

Southern Health and Disability Ethics Committee

Annual Report
2019

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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 Health and Disability Ethics Committee is approved by the Health Research Council Ethics Committee for the purposes of section 25(1)(c) of the [Health Research Council Act 1990](http://legislation.govt.nz/act/public/1990/0068/latest/DLM213017.html).

The Southern Health and Disability Ethics Committee is registered (number 00008713) 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

This was a transitional year for the Southern HDEC, marked by changes in its membership – the most of any committee I am told – and Secretarial support. These continue; including my own appointment as Chairperson in July 2019.

The loss of long-serving members, which continued even beyond this reporting period, was also the loss of much institutional knowledge. It will take time to up-skill new members and for them to gather experience, and with the updated NEAC Guidelines on the horizon even long-term members will be required to go through a period of training.

The ministerial appointments process has been slow, and as a result Southern was left with a disproportionate ratio of lay to non-lay members for the bulk of the reporting year. I am very grateful to the lay members of other committees who were routinely co-opted into our ranks so that we could balance this and reach quorum. While appointments have now been made outside this reporting period it is worth flagging the risk of national ethics committees which lack numbers and breadth of expertise to safely manage their review workload. I am conscious that these problems are still faced by other HDECs.

Recurring frustrations in the quality of ethics applications continue to be the robustness of peer review, the adequacy of sponsor insurance in commercial trials, and researcher cultural literacy (as evidenced in the Māori responsiveness section of the application form). It was enriching being able to discuss these former two issues (among others) with all chairpersons at our recent meeting, and our co-ordinated response is detailed elsewhere in this report. The latter is indicative of a wider problem.

Another substantive ethical issue is of course the application of Right 7(4) of the Code. The ‘Best Interests Test’ for non-consensual research can be challenging, and we look forward to further guidance on this and related issues in the forthcoming Standards. As stated, a tailored training program to accompany these changes in national ethics standards will be an integral part of the year to come.

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.

Sarah Gunningham

Chairperson

Southern Health and Disability Ethics Committee

# Membership and attendance

Due to the resignations of 2 lay members, and the subsequent delay in appointing to these vacant positions, significant co-opting was required throughout the reporting year to ensure that meetings could meet quorum.

## Membership

### List of EC members within the reporting period

**Ms Raewyn Idoine**

Membership category: Consumer and community perspectives

Date of appointment: 27th October 2015

Current term expires: 27th October 2018

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).

**Dr Sarah Gunningham**

Membership category: Intervention Studies

Date of appointment: 27th October 2015

Current term expires: 27th October 2018

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: 13th May 2016

Current term expires: 13th May 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).

**A/Prof Nicola Swain**

Membership category: Observational Studies

Date of appointment: 27th October 2015

Current term expires: 27th October 2018

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.

**A/Prof Mira Harrison-Woolrych**

Membership category: Intervention Studies

Date of appointment: 27th October 2015

Current term expires: 27th October 2018

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 Southampton, and is a Fellow of the Royal College of Obstetricians and Gynaecologists.

**Mrs Kate O’Connor**

Membership category: Ethical and Moral Reasoning

Date of appointment: 14th December 2015

Current term expires: 14th December 2018

Kate O'Connor is the Executive Secretary of the AUT Ethics Committee, having been a member of the committee for 5 years whist working as Senior Research Contracts Specialist in AUT's Research Office. Prior to this she worked as a research Contracts Manager for Uni Services Ltd in the University of Auckland's School of Population Health, and was Secretary for the University of Auckland's Human Participants Ethics Committee, and the Biological Safety Committee. She has Master of Arts in philosophy and a Post Graduate Diploma in Business. She is a member of the NZ Branch Executive of the Australasian Research Management Society. In 2014, Kate began a DHSc investigating how Michel Foucault’s theoretical toolbox may be used to inspire transformation in the practice of research ethics committees.

**Dr Cordelia Thomas (co-opt)**

Membership category: Law

Date of appointment: 20th May 2017

Current term expires: 20th May 2020

Dr Cordelia Thomas. LLB (Otago), LLM(Hons) and PhD (VUW). Barrister and Solicitor, Cordelia is currently Associate Health and Disability Commissioner – Investigations. She was a Specialist Senior Legal Advisor to the Health and Disability Commissioner. She took up that position in 2009 after working as a Senior Legal Adviser to the Bioethics Council working at the Ministry for the Environment. Previous law lecturer at Wellington Polytechnic and then Massey University, Wellington. Currently the New Zealand Law Society’s National Course Director of the Legal Executive Programme.

