

Southern Health and Disability Ethics Committee

Annual Report
2020

Citation: New Zealand Health and Disability Ethics Committee. 2018. *Northern A Health and Disability Ethics Committee: Annual Report 2016.* Wellington: Ministry of Health.

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

ISBN 978-1-98-856808-9 (online)
HP 6954

This document is available on the New Zealand Health and Disability Ethics Committee website: www.ethics.health.govt.nz

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**Contents**

[About the committee 1](#_Toc108676360)

[Chairperson’s report 2](#_Toc108676361)

[Membership and attendance 3](#_Toc108676362)

[Membership 3](#_Toc108676363)

[Attendance 6](#_Toc108676364)

[Training and conferences 6](#_Toc108676365)

[Applications reviewed 7](#_Toc108676366)

[Complaints and overdue application summary 8](#_Toc108676367)

[Complaints received 8](#_Toc108676368)

[Overdue review 9](#_Toc108676369)

[Appendix 1: Details of applications reviewed 11](#_Toc108676370)

[Applications reviewed by full committee 11](#_Toc108676371)

[Declaration by Head of Organisation with Primary Responsibility for the EC 22](#_Toc108676372)

[Declaration by EC Chairperson 22](#_Toc108676373)

[Declaration by Head of Organisation with Primary Responsibility for the EC 22](#_Toc108676374)

# 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

The last three years has seen many notable changes for not only the Southern HDEC, but the rest of the HDECs and secretariat in general. I would like to start off by commending the hard work of the Southern HDEC over the past three years, maintaining a commitment to ensuring safe and ethical outcomes for participants and researchers in New Zealand. 2020 in particular has been a difficult and trying year for everyone. In addition to the stress and additional challenges presented by the change of Chair twice over the last three years, the COVID-19 pandemic meant that operating as we previously had needed to change. The Committee has handled this change to Zoom-only meetings admirably in addition to their own changes and challenges in their own fields outside of the Committee’s work. The members have remained positive and committed in the face of insecurity and uncertainty, and I applaud them.

Since 2017, the Secretariat has faced many different team changes as well as workload changes. The COVID-19 pandemic has presented many challenges that the Secretariat had to overcome to ensure the HDECs could still function. While this has caused some issues, these have only been relatively minor.

2019 saw the rollout of the much-needed new NEAC standards that guides how we and other ethics committees operate. While this presented new challenges, the committee have been applying these since they came into effect rather diligently while accommodating the learning curve researchers have to overcome.

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

Thanks to the support of our hardworking sceretariat we have been able to weather the changes to our environment and maintain work as usual.

Finally, I give my sincere thanks to the members of our committee, past and present, for their on-going hard work and dedication in ensuring sound ethics review of New Zealand health and disability research.

Helen Walker

Chair, Southern Health and Disability Ethics Committee

# Membership and attendance

## Membership

### List of EC members within the reporting period

**Mrs Helen Walker (Chair)**

Membership category: Consumer/Community Perspectives

Date of appointment: 22nd May 2018

Current term expires: 22nd May 2023

Mrs Helen Walker is currently the Chairman Central Health and Disability Ethics Committee, a Member of the Medical Sciences Council, a Trustee of the Cranford Hospice Trust, Chairman of the New Zealand Singing School and the owner and of Kilgaren Farming Partnership. Chairmen or member of various boards, Finance Audit and Risk has been a major part all these roles.

**Dr Sarah Gunningham**

Membership category: Consumer/Community Perspectives

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.

**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 Devonie Eglinton (nee 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 a number of 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 Paul Chin**

Membership category: Intervention Studies

Date of appointment: 27th October 2018

Current term expires: 27th October 2021

Dr Paul Chin is a clinical pharmacologist, employed as a Senior Lecturer at the University of Otago, Christchurch and Senior Medical Officer at Canterbury District Health Board, New Zealand. He is also a qualified general physician, and completed a PhD in pharmacokinetic aspects of gentamicin and dabigatran in 2014. Research interests include therapeutic drug monitoring (including continuing work with anticoagulants and antimicrobials), quality use of medicines, electronic prescribing, and clinical decision support and estimation of renal function.

**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.

**Dr Pauline Boyles**

Membership category: Disability, consumer and 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.

**Ms Raewyn Idoine**

Membership category: Consumer and community perspectives

Date of appointment: 27th October 2018

Current term expires: 27th October 2021

Ms Raewyn Idoine is a director of the NZ Blood Service. Her recent roles include Stakeholder Engagement Manager for the Tertiary Education Commission (2007-2009) and Owner/Manager of a number of large private Tertiary institutions. Ms Idoine was registered as a Nurse at Auckland Public Hospital (1976). Other positions she has undertaken include: Judge of the New Zealand Hospitality Awards (2004-2007), Head Assessor of the New Zealand Tourism Awards (1999-2006) and member of the Ministry of Education Tertiary Advisory Group (1996-2004).

**Associate Professor Prof Nicola Swain**

Membership category: Observational Studies

Date of appointment: 27th October 2018

Current term expires: 27th October 2021

Dr Nicola Swain is currently a Senior Lecturer at the University of Otago (2007-present). Prior to this she was a Research Fellow with the Christchurch Health and Development Study. She has completed a Doctor of Philosophy (1998) and a Bachelor of Science, with honours (1994) at the University of Otago. Dr Swain holds professional memberships with the Centre for Applied Positive Psychology, the International Positive Psychology Association and the New Zealand Pain Society. Dr Swain specialises in Health Psychology and pain research. She has published over 40 refereed journal articles and regularly contributes to conferences. She teaches Health Psychology and Pain to medical students at the Dunedin School of Medicine. She also supervises students studying for PhDs, Masters and summer research projects in fields such as Dr-patient communication, child well-being, child-birth satisfaction and on-line interventions for pain.

**Ms Rochelle Style (Co-opt)**

Membership category: Ethics and Moral Reasoning

Date of appointment: 14th June 2017

Current term expires: 14th June 2020

Rochelle Style holds an Honours Degree in Law (University of Canterbury, 1985) and a Masters of Bioethics & Health Law (Distinction) (University of Otago, 2017).

She was a partner in one of New Zealand’s leading law firms, Bell Gully, and acted as Litigation Counsel on behalf of PHARMAC. She is a current Ministerial appointee on the Northern A Health and Disability Ethics Committee and is a member of an expert Working Party appointed by the Ministry of Health to update the National Ethical Health Research guidelines with particular input on the Health Data Chapter and the Chapter on Artificial Intelligence & Emerging Health Technologies. She also has valuable clinical ethics experience gained through her appointment as a member of the Capital & Coast DHB’s Clinical Ethics Advisory Group.

