisionally approve |  | University of Auckland | academic institution |
| 21/STH/175 | VR-based Balance Training and Assessment System for Older Adults | Mr Peter Fermin Dajime |  | Invalid Application | 19/07/2021 | University of Auckland | academic institution |
| 21/STH/176 | Retrospective cohort review of radiotherapy for head and neck cancer in New Zealand | Miss Rebekah Sizer | 16/07/2021 | Provisionally approve |  | CCDHB | no sponsor |
| 21/STH/18 | Liver Trauma at Auckland City Hospital | Mr Nicholas Fischer |  | Invalid Application | 22/02/2021 |  | no sponsor |
| 21/STH/19 | LEAP: Improving self-regulation through play | Dr Alison Leversha | 25/02/2021 | Approve | 11/03/2021 |  | no sponsor |
| 21/STH/2 | The MoPED Follow-up Study | Dr Eleanor Kennedy |  | Withdrawn by Researcher | 4/02/2021 | University of Auckland | academic institution |
| 21/STH/20 | INTERVENE | Dr Travis Perera | 26/02/2021 | Approve | 14/06/2021 | Capital and Coast District Health Board | collaborative research |
| 21/STH/21 | Review of the SACAT Act 2017 | Ms Marnie Carter | 26/02/2021 | Provisionally approve |  | Allen+ Clarke | other government agency |
| 21/STH/22 | Utility of DNA Methylation analyses in Meningioma | Dr Fouzia Ziad | 26/02/2021 | Approve | 25/03/2021 | Waikato Hospital | no sponsor |
| 21/STH/23 | STELLAR | Prof Lutz Beckert | 26/02/2021 | Approve | 6/05/2021 | University of Otago | pharmaceutical company |
| 21/STH/24 | Venetoclax Extension Study | Ms Eileen Grace Merriman |  | Approve | 12/02/2021 | WDHB | pharmaceutical company |
| 21/STH/25 | Hydrolysed meat in residential aged-care | Miss Xiaojing Wu |  | Decline | 12/02/2021 |  | academic institution |
| 21/STH/26 | REVIVE study - A Real World Evidence ambispective study to assess outcomes of Vivity and Vivity Toric implantation | Professor Helen V Danesh-Meyer | 10/02/2021 | Approve | 3/05/2021 | Eye Institute | medical device company |
| 21/STH/27 | MOR208C310. Tafasitamab plus lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-intermediate and high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBC | Dr Richard Doocey | 26/02/2021 | Approve | 21/04/2021 | Auckland City Hospital | pharmaceutical company |
| 21/STH/28 | Are non-religious spritual support workers needed in Aotearoa/New Zealand public hospitals | Mr Colin Woodhouse |  | Invalid Application | 2/02/2021 | University of Canterbury | no sponsor |
| 21/STH/29 | A Phase 3 Trial of LOXO-305 versus Investigator Choice of BTK inhibitor in Previously Treated Mantle Cell Lymphoma | Dr Rajeev Rajagopal | 26/02/2021 | Approve | 17/05/2021 | Middlemore Clinical Trials | pharmaceutical company |
| 21/STH/3 | BGB-15025 and Tislelizumab in advanced solid tumours | Dr Sanjeev Deva |  | Decline | 4/02/2021 | Auckland City Hospital | pharmaceutical company |
| 21/STH/30 | Safe Medical Abortion via telehealth | Dr Wee Ming Soh |  | Invalid Application | 2/02/2021 |  | no sponsor |
| 21/STH/32 | A comprehensive analysis of the burden of non-vaccination in New Zealand | Professor Rhema Vaithianathan |  | Invalid Application | 4/02/2021 | AUT University | academic institution |
| 21/STH/33 | Advanced hybrid closed loop/artificial pancreas for youth with type 1 diabetes using conventional injection therapy and high-risk glycaemic control. | A/Prof Benjamin J Wheeler | 26/02/2021 | Approve | 25/03/2021 |  | academic institution |
| 21/STH/35 | Comparison of acitretin capsules under fasting conditions. | Dr Noelyn Hung |  | Approve | 26/02/2021 | Zenith Technology Corporation Limited | pharmaceutical company |
| 21/STH/37 | Comparison of acitretin capsules under fed conditions. | Dr Noelyn Hung |  | Approve | 26/02/2021 | Zenith Technology Corporation Limited | pharmaceutical company |