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

Membership category: Ethics & 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 was a member of an expert Working Party appointed by the Ministry of Health to update the National Ethical Health Research guidelines (September 2017-March 2018). She also has valuable clinical ethics experience gained through her appointment, over 5 years, 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 data ethics, including at the University of Otago and Victoria University of Wellington.

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

Membership category: Consumer/Community Perspectives

Date of appointment: 30th July 2017

Current term expires: 20th July 2020

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.

**Professor Jean Hay-Smith**

Membership category: Health & Disability 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.

**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.

**Mrs Helen Walker (co-opt)**

Membership category: Consumer & Community Perspectives

Date of appointment: 1st July 2015

Current term expires: 1st July 2018

Mrs Helen Walker is currently the Chairman of the Central HDEC, Chairman of the Medical Sciences Council, Chairman of Audit for Health Hawkes Bay Ltd, a Kaitiaki/Guardian of the Turnbull Library and the owner and financial controller of Kilgaren Farming Partnership. Mrs Walker is a previous Director of Unison Networks Ltd (2004-2010), the Hawke’s Bay District Health Board (2001-2007) and Chairman of the Central Hawke’s Bay Consumers Power Trust (1993-2003).

##

## Attendance

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | ***Membership category*** | **10 Jul 2018** | **14 Aug 2018** | **11 Sep 2018** | **09 Oct 2018** | **13 Nov 2018** | **11 Dec 2018** | **29 Jan 2019** | **12 Feb 2019** | **12 Mar 2019** | **09 Apr 2019** | **14 May 2019** | **11 Jun 2019** | **Total** |
| Ms Raewyn Idoine | L | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | 10/12 |
| Dr Sarah Gunningham | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | 11/12 |
| Dr Devonie Waaka\* | NL | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 12/12 |
| A/Prof Nicola Swain | NL | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | **Y** | 11/12 |
| A/Prof Mira Harrison-Woolrych | NL | **Y** | **Y** | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | A | **Y** | 10/12 |
| Mrs Kate O’Connor (co-opt) | L | **Y** | / | **Y** | **Y** | / | / | / | / | / | **Y** | / | / | 4 |
| Dr Cordelia Thomas (co-opt) | L | / | **Y** | **Y** | / | **Y** | / | / | / | / | / | / | / | 3 |
| Ms Rochelle Style(co-opt) | L | / | / | **Y** | / | / | / | / | / | / | / | / | / | 1 |
| Ms Sandy Gill \*(co-opt)  | L | / | / | / | **Y** | **Y** | **Y** | / | / | **Y** | / | **Y** | **Y** | 6 |
| Professor Jean Hay-Smith | NL | / | / | / | / | A | **Y** | **Y** | A | Y | Y | Y | Y | 6/8 |
| Dr Paul Chin | NL | / | / | / | / | **Y** | **Y** | A | **Y** | **Y** | **Y** | **Y** | **Y** | 7/8 |
| Mrs Helen Walker(co-opted) | L | / | / | / | / | / | / | **Y** | **Y** | / | / | **Y** | / | 3 |
| **Total no. of members present** |  | **6** | **6** | **6** | **7** | **7** | **8** | **7** | **7** | **8** | **8** | **7** | **8** |  |
| **No. of applications considered** |  | **10** | **9** | **7** | **9** | **12** | **12** | **12** | **7** | **11** | **9** | **12** | **10** |  |

## Training and conferences

### Specify the training undergone by new members

None beyond introduction information packets provided by the secretariat.

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

Individual members as part of their association with academia have attended seminars, but no specifics could be gathered for this time period.

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

The reporting period was a highly transitional period for the HDECs and Secretariat (note for example the re-appointment of Dr Sarah Gunningham as a lay member and Chair of Southern). On-going training provided has been provided since the end of the reporting period due to the impending updated NEAC Standards, finalisation of new appointments around this time, and changes to staff and restructuring of the Secretariat. Full training sessions are planned to be rolled out towards the end of 2019/start of 2020.