Rochelle is also an independent researcher and has published on the governance of health data research in New Zealand and delivered lectures and presentations on health data ethics and ethical issues arising in the use of Artificial Intelligence in the health sector, including at the University of Otago, Victoria University of Wellington and the Waitemata DHB’s Clinical Digital Academy.

**Mrs Leesa Russell (Co-opt)**

Membership category: Intervention/Observational Studies

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Mrs Leesa Russell is a Clinical Audit Manager at St John. She has a Masters and a Bachelors degree in Sociology from the University of Auckland.

**Ms Sandy Gill\* (Co-opt)**

Membership category: Consumer/Community Perspectives

Date of appointment: 30th July 2015

Current term expires: 30th July 2018

Ms Sandy Gill (Nga Puhi) 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. She has a 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 Māori mental health. She and an Associate Member of AMINZ.

##

## Attendance

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | ***Membership category***  | **9 Jul 2019** | **13 Aug 2019** | **10 Sep 2019** | **08 Oct 2019** | **12 Nov 2019** | **10 Dec 2019** | **11 Feb 2020** | **10 Mar 2020** | **14 Apr 2020** | **12 May 2020** | **9 Jun 2020** | **Total** |
| Mrs Helen Walker | L | / | / | **Y** | / | / | / | / | / | X | / | / | 1 |
| Ms Raewyn Idione | L | **Y** | / | / | / | / | / | / | / | X | / | / | 1 |
| A/Prof Nicola Swain | NL | **Y** | / | / | / | / | / | / | / | X | / | / | 1 |
| Dr Sarah Gunningham | L | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | X | **Y** | **Y** | 9 |
| Dr Devonie Eglinton (Waaka)\* | NL | **Y** | A | Y | A | **Y** | **Y** | **Y** | **Y** | X | **Y** | **Y** | 8 |
| A/Prof Mira Harrison-Woolrych | NL | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | X | **Y** | **Y** | 9 |
| Professor Jean Hay-Smith | NL | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | X | **Y** | **Y** | 9 |
| Dr Paul Chin | NL | A | **Y** | A | **Y** | A | **Y** | **Y** | **Y** | X | **Y** | **Y** | 7 |
| Mr Dominic Fitchett | L | / | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | X | **Y** | **Y** | 9 |
| Dr Pauline Boyles | L | / | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | X | A | **Y** | 7 |
| Ms Sandy Gill \* (co-opt)  | L | **Y** | **Y** | / | / | / | / | / | / | X | / | / | 2 |
| Mrs Leesa Russell (co-opt) | NL | / | / | **Y** | / | / | / | / | / | X | / | / | 1 |
| Ms Rochelle Style (co-opt) | L | / | / | / | / | / | / | / | **Y** | X | **Y** | / | 2 |
| **Total no. of members present** |  | **7** | **7** | **6** | **6** | **5** | **7** | **7** | **7** | **-** | **7** | **7** |  |
| **No. of applications considered** |  | **10** | **12** | **12** | **5** | **8** | **12** | **7** | **12** | **-** | **9** | **9** |  |

## Training and conferences

### Specify the training undergone by new members

HDEC New Member Training

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

New National Ethical Standards Training for all current members

# Applications reviewed

**Summary of applications received by full EC.**

|  |  |
| --- | --- |
| No. of applications approved | 0 |
| No. of applications approved subject to non-standard conditions | 21 |
| No. of applications deferred and subsequently approved | 37 |
| No. of applications deferred as at time of report | 15 |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | 2 |
| No. of applications that were declined because of no/insufficient consultation with appropriate cultural group | 0 |
| No. of applications declined (This excludes those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group)  | 15 |
| No. of applications which do not require ethics committee approval (applications submitted to Committee) (Note this can include incomplete applications) | 16 |
| No. of studies withdrawn by researcher | 2 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC  | 0 |
| **Total number of applications received by full EC**  | **108** |

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

|  |  |
| --- | --- |
| No. of applications approved | 45 |
| No. of applications deferred as at time of report | 6 |
| No. of applications which do not require ethics committee approval (Note this can include incomplete applications) | 8 |
| No. of applications referred for full committee review | 0 |
| No. of applications declined | 5 |
| No. of studies withdrawn by researcher | 1 |
| **Total number of applications received under expedited / low risk review** | **65** |

|  |  |
| --- | --- |
| Total number of applications received: | 173 |

#

# Complaints and overdue application summary

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

## Complaints received

**Complaint One**

**Study Reference**: 19/STH/208

**Type of Complaint**: 2 February 2020

**Review Date**: 20 December 2020

**Complaint Received**: Committee Behaviour

**Nature of Complaint:**

Researcher felt that the committee were laughing at them and making fun of their research during the meeting which had to take place via a cell phone due to meeting technology failure.

**Actions Taken:**

* Complaint sent to Manager
* Manager acknowledged the complaint.
* Chair of Southern HDEC Informed.
* Letter of apology sent.

**Outcome:**

A letter of apology was sent to the researcher, informing them of the technological issues of sharing a cell phone around the committee. The Chair assured the researcher that the laughter was due to members handing around the cell phone and not related to the study application. Complaint closed.

**Complaint Two**

**Study Reference**: 19/STH/91

**Type of Complaint**: Timeliness of Decision

**Review Date**: 21 November 2019

**Complaint Received**: 18 November 2020

**Nature of Complaint:**

Complaint received quoting that the HDEC did not adhere to Paragraph 57 of the Standard Operating Procedures which states the HDECs must make a final decision within 35 calendar days. The committee may suspend this timeframe once for up to 90 calendar days where they require additional information in order to make a final decision. In total this application took a full 182 days to give a final approval as the application required health legal and MedSafe input before a final approval could be given.

**Actions Taken:**

* Complaint sent to Manager.
* Manager acknowledged the complaint.
* Chair of Central HDEC Informed.
* Health Legal and Medsafe informed.
* Letter of apology sent to researcher.

**Outcome:**

Complaint upheld. Letter of apology sent to researcher outlining the legal complexities and other regulators in the Ministry involvement which was outside of the control of the HDEC and the Ethics Secretariat. Complaint closed.