| 21/STH/38 | Do digital devices and telehealth have a future role in supporting older adults with dementia in Aotearoa? | Dr Gary Cheung | 19/02/2021 | Approve | 10/03/2021 | University of Auckland | academic institution, collaborative research |
| 21/STH/4 | CT-868-002: Study to Evaluate the Efficacy, Safety, and Tolerability of CT-868 in People with Type 2 Diabetes | Assoc Professor Helen Lunt | 4/02/2021 | Withdrawn by Researcher | 20/04/2021 | Canterbury District Health Board | pharmaceutical company |
| 21/STH/40 | Indefinite Community Treatment Orders - Maori Lived Experiences | Dr Rebecca White | 10/03/2021 | Approve | 1/04/2021 | Northland District Health Board | district health board (DHB) |
| 21/STH/41 | (duplicate) Societal Preferences on Breast Cancer Treatment and Care | Professor Carlo Marra |  | Approve | 10/03/2021 | University of Otago | no sponsor |
| 21/STH/42 | The bioavailability of anthocyanins after consuming a single dose of red kiwifruit and their effects on innate immunity in healthy individuals. | Dr Dominic Lomiwes |  | Approve | 10/03/2021 | The New Zealand Institute for Plant and Food Research Ltd. | other government agency |
| 21/STH/43 | Micronutrient supplementation in metabolic syndrome | Dr Anitra Carr | 25/03/2021 | Approve | 8/04/2021 | University of Otago, Christchurch | academic institution |
| 21/STH/44 | Resistance exercise and immune health | Dr Andrew Carroll |  | Approve | 25/03/2021 | Plant & Food Research | other government agency |
| 21/STH/45 | CLEAR STUDY | Professor Peter Gilling |  | Approve | 25/03/2021 | Tauranga Urology Research Limited | medical device company |
| 21/STH/46 | An Open-label Study to Evaluate the Long-term Safety and Efficacy of CSL312 (Garadacimab) in the Prophylactic Treatment of Hereditary Angioedema | Dr Hilary Longhurst | 25/03/2021 | Approve | 20/05/2021 | Auckland City Hospital | pharmaceutical company |
| 21/STH/47 | Retrospective review of unmonitored dissolution therapy for renal calculi | Dr David Chapman |  | Out Of Scope | 25/02/2021 |  | no sponsor |
| 21/STH/5 | A study on the respiratory syncytial virus(RSV) when given alone and together with a vaccine against influenza in adults aged 60 years and above. | Dr Dean Quinn | 4/02/2021 | Approve | 19/03/2021 | P3 Research Ltd | pharmaceutical company |
| 21/STH/50 | AMO-02-MD-2-003: Tideglusib Versus Placebo for the Treatment of Children and Adolescents with Congenital Myotonic Dystrophy (REACH CDM) | Dr Gina O'Grady | 25/03/2021 | Approve | 25/05/2021 | Auckland Clinical Studies Ltd and Starship Hospital | pharmaceutical company |
| 21/STH/51 | Home Care and Aged Residential Care services for Māori and non-Māori - access pathways and exit points | Ms Joanna Hikaka |  | Out Of Scope | 25/02/2021 | Waitematā DHB | district health board (DHB) |
| 21/STH/52 | Administrative follow-up of family violence fatalities | Dr Pauline Gulliver |  | Decline | 25/03/2021 |  | no sponsor |
| 21/STH/53 | (duplicate) Non-invasive lung imaging system | Dr Kelly Burrowes |  | Approve | 25/03/2021 |  | academic institution |
| 21/STH/54 | Microfracture and ABEC in Osteochondral Lesions of the Talus (MALT) | Mr NJ Willis | 25/03/2021 | Approve | 17/06/2021 | Capital and Coast District Health Board | no sponsor |
| 21/STH/55 | ABI-H0731-204 - Vebicorvir plus AB-729 plus standard treatment for the treatment of patients with chronic hepatitis B | Prof Edward Gane | 25/03/2021 | Approve | 10/05/2021 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 21/STH/56 | Proof-of-concept study of BAY 1817080 in OAB patients | Dr Sharon English | 30/04/2021 | Approve | 6/05/2021 | Canterbury urology Research Trust | pharmaceutical company |