# Applications reviewed

### Summary of applications received by full EC

|  |  |
| --- | --- |
| No. of applications approved  | 3 |
| No. of applications approved subject to conditions / pending | 35 |
| No. of applications deferred and subsequently approved | 50 |
| No. of applications deferred as at time of report | 4 |
| No. of applications deferred and subsequently declined | 1 |
| 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.) | 22 |
| No. of applications which do not require ethics committee approval (out of HDEC scope of review across all 4 HDECs)\* | 473 |
| No. of studies withdrawn by researcher | 2 |
| No. of studies withdrawn by HDEC | 2 |
| No. of invalid applications  | 21 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC  | 0 |
| **Total number of applications received by full EC** Does not include No. of applications which do not require ethics committee approval\* | **141** |

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

|  |  |
| --- | --- |
| No. of applications approved | 50 |
| No. of applications which do not require ethics committee approval (Invalid) | 7 |
| No. of applications referred for full committee review | N/A |
| No. of deferred applications as of time of report  | 2 |
| No. of applications declined | 5 |
| No. of applications withdrawn by HDEC | 2 |
| **Total number of applications received under expedited / low risk review** | **66** |

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

#

# Complaints and overdue application summary

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

## Complaints received

**Complaint One**

**Type of Complaint:** Committee Member Conduct

**Review Date:** 14 August 2018

**Complaint Received:** 22 August 2018

**Nature of Complaint:**

The CI submitted a formal complaint against the Chair regarding alleged unprofessional and insensitive comments made to the CI during the committee meeting. The CI also found that comments made by other committee members were unhelpful and that they were not given adequate time, only 25 minutes instead of the 30 minutes, to discuss the application as per section 64 of the HDEC SOPs. CI also informed that they had yet to receive their final decision letter.

**Actions Taken:**

* Ethics Manager acknowledged complainant and STH Chair notified
* Ethics Manager commenced investigation interviewing Secretariat staff in attendance on the day
* Group Manager responsible for Ethics formally informed.

**Outcome:**

* Complaint against Chair was substantiated. Chair verbally apologised to CI and to follow up with letter
* Complaint against committee members, not substantiated – no further action
* Secretariat sent a letter of apology regarding the amount of time given to hear the application and the delay in final decision letters.

**Complaint Two**

**Type of Complaint:** Committee Member Conduct/application review process

**Review Date:** 11 December 2018

**Complaint received:** 08 January 2019

**Nature of Complaint:**

CI and research student allege that during their application hearing they received rapid fire of questions without time to answer the Committee’s concerns fully. The CI disagreed with the declined decision and the Committee’s request to justify why he was to include children in the study, the need for an adequate peer review, and feedback regarding the interview questions.

**Action Taken:**

* Ethics Manager acknowledged complainant and STH Chair notified
* Ethics Manager commenced investigation interviewing Secretariat staff in attendance on the day.
* Ethics Manager reviewed committee decision against the SOPs and NEAC Guidelines.

**Outcome:**

* Committee behaviour was substantiated. Chair apologised in writing to the CI.
* Secretariat found that all points made by the committee were valid and within the HDEC SOPs and NEAC Guidelines.

**Complaint Three**

**Type of Complaint:** Administration and Committee Conduct

**Review Date:** 11 December 2018

**Complaint Received:** 8 January 2019

**Nature of Complaint:**

CI sent through complaint to the Director General of Health. CI was the complainant of complaint one. CI had been given time for application hearing by the Secretariat. On the day of the meeting the time in which the CI had been given, needed to be changed due to a Co-Opted Member requiring to leave the meeting early. This was communicated to the CI. There was confusion between the CI and the Secretariat on the final agreed time to attend the meeting. Committee proceeded at the new agreed time with no CI present as per the HDEC SOPs and the study was declined for the second time. During this time the Administrators in the Secretariat had tried to contact the CI with no success. CI and research team arrived at their original meeting time, some members of the Committee had left and the HDEC was no longer meeting quorum. CI felt that the members remaining were hostile.

CI also confirmed that the written apology in relation to complaint one, that was to be written by the STH Chair had not been received.

**Action Taken:**

* Ethics Manager acknowledged complainant and STH Chair notified
* Ethics Manager commenced investigation interviewing Secretariat staff in attendance on the day.
* Discussion of event at Secretariat Team Meeting.
* Group Manager informed

**Outcome:**

* Letter sent from Secretariat apologising for breakdown in communication.
* Secretariat internal processes reviewed and discussed at team meeting – Team phone purchased so Advisor in attendance can contact researchers directly from the meeting with changes in meeting requests instead of going through Administrators in Wellington.
* Group Manager contacted Chair of STH and asked for written apology for behaviour in complaint one. Letter sent.
* Complaint regarding committee behaviour could not be substantiated as the HDEC was not in session. Any views expressed by individuals were not the views of the HDEC as there was no quorum.
* Official Information Act Request on all complaints against the STH Chair and or committee filed by the CI.

**Complaint Four**

**Type of complaint:** Committee Conduct/application review process

**Review Date:**  9 April 2019

**Complaint Received:** 14 June 2019

**Nature of Complaint:**

CI provided reflections regarding committee behaviour and their requests regarding a declined application.