## Overdue review

Average review times take into account the time taken for the Secretariat to process applications and the time taken for the Committee to review applications. The clock is stopped when a decision letter is emailed to applicants. Average review times exclude time taken for researchers to respond to requests for further information. Researchers have up to 90 days to respond

Average review time was 42 days for full applications. Target timeframe for full applications is 35 calendar days. The delay in this has been caused primarily by COVID-19 challenges to the Secretariat.

Average review time was 34 days for expedited applications. Target timeframe for expedited applications is 15 calendar days. The delay was largely caused by COVID-19 work taking priority, and the strain changes to working arrangements and workloads as a result had on the Secretariat.

13 outliers have been identified with the expedited applications and are as follows:

19/STH/205 (73 Days) – Clock started 11 November and paused 25 November . A response to provisional approval was received in 12 December which was close to the Ministry Christmas shut-down period. The clock remained active while the HDECs and Ministry were not operating, and was stopped start of February 2020.

19/STH/207 (122 days) – Clock started 18 November and paused on 25 November. A response to provisional approval was not received until early March 2020. COVID-19 caused significant delays and unfortunately decision was not processed until 19 June 2020.

19/STH/221 (85 Days) – Application received in December and clock started 5 December. Ministry closed for Christmas within the review timeframe and clock was still running. Clock paused in early February 2020 with provisional approval outcome. Researcher responded to provisional approval 5 March. Clock stopped 16 March 2020.

19/STH/225 (122 days) – Application clock started 9 December. Decision had not been reached at time of Ministry closing for Christmas. Clock paused in January 2020. More information received in March and clock restarted. Unfortunately due to COVID-19, significant delays in processing the decision occurred and the clock was stopped on 3 July 2020.

19/STH/226 (108 days) – Application clock started 10 December. Decision had not been reached at time of Ministry closing for Christmas. Clock paused in February 2020. Response was received 5 March 2020. Unfortunately due to COVID-19, significant delays in processing the decision occurred and the clock was stopped on 10 April 2020.

20/STH/5 (71 days) – Application clock started 27 January 2020. Delay in processing response by Secretariat, and clock was paused 18 March 2020. Response from researcher received 01 April. Decision processed 14 April 2020 after delay in response by Committee.

20/STH/6 (94 days) – Application clock started 27 January 2020. Delay in processing response by Secretariat, and clock was paused 18 March 2020. Response from researcher received 06 May 2020. Decision processed 12 June 2020 after delay in response by Committee.

20/STH/7 (89 days) – Application clock started 16 January 2020 (retroactively) and assigned to review meeting 28 January. Discussion between Secretariat and HDEC was undertaken regarding the submitted peer-review. There was a delay in processing the outcome by the Secretariat and the clock was stopped 14 April 2020.

20/STH/8 (89 days) – Same as 20/STH/7 (submitted by same researcher)

20/STH/22 (74 days) – Application clock started 30 January 2020 (retroactively) and assigned to review meeting 10 February 2020. Delay in committee decision and Secretariat processing meant that clock was paused 24 March 2020. Researcher responded to this decision 20 June. Committee delay in decision, clock stopped 10 July 2020

20/STH/49 (76 days) - Application clock started 17 March 2020 (retroactively) and assigned to review meeting 03 April 2020 Delay in committee decision and Secretariat processing meant that clock was paused 15 May 2020. Researcher responded to this decision 25 June. Committee delay in decision, clock stopped 13 July 2020

20/STH/73 (70 days) – Application clock started 04 May 2020. Secretariat failed to action decision until 03 July 2020 due to staff shortages. Researcher response received 10 August 2020. Clock stopped with final decision 20 August 2020.

20/STH/77 (84 days) – Application clock started 20 May 2020. Secretariat failed to action decision until 29 July 2020 due to staff shortages and delay in Committee response. Clock paused then researcher responded on 10 August 2020. Clock stopped with final decision 19 August 2020.