| 21/STH/57 | The NOMAD Study | Dr Eric Lim |  | Out Of Scope | 25/02/2021 | Canterbury District Health Board | medical device company, collaborative research , non-governmental organisation (NGO) |
| 21/STH/58 | The NOMAD Study - MSNA testing | Dr Eric Lim |  | Out Of Scope | 25/02/2021 | Canterbury District Health Board | medical device company, collaborative research , non-governmental organisation (NGO) |
| 21/STH/59 | A Phase II double blind study of Clenbuterol and Nadolol on cognitive performance in Neurodegenerative Disorders | Prof Tim Anderson | 25/03/2021 | Approve | 6/05/2021 | University of Otago | pharmaceutical company |
| 21/STH/6 | CLEAR STUDY | Prof Peter Gilling |  | Decline | 4/02/2021 | Urology BOP Ltd | medical device company |
| 21/STH/60 | Metabolic Therapy Program in Conjunction with Standard Treatment for Glioblastoma Multiforme | Dr Matthew Phillips | 25/03/2021 | Approve | 13/04/2021 |  | no sponsor |
| 21/STH/61 | HELIOS-B A study to Evaluate Vutrisiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy | Dr Tim Sutton | 25/03/2021 | Approve | 3/05/2021 | Middlemore Clinical Trials | pharmaceutical company |
| 21/STH/62 | Virtual Reality as analgesia for Cystoscopy | Dr Thomas Clarkson | 25/03/2021 | Approve | 17/05/2021 | Southern District Health Board | no sponsor |
| 21/STH/66 | CLiPNZ-II | Dr Shay McGuinness | 25/03/2021 | Approve | 30/04/2021 | Auckland District Health Board | collaborative research |
| 21/STH/67 | The role of Respiratory Nurses in New Zealand | Mrs Melinda McGinty | 25/03/2021 | Approve | 27/05/2021 | HVDHB | no sponsor |
| 21/STH/69 | A feasibility study to investigate individualised exercise prescription for people with cancer | Ms Jessica Allan | 4/05/2021 | Provisionally approve |  | University of Canterbury | academic institution |
| 21/STH/7 | A Study in Healthy Participants and Patients with Mild Asthma to Investigate a New Drug for the Treatment of Asthma | Dr Irene Braithwaite | 4/02/2021 | Approve | 24/03/2021 | Medical Research Institute of New Zealand | pharmaceutical company |
| 21/STH/70 | Direct oral anticoagulants for cerebral venous thrombosis | Dr Teddy WU | 4/05/2021 | Provisionally approve |  | Canterbury District Health Board | academic institution |
| 21/STH/71 | (duplicate) Kia Mataara. | ms anne fraser |  | Approve | 30/04/2021 | ADHB | academic institution, district health board (DHB) |
| 21/STH/72 | CH-ALV-2101: A study assessing single doses of Prolia®, in healthy postmenopausal women. | Dr Chris Wynne |  | Approve | 19/04/2021 | Christchurch Clinical Studies Trust Ltd | other |
| 21/STH/73 | Rituximab in pemphigus | Dr Jenny Chung |  | Invalid Application | 25/03/2021 |  | no sponsor |
| 21/STH/74 | HBI-8000-303: HBI-8000 Combined with Nivolumab versus Placebo with Nivolumab in Patients with Unresectable or Metastatic Melanoma | Dr Gareth Rivalland | 4/05/2021 | Provisionally approve |  | Auckland Regional Blood & Cancer Service | pharmaceutical company |
| 21/STH/75 | A Study to Investigate the Clinical Effectiveness and Safety of ARO-APOC3 in Adults with Severe Hypertriglyceridemia | Dr John Baker | 4/05/2021 | Approve | 24/06/2021 | Middlemore Clinical Trials | pharmaceutical company |
| 21/STH/76 | Melanoma sentinel lymph node biopsy and completion lymph node dissection: The New Zealand experience | Mr Brandon Adams | 4/05/2021 | Provisionally approve |  | Bay of Plenty District Health Board | no sponsor |
| 21/STH/77 | RESPOND PICU RCT | Dr David Buckley | 4/05/2021 | Approve | 14/06/2021 | Auckland District Health Board | no sponsor |
| 21/STH/78 | The Effect of Food on ZN-d5 in healthy female volunteers | Dr Chris Wynne | 4/05/2021 | Approve | 17/06/2021 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 21/STH/79 | EQRx143-101: A study comparing the Pharmacokinetics of EQRx143 in healthy Caucasian and Ethnic Chinese populations. | Dr Paul Hamilton |  | Approve | 4/05/2021 | Auckland Clinical Studies Ltd. | pharmaceutical company |