**Action Taken:**

* Ethics Manager acknowledged complainant and STH Chair notified
* Ethics Manager commenced investigation interviewing Secretariat staff in attendance on the day.
* Secretariat reviewed minutes and audio recording of meeting.

**Outcome:**

* Complaint regarding committee conduct not substantiated.
* Second Opinion on the merits of the decision submitted to NTA, but was received as a new application.
* Official Information Act Request for the audio recording of the application requested by CI.
* Further information related to complaints:
* The Minister did not elect to reappoint the Chairperson and one other committee member to the STH HDEC in June 2019.

## 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 29 days for expedited applications. Target timeframe for expedited applications is 15 calendar days. This was due to some restructuring in both the committees and the secretariat during this report period.

Average review time was 30 days for full applications. Target timeframe for full applications is 35 calendar days.

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

| **Reference no.** | **Protocol title** | **Name of principal investigator** | **Date received** | **Date of provisional approval** | **Status at time of report** | **Date of final decision** | **CI’s Organisation** | **Main sponsor type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 18/STH/146 | HCV sero-prevalence NZ | Dr Arlo Upton | 1/08/2018 |  | Decline | 27/08/2018 | Southern Community Laboratories | no sponsor |
| 18/STH/147 | Stomach cancer in Pasifika peoples | Dr Lis Ellison-Loschmann | 3/07/2018 |  | Approve | 29/08/2018 | Massey University | academic institution |
| 18/STH/149 | Subdural spinal collection | Dr William Caughey | 13/07/2018 | 17/08/2018 | Approve | 1/10/2018 |  | no sponsor |
| 18/STH/150 | Clinical predictors of radiotherapy response for rectal cancer | Dr Jesse Fischer | 9/07/2018 | 29/08/2018 | Approve | 1/10/2018 | University of Otago, Christchurch | no sponsor |
| 18/STH/152 | Exercise and mitochondrial-derived peptides | Dr Troy Merry | 25/07/2018 |  | Decline | 13/09/2018 | University of Auckland | academic institution |
| 18/STH/153 | Livewell Programme | Ms Denise Butter | 27/07/2018 |  | Decline | 31/08/2018 | Canopy Cancer Care | other |
| 18/STH/154 | The COMFORT-PSYKI Study | Professor Richard Gearry | 1/08/2018 | 29/08/2018 | Approve | 18/09/2018 | University Of Otago | other government agency |
| 18/STH/155 | Phase I, Double-blind, Randomized, Parallel Group Study to Demonstrate the Equivalent Pharmacokinetic Properties of a Single Intravenous Dose of HD204 and Avastin in Healthy Male Subjects | Doctor Christian Schwabe | 2/08/2018 |  | Approve | 27/08/2018 | ACS | pharmaceutical company |
| 18/STH/156 | Prophylaxis in gout | Professor Lisa Stamp | 2/08/2018 |  | Approve | 27/08/2018 | University of Otago, Christchurch | no sponsor |
| 18/STH/158 | Cerebral Microemboli in Takotsubo Cardiomyopathy | Dr Patricia Ding | 13/08/2018 | 3/09/2018 | Approve | 2/10/2018 | Auckland City Hospital/Auckland District Health Board | no sponsor |
| 18/STH/159 | Holter monitoring in takotsubo syndrome | Dr Paul Bridgman | 27/07/2018 |  | Approve | 3/09/2018 | Canterbury DHB | no sponsor |
| 18/STH/161 | 298 YHC ACE Survey | Dr Ronan Whyte | 2/08/2018 |  | Decline | 27/08/2018 | 298 Youth Health Centre | non-governmental organisation (NGO) |
| 18/STH/162 | RELIEF: RE-LInk Feasibility | Dr Andrew McDaid | 2/08/2018 | 27/08/2018 | Approve | 25/09/2018 | University of Auckland | academic institution |
| 18/STH/163 | RELEVENT Study -Resolution of left ventricular thrombus with different anticoagulation strategies | Professor Ralph Stewart | 2/08/2018 | 27/08/2018 | Approve | 2/10/2018 | Auckland District Health Board | district health board (DHB) |