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

## Applications reviewed by full committee

| **Study reference** | **Short title** | **CI Name** | **Clock Start** | **Date of provisional approval** | **Study status** | **Date of final decision** | **CI Organisation[locality not captured]** | **Main sponsor type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 19/STH/135 | Stress, dopamine, and motor deficits in PD | Dr Rebekah Blakemore | 25/07/2019 | 27/08/2019 | Approved | 09/10/2019 | University of Otago | no sponsor |
| 19/STH/137 | Study 212669: A Phase I Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of GSK2798745 in Participants with Diabetic Macular Edema | Prof Russell Scott | 01/08/2019 |  | Withdrawn | 07/08/2019 | Christchurch Hospital | Pharmaceutical Company |
| 19/STH/139 | Randomised control trial comparing ACL reconstruction with Quadriceps or Hamstring autograft | Dr Jessica Mowbray | 01/08/2019 | 30/07/2019 | Approved | 27/08/2019 | Northland District Health Board | NGO |
| 19/STH/141 | PD Research Priorities | Dr Toni Pitcher | 27/07/2019 | 21/10/2019 | Approved | 23/10/2019 | University of Otago | no sponsor |
| 19/STH/143 | Response to mass shooting event | Dr Sandra Richardson | 01/08/2019 | 10/09/2019 | Approved | 01/10/2019 | Canterbury District Health Board | no sponsor |
| 19/STH/144 | A probiotic to improve ileal pouch health: a randomised control trial | Assoc. Prof. Mark Thompson-Fawcett | 28/07/2019 |  | Approved | 27/08/2019 | University of Otago | No sponsor |
| 19/STH/145 | Pre-school screening to detect emotional, behavioural and developmental problems in children with critical congenital heart disease. | Dr Sarah Pennalligen | 30/07/2019 | 20/08/2019 | Approved | 23/09/2019 | Lakes District Health Board | No sponsor |
| 19/STH/146 | Being a teenager can be stressful. Does being kinder to yourself increase coping? | Mrs Amanda Helen Smith | 01/08/2019 |  | Declined | 27/08/2019 | None | No sponsor |
| 19/STH/147 | Impact of re-operation within one month on early and long term outcomes after renal transplantation: A single centre experience. | Dr Sam Taylor | 31/07/2019 |  | Approved | 20/08/2019 | Auckland District Health Board | No sponsor |
| 19/STH/149 | Mental health access to care in ED | Dr Iris Chan | 30/07/2019 | 27/08/2019 | Approved | 23/10/2019 | University of Otago | No sponsor |
| 19/STH/150 | Uromune-C® in the prevention of recurrent vulvovaginal candidiasis | Dr Nicky Perkins | 01/08/2019 |  | Declined | 27/08/2019 | Auckland District Health Board | DHB |
| 19/STH/151 | Novel methods of infant feeding in New Zealand - cause for concern or optimism? | Associate Professor Anne-Louise Heath | 01/08/2019 | 27/08/2019 | Approved | 13/11/2019 | University of Otago | No sponsor |
| 19/STH/152 | A Study to Investigate the Safety and Efficacy of ABBV-105 and Upadacitinib in Subjects with Systemic Lupus Erythematosus (SLE). | Dr Douglas White | 01/08/2019 |  | Approved | 27/08/2019 | Waikato District Health Board | Pharmaceutical Company |
| 19/STH/153 | Te Ao Mārama (Phase 1) | Mrs Bernadette Jones | 01/08/2019 |  | Approved | 27/08/2019 | University of Otago | No sponsor |
| 19/STH/155 | NP40435: DOSE ESCALATION AND EXPANSION STUDY OF PD-1/TIM-3 BISPECIFIC ANTIBODY IN PATIENTS WITH ADVANCED AND/OR METASTATIC SOLID TUMORS | Dr Sanjeev Deva | 01/08/2019 |  | Declined | 27/08/2019 | Auckland City Hospital | Pharmaceutical Company |
| 19/STH/156 | DUAL-ACS | Dr Philip Adamson | 01/08/2019 |  | Approved | 27/08/2019 | Christchurch Heart Institute | Academic Institution |
| 19/STH/158 | A Phase 3,open label study comparing Zanubrutinib plus Rituximab vs Bendamustine plus rituximab in Patients with Previously untreated Mantle cell Lymphoma | Dr Marie Hughes | 29/08/2019 |  | Approved | 20/09/2019 | Bay of Plenty District Health Board | Pharmaceutical Company |
| 19/STH/159 | A Phase 2/3 Safety Study of MEDI8897 Against Respiratory Syncytial Virus, in High- risk children. | Mr. Jane Alsweiler | 29/08/2019 | 20/09/2019 | Approved | 17/12/2019 | The University of Auckland | Pharmaceutical Company |
| 19/STH/160 | A Phase 3 Efficacy Study of MEDI8897 Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants The MELODY Trial. | Mr. Jane Alsweiler | 29/08/2019 | 20/09/2019 | Approved | 17/12/2019 | The University of Auckland | Pharmaceutical Company |
| 19/STH/161 | The ADESTE Study | Professor Richard Troughton | 29/08/2019 |  | Declined | 20/09/2019 | University of Otago | Collaborative |
| 19/STH/162 | Working Memory Training in Adult TBI | Dr Kristin Gozdzikowska | 29/08/2019 |  | Approved | 20/09/2019 | Laura Fergusson Trust | No sponsor |
| 19/STH/163 | BETTER SLEEP | Dr Michael Hlavac | 29/08/2019 | 20/09/2019 | Approved | 15/10/2019 | Canterbury District Health Board | Medical Device Company |
| 19/STH/164 | Pembrolizumab or Placebo Plus Gemcitabine/Cisplatin for First-Line Advanced and/or Unresectable Biliary Tract Carcinoma (KEYNOTE-966) | Dr Rita Sasidharan | 29/08/2019 | 20/09/2019 | 10/12/2019 | Approved | Auckland City Hospital | Pharmaceutical Company |
| 19/STH/165 | Biomarker-guided Management Post-Acute Coronary Syndromes | Professor Rob Doughty | 29/08/2019 | 20/09/2019 | 25/11/2019 | Approved | University of Auckland | No sponsor |
| 19/STH/166 | RURAL: Rural vs. Urban Risks of Appendicitis CompLications | Dr Michael Roberts | 29/08/2019 |  | 20/09/2019 | Declined | Northland District Health Board | District Health Board |
| 19/STH/167 | Cefazolin for surgical antimicrobial prophylaxis - The incidence of anaphylaxis and of cross-sensitivity with penicillin. | Ms Davina McAllister | 7/09/2019 | 23/09/2019 | 11/11/2019 | Approved | Auckland District Health Board | No sponsor |