| 21/STH/8 | Immunity to measles in immunised young adults – is it waning and does it matter? | Professor Peter McIntyre | 28/01/2021 | Approve | 10/02/2021 |  | no sponsor |
| 21/STH/80 | DF-006-1001: A Phase 1 study of DF-006-1001 in Healthy Volunteers and patients with Chronic Hepatitis B | Prof Edward Gane | 4/05/2021 | Approve | 18/05/2021 | Auckland Clinical Studies Ltd and Auckland City Hospital | pharmaceutical company |
| 21/STH/81 | Frequency of manual therapy for individuals with knee osteoarthritis: The Opti-OK Trial | Dr Cathy Chapple |  | Approve | 29/04/2021 | University of Otago | academic institution |
| 21/STH/82 | Reflecting informed choice in prenatal screening | Dr Sara Filoche | 6/05/2021 | Approve | 16/06/2021 | University of Otago | academic institution |
| 21/STH/83 | Community Implementation of the ‘Cascade’ Online Programme for Parents/Primary Caregivers of Child Cancer Survivors: A Phase-III Trial | Miss Olivia Jennison |  | Decline | 27/04/2021 | Massey University | academic institution |
| 21/STH/84 | Investigation of Yersiniosis in New Zealand | Dr Brent Gilpin | 30/04/2021 | Approve | 14/06/2021 | ESR | no sponsor |
| 21/STH/85 | Efficient management pathway of carpal tunnel syndrome | Dr Dominique Brown |  | Invalid Application | 31/03/2021 | Palmerston North Hospital | no sponsor |
| 21/STH/86 | Effect of pre-operative patient function on the risk tolerances in the arthroplasty setting | Dr Dominique Brown |  | Invalid Application | 1/04/2021 | Palmerston North Hospital | no sponsor |
| 21/STH/87 | Usefulness of the digital knee for rehabilitation post knee Surgery | Miss Anja van Gulden |  | Invalid Application | 7/04/2021 | Auckland university of Technology | academic institution |
| 21/STH/88 | Exposure During Orthopaedic Training | Dr Ravi Ram |  | Invalid Application | 8/04/2021 |  | no sponsor |
| 21/STH/89 | Health Outcomes for Paediatric Osteomyelitis and Septic Arthritis, Waikato Hospital | Dr Sarah Hunter |  | Invalid Application | 8/04/2021 |  | no sponsor |
| 21/STH/9 | ICare-FASTER | Dr MARTIN THAN | 26/02/2021 | Approve | 6/05/2021 | Christchurch Hospital | no sponsor |
| 21/STH/90 | Antibiotic prescribing in Hand Injuries | Dr Emma Littlehales |  | Invalid Application | 8/04/2021 |  | no sponsor |
| 21/STH/91 | Antenatal detection of small for gestational age babies | Dr Emma Deverall |  | Invalid Application | 8/04/2021 |  | no sponsor |
| 21/STH/92 | (duplicate) (duplicate) Dignified Dying, Reality of Human Mortality- the New Zealand context | Mrs Inderpreet Kaur | 25/05/2021 | Provisionally approve |  | Massey University | academic institution, other |
| 21/STH/95 | LPP study | Dr Subramanya Adiga | 30/04/2021 | Provisionally approve |  |  | no sponsor |
| 21/STH/96 | The PACE Trial | Dr Giuseppe Sasso |  | Invalid Application | 28/04/2021 | Auckland City Hospital | collaborative research |
| 21/STH/97 | NOMAD Study | Dr Eric Lim | 25/05/2021 | Approve | 24/06/2021 | Canterbury District Health Board | no sponsor |
| 21/STH/98 | Nurturing lifelong skills and capabilities of Pasifika youth against food insecurity | Dr Malakai 'Ofanoa |  | Invalid Application | 28/04/2021 | University of Auckland | academic institution |
| 21/STH/99 | Metabolic syndrome in Huntington’s disease: A retrospective study. | Dr Eileen Mc Manus |  | Invalid Application | 28/04/2021 |  | no sponsor |

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

## Declaration by EC Chairperson

**Name of EC: Southern 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: 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 :** 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)