| 18/STH/164 | RESOLVE | Dr Mark Marshall | 2/08/2018 |  | Approve | 27/08/2018 | Middlemore Hospital | no sponsor |
| 18/STH/165 | Gaps in the provision of radiotherapy for early breast cancer. | Dr Karen Bartholomew | 2/08/2018 |  | Approve | 27/08/2018 | Waitemata DHB | district health board (DHB) |
| 18/STH/167 | BGB-A333 alone and in combination with Tislelizumab Dose Escalation and Dose Expansion Study in Solid Tumors | Dr Peter Fong | 2/08/2018 |  | Approve | 27/08/2018 | Auckland District Health Board | pharmaceutical company |
| 18/STH/170 | Ketamine and Neuromodulation in Anorexia Nervosa | Professor Paul Glue | 30/08/2018 |  | Decline | 28/09/2018 |  | no sponsor |
| 18/STH/171 | The role of intra-operative flow rate during TURP procedure | Dr Christian Robinson | 10/08/2018 | 3/09/2018 | Approve | 31/10/2018 | Southern DHB | no sponsor |
| 18/STH/172 | Wholegrain structure and blood glucose control in T2 | Dr Andrew Reynolds | 20/08/2018 |  | Approve | 3/09/2018 | University of Otago | no sponsor |
| 18/STH/173 | p-PROF STUDY | Dr Simon Richards | 20/08/2018 | 2/10/2018 | Approve | 30/10/2018 | Canterbury District Health Board | no sponsor |
| 18/STH/176 | The SORE Study | Dr Marinus Stowers | 30/08/2018 |  | Decline | 28/09/2018 |  | no sponsor |
| 18/STH/177 | BEDROC Study | Professor Paul Glue | 30/08/2018 | 28/09/2018 | Approve | 20/12/2018 | University of Otago | pharmaceutical company |
| 18/STH/178 | (duplicate) DBT at Korowai Manaaki: A Process Evaluation | Dr Clare-Ann Fortune | 30/08/2018 |  | Decline | 28/09/2018 | Victoria University of Wellington | academic institution, district health board (DHB), other government agency |
| 18/STH/180 | Improving Nutrition in Youth Offenders: Barriers and Solutions | Dr Hermione Roy | 30/08/2018 | 28/09/2018 | Approve | 16/10/2018 |  | no sponsor |
| 18/STH/181 | Co-Designing Health in Cerebral Palsy | Mrs Melinda E Silva | 30/08/2018 | 28/09/2018 | Approve | 2/11/2018 | University of Otago | no sponsor |
| 18/STH/182 | A Prospective, International Hip Dysplasia Registry (IHDR) | Mr Matthew Boyle | 28/08/2018 | 2/10/2018 | Approve | 28/01/2019 | Starship Children's Hospital | no sponsor |
| 18/STH/183 | MyeChild 01 | Dr Siobhan Cross | 30/08/2018 | 28/09/2018 | Approve | 30/10/2018 | Christchurch Hospital | collaborative research |
| 18/STH/184 | Pre-emptive kidney transplantation from deceased donors in New Zealand: does it lead to improved outcomes after transplantation? | Dr Michael Collins | 31/08/2018 |  | Approve | 25/09/2018 | Auckland District Health Board | no sponsor |
| 18/STH/185 | Lichen sclerosus and metabolic syndrome | Dr Harriet Cheng | 3/09/2018 |  | Approve | 2/10/2018 |  | no sponsor |
| 18/STH/186 | Addressing the Issue of High Attenders in General Practice | Dr Nigel Tapper | 6/09/2018 | 25/09/2018 | Approve | 21/12/2018 | Medical Corner Doctors | no sponsor |
| 18/STH/187 | Effects of InfraSlow Neurofeedback on the Autonomic Nervous System (ISANS) | Dr Tyson Perez | 18/09/2018 |  | Approve | 4/10/2018 | University of Otago | no sponsor |
| 18/STH/188 | Gut Microbiome Transfer for the Treatment of Crohn’s Disease | Assoc. Prof. Justin O'Sullivan | 21/09/2018 | 12/10/2018 | Approve | 16/01/2019 | University of Auckland | no sponsor |
| 18/STH/190 | Biomarker guided treatment following a heart attack | Professor Rob Doughty | 27/09/2018 |  | Approve | 19/10/2018 | University of Auckland | no sponsor |
| 18/STH/197 | Outcomes of serial casting for ITW | Dr Nichola Wilson | 27/09/2018 | 18/10/2018 | Approve | 11/12/2018 |  | no sponsor |
| 18/STH/198 | A clinical trial to assess the safety and efficacy of seladelpar in patients with primary biliary cholangitis (PBC) and an inadequate response to or intolerance to ursodeoxycholic acid (UDCA). | Dr Jing Hieng (Jeffrey) Ngu | 27/09/2018 |  | Approve | 18/10/2018 | Canterbury District Health Board | pharmaceutical company |