| 19/STH/168 | Flexible sigmoidoscopy; use of video information & inhalational analgesia | Associate Professor Philip F Bagshaw | 29/08/2019 | 6/09/2019 | - | Provisionally Approved (Deferred) | Canterbury Charity Hospital Trust | No sponsor |
| 19/STH/169 | Study Designed to Assess the Safety, Tolerability and PK of PTI-808 in Adults With Cystic Fibrosis | Dr Mark O'Carroll | 29/08/2019 | 20/09/2019 | 15/10/2019 | Approved | Auckland Clinical Studies (City Hospital) | Pharmaceutical Company |
| 19/STH/170 | Bronchodilator speed of onset. | Professor Richard Beasley | 29/08/2019 |  | 20/09/2019 | Approved | The Medical Research Institute of New Zealand | Institute |
| 19/STH/171 | Check Mate 9DW: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 9DW | Professor Ed Gane | 29/08/2019 | 20/09/2019 | 6/12/2019 | Approved | Auckland District Health Board | Pharmaceutical Company |
| 19/STH/174 | KETAMINE AND SPIDER PHOBIA | Prof Paul Glue | 26/09/2019 | 30/10/2019 | 16/12/2019 | Approved | University of Otago | No sponsor |
| 19/STH/176 | Haemochromatosis - red cell indices and impact of venesection | Dr Steven Shih | 10/10/2019 | 23/10/2019 | 12/11/2019 | Approved | None | No sponsor |
| 19/STH/178 | Fusionless Scoliosis Correction Device in Children | Mr Bruce Hodgson | 26/09/2019 | 30/10/2019 | 25/02/2020 | Approved | None | No sponsor |
| 19/STH/179 | (duplicate) RSV MAT-004 - a research study to vaccinate pregnant women against RSV and assess the incidence of RSV associated events in the children born to these mothers | Dr Thorsten Stanley | 27/09/2019 |  | 30/10/2019 | Approved | None | Pharmaceutical Company |
| 19/STH/181 | AcrySof IQ Vivity Extended Vision IOL vs. TECNIS Symfony and AT LARA Extended Depth of Focus IOLs | Dr Dean Corbett | 26/09/2019 | 30/10/2019 | 15/01/2020 | Approved | Auckland Eye | Medical Device Company |
| 19/STH/182 | Efficacy and safety of WVE-210201 in ambulatory boys with DMD | Dr Gina O'Grady | 27/09/2019 | 30/10/2019 | 6/12/2019 | Approved | Auckland Clinical Studies Ltd and Startship Hospital | Pharmaceutical Company |
| 19/STH/183 | (duplicate) Olfactory mucosa in Parkinson's disease | Dr Tary Yin | 30/09/2019 | 15/10/2019 | 7/11/2019 | Approved | The University of Auckland | No sponsor |
| 19/STH/184 | Transplanting HCV positive deceased donor kidneys in to HCV negative recipients | Dr John Schollum | 31/10/2019 |  | 28/11/2019 | Declined | Southern District Health Board | Other government agency |
| 19/STH/185 | National Quality Improvement Indicators Project | Dr Daniel Ramsay | 15/10/2019 | 7/11/2019 | 19/11/2019 | Approved | Hutt Valley District Health Board | No sponsor |
| 19/STH/186 | The Immunological Effects of Gene Variants | Dr Troy Merry | 16/10/2019 | 13/11/2019 | 16/12/2019 | Approved | University of Auckland | Academic Institution |
| 19/STH/188 | Autoimmune brain project | Dr Yeri Ahn | 23/10/2019 |  | 7/11/2019 | Declined | None | No sponsor |
| 19/STH/189 | MANTRA Self-Help Feasibility Trial | Dr Marion Roberts | 24/10/2019 | 13/11/2019 | 16/12/2019 | Approved | University of Auckland | Academic Institution |
| 19/STH/190 | Utility of an intra-vaginal biofeedback device (FemFit®) to resolve incontinence. | Dr Jennifer Kruger | 24/10/2019 | 13/11/2019 | 29/11/2019 | Approved | University of Auckland | Academic Institution |
| 19/STH/191 | A clinical study of Δ133p53 expression in Ulcerative Colitis | Prof Michael Schultz | 31/10/2019 |  | 28/11/2019 | Declined | Dunedin Hospital | No sponsor |
| 19/STH/195 | Deferred Cord Clamping to Reduce Need for Neonatal Blood Transfusion: the Transfusions In The APTS Newborns Study (TITANS) | Dr Liza Edmonds | 29/10/2019 |  | 13/11/2019 | Approved | Dunedin Hospital | No sponsor |
| 19/STH/197 | Effect of multi-target transcranial current stimulation on cognition and pain. | Dr Divya Adhia | 31/10/2019 | 28/11/2019 | 20/12/2019 | Approved | University of Otago | No sponsor |
| 19/STH/198 | ION-682884 for the treatment of Hereditary Transthyretin-Mediated Amyloid Polyneuropathy | Professor Ed Gane | 31/10/2019 | 28/11/2019 | 11/02/2020 | Approved | Auckland District Health Board | Pharmaceutical Company |
| 19/STH/199 | Atezolizumab Plus Bevacizumab in Patients With Hepatocellular Carcinoma After Surgical Resection or Ablation | Professor Ed Gane | 31/10/2019 | 29/11/2019 | 9/03/2020 | Approved | Auckland District Health Board | Pharmaceutical Company |
| 19/STH/201 | ctDNA for early cancer detection | Dr Dianne Sika-Paotonu | 31/10/2019 | 29/11/2019 | 10/03/2020 | Approved | University of Otago Wellington | Academic Institution |
| 19/STH/202 | Neonatal Nutritional Interventions Early School-age Outcomes Studies | Dr Chris McKinlay | 31/10/2019 |  | 29/11/2019 | Approved | University of Auckland | Academic Institution |
| 19/STH/203 | Beliefs about antibiotics | Dr Amy Chan | 5/11/2019 | 13/11/2019 | 20/12/2019 | Approved | Auckland District Health Board | No sponsor |
| 19/STH/204 | Manaaki | Ms Gayl Humphrey | 5/11/2019 | 25/11/2019 | 6/12/2019 | Approved | National Institute for Health Innovation | Academic Institution |
| 19/STH/205 | Topical tranexamic acid in endoscopic sinus surgery | Dr Andrew Wood | 11/11/2019 | 25/11/2019 | 7/02/2020 | Approved | The University of Auckland | No sponsor |
| 19/STH/206 | Analyzing clustered epidemiological studies from complex surveys: Study protocol | Dr Claudia Rivera Rodriguez | 11/11/2019 | 25/11/2019 | 27/02/2020 | Approved | The University of Auckland | Academic Institution |
| 19/STH/207 | Title: Rescue Cervical Cerclage with natural Progesterone supplementation; a personal experience with five cases. | Dr Antoine Habboub | 19/11/2019 | 25/11/2019 | 19/06/2020 | Declined | Hutt Valley District Health Board | No sponsor |