| 18/STH/199 | Comparison of nicotine blood levels obtained with e-cigarette and traditional cigarette products, in healthy adult smokers. | Dr Chris Wynne | 27/09/2018 |  | Approve | 18/10/2018 | Christchurch Clinical Studies Trust Ltd | other |
| 18/STH/200 | A STUDY OF ATEZOLIZUMAB PLUS BEVACIZUMAB IN PATIENTS WITH SOLID TUMOURS | Professor Edward Gane | 27/09/2018 | 18/10/2018 | Approve | 14/11/2018 | Auckland City Hospital | pharmaceutical company |
| 18/STH/201 | MAGNOLIA Study | Dr Henry Chan | 27/09/2018 | 18/10/2018 | Approve | 9/01/2019 | Waitemata District Health Board | pharmaceutical company |
| 18/STH/202 | Randomised controlled trial of prescription charges | Professor Pauline Norris | 27/09/2018 |  | Decline | 18/10/2018 | University of Otago | academic institution |
| 18/STH/203 | Māori Experiences and Perceptions in Aged Residential Care | Ms Karen Keelan | 27/09/2018 |  | Approve | 18/10/2018 | University of Otago, Christchurch | no sponsor |
| 18/STH/204 | A research project testing the ability of intravenous FDY-5301 compared to placebo to prevent muscle wasting and weakness (sarcopenia) | Dr Nigel Gilchrist | 27/09/2018 |  | Approve | 18/10/2018 | CGM Research Trust | pharmaceutical company |
| 18/STH/207 | Antimicrobial prescribing in New Zealand: comparison between different prescriber groups | Ms Betty Poot | 4/10/2018 | 3/11/2018 | Approve | 29/11/2018 | Victoria University of Wellington | no sponsor |
| 18/STH/208 | BuzzNudge Usability Trial | Dr Nada Signal | 4/10/2018 | 28/11/2018 | Approve | 20/12/2018 | Auckland University of Technology | academic institution |
| 18/STH/209 | Real B | Dr Hannah Giles | 15/10/2018 | 29/11/2018 | Approve | 6/12/2018 | Counties Manukau Health | no sponsor |
| 18/STH/210 | Predicting Outcomes in Patients with C3-Glomerulopathy | Dr Luke Sutherland | 16/10/2018 | 13/12/2018 | Approve | 20/12/2018 |  | no sponsor |
| 18/STH/212 | ROCKet – Reduction Of Chronic Post-surgical Pain with Ketamine | Dr Andrew Pitcher | 1/11/2018 | 22/11/2018 | Approve | 16/01/2019 | Auckland District Health Board | collaborative research |
| 18/STH/213 | Feasibility of measuring PCT using existing blood samples | Dr Jacqueline Hannam | 1/11/2018 | 22/11/2018 | Approve | 11/12/2018 | The University of Auckland | academic institution |
| 18/STH/214 | QRK309: QPI-1002 Phase 3 for Prevention of MAKE in Subjects at High Risk for AKI Following Cardiac Surgery | Dr Shay McGuinness | 1/11/2018 | 22/11/2018 | Approve | 29/01/2019 | Auckland District Health Board | pharmaceutical company |
| 18/STH/215 | A first in human study of DCR-HBVS in Healthy Volunteers and Patients with Chronic Hepatitis B | Professor Edward Gane | 1/11/2018 | 22/11/2018 | Approve | 17/12/2018 | Auckland District Health Board | pharmaceutical company |
| 18/STH/217 | A study of the safety and efficacy of intravenous CR845 in hemodialysis patients with moderate to severe itching | DR Kannaiyan Rabindranath | 1/11/2018 |  | Approve | 22/11/2018 | Waikato Ditrict Health Board | pharmaceutical company |
| 18/STH/218 | Study of VTS-270 (2-hydroxypropyl-β-cyclodextrin) to Treat Niemann-Pick Type C1 (NPC1) Disease | Dr Kelly Byrne | 1/11/2018 |  | Decline | 22/11/2018 | Waikato District Health Board | pharmaceutical company |
| 18/STH/219 | A study of Zanubrutinib Compared with Ibrutinib in patients with Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma | Dr Robert Weinkove | 1/11/2018 |  | Approve | 22/11/2018 | Capital & Coast District Health Board | pharmaceutical company |
| 18/STH/220 | A study of the influenza drug Boloxavir Maroboxil in combination with standard care in hospitalised patients with severe influenza | Dr DIANE HANFELT-­GOADE | 1/11/2018 | 4/02/2019 | Approve | 4/02/2019 | TAURANGA HOSPITAL | pharmaceutical company |