| 19/STH/208 | Pēpi Splint Project | Dr Deborah Harris | 28/11/2019 |  | 20/12/2019 | Declined | Victoria University of Wellington | Academic Institution |
| 19/STH/209 | Group A streptococcus PCR for throat swabs | Dr Amanda Taylor | 28/11/2019 | 20/12/2019 |  | Provisionally Approved | Middlemore Hospital | No sponsor |
| 19/STH/210 | Bronchiolitis in Infants Placebo versus Epinephrine Dexamethasone - BIPED | Prof Stuart Dalziel | 28/11/2019 |  | 20/12/2019 | Approved | None | No sponsor |
| 19/STH/211 | Comparison of the blood levels of two forms of tretinoin under fasting conditions. | Dr Noelyn Hung | 28/11/2019 |  | 20/12/2019 | Approved | Zenith Technology Corporation Limited | Pharmaceutical Company |
| 19/STH/212 | Comparison of the blood levels of two forms of tretinoin under fed conditions. | Dr Noelyn Hung | 28/11/2019 |  | 20/12/2019 | Approved | Zenith Technology Corporation Limited | Pharmaceutical Company |
| 19/STH/213 | Transcranial electrical stimulation for early Alzheimer’s disease. | Dr Divya Adhia | 28/11/2019 |  | 20/12/2019 | Declined | University of Otago | No sponsor |
| 19/STH/214 | The New Zealand-China Berry Lung Health (EDIBLE) study | Dr. Olivier Gasser | 28/11/2019 | 20/12/2019 |  | Withdrawn by researcher | Malaghan Institute of Medical Research | NGO |
| 19/STH/215 | Kōwhai Study | Prof Alexandra McCarthy | 28/11/2019 | 20/12/2019 | 19/02/2020 | Approved | University of Auckland | Academic Institution |
| 19/STH/216 | RMHA gain adjustment for amblyaudia | Dr Joan Leung | 28/11/2019 | 20/12/2019 | 10/04/2020 | Approved | University of Auckland | Collaborative Research |
| 19/STH/217 | A Phase 1/2 Study of DCR-A1AT in Healthy Adult Volunteers and Patients with A1ATD-Associated Liver Disease | Professor Ed Gane | 28/11/2019 | 20/12/2019 | 7/02/2020 | Approved | Auckland District Health Board | Pharmaceutical Company |
| 19/STH/218 | A Phase 3 study of Viltolarsen in boys with Duchenne Muscular Dystrophy (DMD) | Dr Gina O'Grady | 28/11/2019 | 20/12/2019 | 8/04/2020 | Approved | Auckland Clinical Studies Ltd and Startship Hospital | Pharmaceutical Company |
| 19/STH/219 | Detecting changes in habits in rapid eye movement sleep behaviour disorder (RBD): a pilot study. | Professor John Reynolds | 28/11/2019 | 20/12/2019 | 8/04/2020 | Approved | University of Otago | No sponsor |
| 19/STH/220 | The effect of high flow humidified nasal oxygen on peripheral surgical site oxygen concentration | Dr Jane Carter | 4/12/2019 | 12/04/2020 |  | Provisionally Approved | Capital and Coast District Health Board | No sponsor |
| 19/STH/221 | Evaluating the mySugr app for adults with type 1 diabetes | Dr Anna Serlachius | 4/12/2019 | 13/02/2020 | 16/03/2020 | Approved | The University of Auckland | Academic Institution |
| 19/STH/223 | Retrospective Review of Obesity, Ethnicity and Deprivation in relation to Gastro-Oesophageal Adenocarcinoma | Mr Andrew MacCormick | 10/12/2019 | 16/01/2020 | 26/05/2020 | Approved | None | No sponsor |
| 19/STH/224 | Immune microenvironment in liver cancer | Dr Cositha Santhakumar | 5/12/2019 | 20/12/2019 | 5/02/2020 | Approved | None | District Health Board |
| 19/STH/225 | HGG and clozapine | Dr Yeri Ahn | 10/12/2019 | 6/01/2020 | 3/07/2020 | Declined | Auckland District Health Board | No sponsor |
| 19/STH/226 | Acute Clinical Evidence of Digestive, Metabolic and Nutritional Differences in Beef and Meat-Alternative Meals | Dr Andrea Braakhuis | 6/12/2019 | 7/02/2020 | 10/04/2020 | Approved | The University of Auckland | No sponsor |
| 20/STH/1 | CREATE (Community deRivEd AutomaTEd insulin delivery)trial | Dr Martin de Bock | 6/02/2020 | 28/02/2020 | 14/04/2020 | Approved | University of Otago | Academic Institution |
| 20/STH/2 | Praluent in the post-trial access setting | Professor John Elliott | 15/01/2020 | 14/04/2020 |  | Withdrawn by researcher | University of Otago | Pharmaceutical Company |
| 20/STH/3 | Pfizer C3671009 | Dr Simon Carson | 16/01/2020 | 31/01/2020 | 28/02/2020 | Approved | Southern Clinical Trials Ltd | Pharmaceutical Company |
| 20/STH/5 | Novel biomarkers for Escherichia coli-induced sepsis | Prof Stephen Chambers | 20/01/2020 | 18/03/2020 | 14/04/2020 | Approved | None | Academic Institution |
| 20/STH/6 | Driving in an upper limb cast | Dr Keith Lee | 22/01/2020 | 19/03/2020 | 12/06/2020 | Approved | None | No sponsor |
| 20/STH/7 | 5-year follow up: Cardiac biomarkers and outcomes of exacerbations of COPD | Dr Eskandarain Shafuddin | 16/01/2020 |  | 14/04/2020 | Approved | None | No sponsor |
| 20/STH/8 | 10-year follow up: Cardiac biomarkers and outcomes of exacerbations of COPD | Dr Eskandarain Shafuddin | 16/01/2020 |  | 14/04/2020 | Approved | None | No sponsor |
| 20/STH/9 | Dermatology patients with Staphylococcus aureus bacteraemia | Dr Shaochen Liu | 22/01/2020 | 12/02/2020 | 17/03/2020 | Approved | Counties Manukau District Health Board | No sponsor |
| 20/STH/10 | Using NMDS data to investigate the metric Days Alive Out of Hospital in New Zealand | Mr Luke Boyle | 24/01/2020 |  | 3/03/2020 | Approved | University of Auckland | Other |
| 20/STH/13 | Cognitive and behavioural profiles of children in Tamaki | Dr Alison Leversha | 23/01/2020 | 28/02/2020 | 1/04/2020 | Approved | None | No sponsor |
| 20/STH/15 | Inflammation after myocardial infarction | Dr Ana Holley | 30/01/2020 |  | 28/02/2020 | Approved | None | No sponsor |
| 20/STH/17 | Phase 1/2 study of IMC-I109V in non-cirrhotic HBeAg-negative chronic HBV infection | Prof Ed Gane | 23/01/2020 | 28/02/2020 | 26/03/2020 | Approved | Auckland District Health Board | Pharmaceutical Company |
| 20/STH/18 | Dietary sodium and potassium intakes in children | Dr Helen Eyles | 30/01/2020 |  | 28/02/2020 | Declined | The University of Auckland | No sponsor |
| 20/STH/19 | SELECT 2 | Dr Teddy WU | 30/01/2020 | 27/02/2020 | 24/06/2020 | Approved | Canterbury District Health Board | Academic Institution, Collaborative Research |
| 20/STH/20 | Comparison of Tretinoin capsules in Healthy Male Subjects. | Dr Noelyn Hung | 30/01/2020 |  | 28/02/2020 | Approved | Zenith Technology Corporation Limited | Pharmaceutical Company |
| 20/STH/22 | Healthy sinonasal microbiota study | Dr Tary Yin | 30/01/2020 | 24/03/2020 | 10/07/2020 | Approved | The University of Auckland | No sponsor |
| 20/STH/23 | A brief intervention for improving diabetes (BIFID) | Dr Sara Boucher | 5/02/2020 | 12/03/2020 | 1/04/2020 | Approved | University of Otago | Academic Institution |
| 20/STH/24 | Longitudinal cystic fibrosis study | Dr Brett Wagner | 5/02/2020 | 13/03/2020 | 3/07/2020 | Approved | University of Auckland | No sponsor |
| 20/STH/26 | MAPED | Dr Daniel Faulke | 12/02/2020 | 1/04/2020 | 3/07/2020 | Approved | Auckland District Health Board | No sponsor |
| 20/STH/27 | Ageing Well in Outdoor Gym | Dr Ruth Teh | 13/02/2020 | 9/03/2020 | 1/04/2020 | Approved | None | Academic Institution |
| 20/STH/28 | A study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn’s Disease Study to evaluate the safety and effectiveness of guselkumab - GALAXI 2 and 3 (Pha | Prof Michael Schultz | 30/01/2020 |  | 27/02/2020 | Declined | Dunedin Hospital | Pharmaceutical Company |
| 20/STH/29 | Routes to diagnosis for colorectal cancer in Central New Zealand | Ms Melissa Warren | 19/02/2020 | 9/03/2020 | 1/04/2020 | Approved | Breast Cancer Foundation NZ | Academic Institution |
| 20/STH/31 | CH-ALV-2001: A study assessing variations in how quickly STELARA is processed and cleared by the body, in healthy adult males. | Dr Chris Wynne | 27/02/2020 |  | 1/04/2020 | Approved | Christchurch Clinical Studies Trust Ltd | Pharmaceutical Company |
| 20/STH/33 | 0170 - Phase 3 Clinical Effect Durability of TD-9855 for Treating snOH in Subjects with Primary Autonomic Failure | Prof. Timothy Anderson | 27/02/2020 |  | 1/04/2020 | Approved | NZ Brain Research Institute | Pharmaceutical Company |
| 20/STH/34 | A study of EDP-938 in Ambulatory Patients with Respiratory Syncytial Virus | Dr Michael Williams | 27/02/2020 | 1/04/2020 | 26/05/2020 | Approved | Lakeland Clinical Trials Group | Pharmaceutical Company |
| 20/STH/35 | Emerging Biomarkers for Monitoring of Congenital Adrenal Hyperplasia | Mrs Lauren Bresnahan | 27/02/2020 |  | 1/04/2020 | Declined | LabPLUS, Auckland District Health Board | No sponsor |
| 20/STH/36 | M19-850 - Open-label extension of Upadacitinib to adults with moderate to severe Atopic Dermatitis | Prof Marius Rademaker | 27/02/2020 | 1/04/2020 | 1/05/2020 | Approved | Clinical Trials New Zealand Ltd | Pharmaceutical Company |
| 20/STH/37 | The Metformin Aneurysm Trial | Professor Greg Jones | 27/02/2020 | 1/04/2020 | 27/08/2020 | Approved | University of Otago | Academic Institution, Collaborative Research |
| 20/STH/38 | A Study of Nivolumab or Placebo in Combination with Docetaxel in Men with Metastatic Castration-resistant Prostate Cancer | Dr Navin Wewala | 27/02/2020 |  | 1/04/2020 | Declined | MidCentral Health | Pharmaceutical Company |
| 20/STH/39 | Evaluation of the Nu Vera ICE Catheter during Percutaneous Procedures via transseptal puncture | Dr Ian Crozier | 27/02/2020 | 1/04/2020 | 16/07/2020 | Approved | Canterbury District Health Board | Medical Device Company |
| 20/STH/40 | GS-US-200-4330: A study comparing how fast the trial drug GS-6207 is processed and cleared from the body, in healthy adults and in adults with severely reduced kidney function. | Dr Richard Robson | 27/02/2020 |  | 1/04/2020 | Approved | Christchurch Clinical Studies Trust Ltd | Pharmaceutical Company |
| 20/STH/41 | Scabies survey and case-control study | Dr Simon Thornley | 27/02/2020 | 1/04/2020 |  | Provisionally Approved | University of Auckland | Other government agency |
| 20/STH/43 | Transcranial electrical stimulation for early Alzheimer’s disease | Dr Divya Adhia | 27/02/2020 |  | 1/04/2020 | Approved | University of Otago | No sponsor |
| 20/STH/45 | Phase 3 Study of Pembrolizumab and Lenvatinib in Combination with TACE for Incurable/Non-metastatic Hepatocellular Carcinoma (LEAP-012) | Professor Ed Gane | 27/02/2020 | 1/04/2020 | 18/05/2020 | Approved | Auckland District Health Board | Pharmaceutical Company |
| 20/STH/49 | Ka ora ai te iwi - Oranga Whānau: Māori experiences of Mate Wareware (Dementia). | Dr Julie Maria Wharewera-Mika | 18/03/2020 | 15/05/2020 | 13/07/2020 | Approved | Auckland University | Collaborative research |
| 20/STH/51 | NZ DIETS \_ASIA Study | Prof Sally D Poppitt | 5/04/2020 | 28/07/2020 |  | Provisionally Approved | The University of Auckland | Academic Intistution |
| 20/STH/52 | Perceptions of Methotrexate for inflammatory arthritis: An Intervention Study | Professor Keith Petrie | 27/03/2020 | 14/04/2020 | 11/05/2020 | Approved | University of Auckland | No sponsor |
| 20/STH/56 | Nocebo Hypothesis Cognitive Behavioural Therapy for Functional Neurological Symptoms Disorder | Dr Matt Richardson | 2/04/2020 |  | 14/04/2020 | Approved | University of Otago | Academic Institution |
| 20/STH/57 | Correlation of cytogenetic data with overall survival in uveal melanoma patients | Dr Peter Hadden | 2/04/2020 | 25/05/2020 | 29/07/2020 | Approved | University of Auckland | No sponsor |
| 20/STH/58 | Down's dementia | Prof. Tim Anderson | 30/04/2020 |  | 5/06/2020 | Declined | University of Otago | No sponsor |
| 20/STH/59 | Feasibility study of a new IUD insertion device | Associate Professor Michael Stitely | 30/04/2020 | 5/06/2020 | 29/07/2020 | Approved | University of Otago | Academic Institution |