| 18/STH/221 | Taking MARS Spectral CT to Human Imaging | Prof Anthony Butler | 1/11/2018 | 22/11/2018 | Approve | 10/04/2019 | University of Canterbury | collaborative research |
| 18/STH/222 | The effects of oral health and family function on quality of life in young children. | Dr Arun Natarajan | 29/11/2018 |  | Decline | 21/12/2018 | Canterbury DHB | no sponsor |
| 18/STH/223 | Vitamin C status of patients with cancer | Assoc Prof Gabi Dachs | 22/10/2018 |  | Approve | 7/11/2018 | University of Otago, Christchurch | no sponsor |
| 18/STH/224 | Injuries in women's rugby union | Dr Doug King | 22/10/2018 | 15/01/2019 | Approve | 25/02/2019 | Massey University | no sponsor |
| 18/STH/225 | A Phase 1/2 Study of Durvalumab and Monalizumab in Adult Subjects with Select Advanced Solid Tumors | Dr Sanjeev Deva | 1/11/2018 |  | Approve | 22/11/2018 | Auckland City Hospital | pharmaceutical company |
| 18/STH/226 | Assessment of the trial drug AG-B1512 in adults with growth hormone deficiency. | Dr Chris Wynne | 1/11/2018 | 22/11/2018 | Approve | 20/12/2018 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 18/STH/227 | The C\*STEROID Feasibility Study: Corticosteroids before planned caesarean section from 35+0 to 39+6 weeks | Associate Professor Katie Groom | 1/11/2018 | 22/11/2018 | Approve | 31/01/2019 | The University of Auckland | academic institution |
| 18/STH/231 | STOP-MSU | Dr Teddy WU | 29/11/2018 | 21/12/2018 | Approve | 28/03/2019 | Canterbury District Health Board | collaborative research |
| 18/STH/232 | Understanding Skin Conditions and Developing New Treatments | Dr Hilary Sheppard | 13/11/2018 |  | Decline | 21/12/2018 | Universtiy of Auckland | academic institution |
| 18/STH/233 | Comparison of two brincidofovir formulations, in healthy adults. | Dr Chris Wynne | 29/11/2018 |  | Approve | 21/12/2018 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 18/STH/234 | Choosing medications wisely for older people | Dr Aileen Collier | 12/11/2018 |  | Approve | 4/12/2018 | University of Auckland Private | academic institution |
| 18/STH/235 | IDI Health Research Study | Dr Hiran Thabrew | 29/11/2018 |  | Decline | 18/12/2018 | University of Auckland | no sponsor |
| 18/STH/236 | Point of care device for skin cancer diagnosis | Prof M. Cather Simpson | 14/11/2018 | 13/02/2019 | Approve |  | The University of Auckland | other government agency |
| 18/STH/238 | Epidermolysis Bullosa in New Zealand | Doctor Russell Gear | 19/11/2018 | 21/12/2018 | Approve | 18/04/2019 | Capital and Coast District Health Board | non-governmental organisation (NGO) |
| 18/STH/239 | Toward understanding how contraction stimulates glucose uptake in skeletal muscle | Dr Jessica Dent | 29/11/2018 |  | Approve | 21/12/2018 | University of Auckland | academic institution |
| 18/STH/240 | TARGET Protein Feasibility Study | Dr Paul Young | 22/11/2018 |  | Approve | 21/12/2018 | Capital Coast District Health Board | collaborative research |
| 18/STH/241 | IM011047: A Study to Measure How Safe and Effective BMS-986165 is for the Treatment of Moderate-to-Severe Plaque Psoriasis. | Assoc. Prof Marius Rademaker | 29/11/2018 |  | Approve | 21/12/2018 | Clinical Trials New Zealand Ltd | pharmaceutical company |
| 18/STH/242 | WORTH study | Assoc Prof Rinki Murphy | 29/11/2018 | 21/12/2018 | Approve | 12/02/2019 | University of Auckland | academic institution |
| 18/STH/243 | 298 Youth Health Centre ACE Survey | Dr Ronan Whyte | 29/11/2018 |  | Decline | 22/12/2018 | 298 Youth Health Centre | no sponsor |
| 18/STH/245 | MK3475 799 | Dr Gareth Rivalland | 29/11/2018 |  | Approve | 21/12/2018 | Auckland City Hospital | pharmaceutical company |
| 18/STH/248 | Using IOS, MBNW and FENO in asthma to determine the site and degree of airways inflammation | Dr Jack Dummer | 23/11/2018 |  | Approve | 20/12/2018 | University of Otago | no sponsor |