| 20/STH/60 | AK120-101: Assessment of single doses of the investigational drug AK120, in healthy adults. | Dr Chris Wynne | 30/04/2020 |  | 5/06/2020 | Approved | Christchurch Clinical Studies Trust Ltd | Pharmaceutical Company |
| 20/STH/62 | JBT101-RIS-001: A study comparing how fast the trial drug lenabasum is processed and cleared from the body, in adults with varying levels of kidney function. | Dr Richard Robson | 23/04/2020 |  | 5/06/2020 | Approved | Christchurch Clinical Studies Trust Ltd | Pharmaceutical Company |
| 20/STH/63 | Evaluation of Safety, Tolerability and Preliminary Efficacy of EHP-101 in Patients with Diffuse Cutaneous Systemic Sclerosis | Mrs Marina Dzhelali | 23/04/2020 | 5/06/2020 | 29/07/2020 | Approved | None | Pharmaceutical Company |
| 20/STH/65 | Biolen-PC | Dr Mark Fraundorfer | 30/04/2020 | 5/06/2020 | 1/07/2020 | Approved | Tauranga Urology | Medical Device Company |
| 20/STH/67 | BO41843 - A study to compare GDC-9545 plus palbociclib versus letrozole plus palbociclib in people with estrogen receptor-positive, HER2-negative breast cancer (BO41843) | Dr Soizick Mesnage | 30/04/2020 | 5/06/2020 |  | Provisionally Approved | Auckland District Health Board | Pharmaceutical Company |
| 20/STH/69 | Echo Short Axis Stack | Dr Sean Coffey | 30/04/2020 | 5/06/2020 | 13/07/2020 | Approved | None | Academic Institution |
| 20/STH/70 | C3671008: A study assessing the safety and effectiveness of an investigational Respiratory Syncytial Virus (RSV) vaccine, in infants born to women vaccinated during pregnancy. | Dr Joanna (Jo) Gullam | 30/04/2020 |  | 17/06/2020 | Approved | Christchurch Clinical Studies Trust Ltd | Pharmaceutical Company |
| 20/STH/71 | Photonic Probe for Rapid Prostate Cancer Detection | Dr Claude Aguergaray | 30/04/2020 |  | 17/06/2020 | Declined | University of Auckland | Academic Institution |
| 20/STH/73 | Impact of Human Papillomavirus (HPV) Immunisation on Rates of High GradeCervical Intraepithelial Neoplasia (CIN2/3) in Young Women (2016-2019) | Dr Carrie Innes | 4/05/2020 | 3/07/2020 | 20/08/2020 | Approved | University of Otago | No sponsor |
| 20/STH/74 | Improving the Respiratory Health of Children in NZ | Mrs Jacinta Fa'alili-Fidow | 11/05/2020 |  | 11/06/2020 | Declined | Moana Research | NGO |
| 20/STH/75 | The effect of New Zealand green shell mussel on promoting muscle recovery following eccentric-induced muscle damage. | Dr Jocelyn Eason | 8/05/2020 | 19/06/2020 | 14/07/2020 | Approved | The New Zealand Institute for Plant and Food Research Ltd. | Other government agency |
| 20/STH/77 | 3D pelvic floor ultrasound appearances and patient reported outcomes following placement of fascial slings | Dr Eva Fong | 20/05/2020 | 29/07/2020 | 19/08/2020 | Approved | None | No sponsor |
| 20/STH/79 | Ketamine and spider phobia replication study | Prof Paul Glue | 28/05/2020 | 26/06/2020 |  | Provisionally Approved | University of Otago | No sponsor |
| 20/STH/84 | Galderma LTE study - 118163 | Prof Marius Rademaker | 28/05/2020 | 26/06/2020 |  | Provisionally Approved | Clinical Trials New Zealand Ltd | Pharmaceutical Company |
| 20/STH/85 | The MoPED Study | Dr Eleanor Kennedy | 28/05/2020 | 26/06/2020 |  | Provisionally Approved | University of Auckland | Academic Institution |
| 20/STH/86 | Study of Cemiplimab (REGN2810 (Anti-PD-1)) in Patients With Advanced Malignancies | Associate Professor Michael Jameson | 28/05/2020 | 26/06/2020 |  | Provisionally Approved | Waikato District Health Board | Pharamceutical Company |
| 20/STH/87 | (duplicate) A study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn’s Disease Study to evaluate the safety and effectiveness of guselkumab - GALAXI | Prof Michael Schultz | 28/05/2020 | 26/06/2020 |  | Provisionally Approved | Dunedin Hospital | Pharmaceutical Company |
| 20/STH/88 | A study comparing the pharmacokinetic similarity of MB02-SP, MB02-DM and US-licensed Avastin®. | Mr Christian Schwabe | 28/05/2020 | 26/06/2020 | 10/08/2020 | Approved | Auckland Clinical Studies | Pharmaceutical Company |
| 20/STH/92 | Zoster Eye Disease Study (ZEDS) | Dr Jay Meyer | 28/05/2020 | 26/06/2020 |  | Provisionally Approved | University of Auckland | Academic Institution |
| 20/STH/93 | MANA: Meaning, Agency & Nurturing Autonomy | Dr Fiona Graham | 28/05/2020 | 26/06/2020 | 20/08/2020 | Approved | University of Otago | Academic Institution |
| 20/STH/94 | Service user and clinician experiences of self-harm services | Dr Sarah Fortune | 28/05/2020 | 26/06/2020 |  | Provisionally Approved | University of Otago | No sponsor |
| 20/STH/95 | The association between prioritisation scores and subsequent improvements in QoL as measure by the IoL questionnaire. | Dr Andrew McCombie | 9/06/2020 | 30/06/2020 |  | Provisionally Approved | University of Otago | Academic Institution |
| 20/STH/96 | Benefits of a bio-active yogurt in postmenopausal women | Dr Noha Nasef | 9/06/2020 | 14/07/2020 |  | Provisionally Approved | None | No sponsor |
| 20/STH/99 | (duplicate) Title: Rescue Cervical Cerclage with natural Progesterone supplementation; a personal experience with five cases. | Dr Antoine Habboub | 21/06/2020 |  | 29/07/2020 | Approved | Hutt Valley District Health Board | 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:** Mrs Helen Walker \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature: Date: 25 September 2020**

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

**Name of EC: Pre-populated by HRC**

**Name of organisation: Pre-populated by HRC**

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

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

**Name:** Mr Nic Aagaard

 Title First Name Last Name

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

**E-mail :** Nic.Aagaard@health.govt.nz



**Signature: Date:** 7 October 2020

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