| 18/STH/249 | Evaluation of the STATUS trial | Dr Karen Bissell | 23/11/2018 |  | Approve | 7/12/2018 | University of Auckland | no sponsor |
| 18/STH/265 | Developing a National Clinical Guidelines Dissemination and Implementation Model for New Zealand's Maternity System | Ms Tarra Kathleen McNally | 21/12/2018 |  | Approve | 10/01/2019 | Victoria University of Wellington | academic institution |
| 18/STH/267 | Effect of an appetite suppressant on hunger during intermittent fasting | Dr Edward Walker | 30/11/2018 |  | Approve | 20/12/2018 | The New Zealand Institute of Plant and Food Research | other |
| 19/STH/1 | Assessment of two insulin pump insulin delivery systems in type 1 diabetes. | Dr Martin de Bock | 17/01/2019 |  | Approve | 8/02/2019 | University of Otago | no sponsor |
| 19/STH/10 | Closed vs open abdomen in severe secondary peritonitis | Dr Li Hsee | 17/01/2019 |  | Decline | 8/02/2019 | Auckland City Hospital | no sponsor |
| 19/STH/100 | Manaakai | Ms Gayl Humphrey | 30/05/2019 | 20/06/2019 | Approve | 19/07/2019 | University of Auckland | other |
| 19/STH/101 | ZiPP-LTE | Dr Anne Horne | 30/05/2019 | 20/06/2019 | Approve | 23/07/2019 |  | academic institution |
| 19/STH/102 | The PRESERVE Aotearoa pilot study (Prevent delirium through Eating and drinking, Sleep, Exercise, Reorientation, Vision and hearing, and Enabling family) | Dr Aileen Collier | 30/05/2019 | 20/06/2019 | Approve | 31/07/2019 | University of Auckland Private | academic institution |
| 19/STH/103 | Utility of an intra-vaginal device (FemFit®) to resolve incontinence. | Dr Jennifer Kruger | 5/06/2019 | 18/06/2019 | Decline | 3/09/2019 | University of Auckland | academic institution |
| 19/STH/104 | HRcSCC | Mr Richard C W Martin | 30/05/2019 |  | Decline | 20/06/2019 | Waitemata District Health Board | no sponsor |
| 19/STH/107 | Olfactory mucosa in Parkinson's disease | Dr Tary Yin | 30/05/2019 | 20/06/2019 | Provisionally approve |  | The University of Auckland | no sponsor |
| 19/STH/108 | PETAL Study: Preventing recurrent acute lower respiratory infections study | Assoc Prof Catherine Byrnes | 30/05/2019 | 20/06/2019 | Approve | 18/07/2019 | University of Auckland | other |
| 19/STH/11 | Asahi Outrider Study | Dr Scott Harding | 17/01/2019 | 8/02/2019 | Approve | 11/03/2019 | Capital and Coast District Health Board | medical device company |
| 19/STH/110 | Q122-2001: A study assessing the safety and effectiveness of Q-122 for treating hot flushes, in women who have, or have had, breast cancer. | Dr Chris Wynne | 30/05/2019 | 20/06/2019 | Approve | 22/07/2019 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 19/STH/111 | REOPEN 2 STUDY. A study of intranasal OPN-375 in participants with chronic sinusitis without nasal polyps | Dr Dean Quinn | 30/05/2019 | 20/06/2019 | Decline | 21/08/2019 | P3 Research | pharmaceutical company |
| 19/STH/113 | MRI identification of bio-markers of ocular aging | Professor Paul J Donaldson | 30/05/2019 | 20/06/2019 | Provisionally approve |  | University of Auckland | academic institution |
| 19/STH/114 | Microdrop Administration of Phenylephrine and Cyclopentolate Eye Drops in Neonates | Miss Lisa Kremer | 31/05/2019 |  | Approve | 20/06/2019 | University of Otago | no sponsor |
| 19/STH/115 | Long term effects of heavy cannabis use | A/Prof Joseph M. Boden | 27/06/2019 | 26/07/2019 | Provisionally approve |  | University of Otago, Christchurch | no sponsor |
| 19/STH/116 | Chewing duration and glycaemic response | Dr Esther Kim | 10/06/2019 | 26/06/2019 | Provisionally approve |  |  | other government agency |
| 19/STH/117 | (duplicate) ICON Trial | Dr. Tzu Yu Chen | 18/06/2019 | 4/07/2019 | Approve | 3/09/2019 |  | other |
| 19/STH/119 | A Comparative Clinical Evaluation of a New TECNIS Presbyopia-Correcting Intraocular Lens Against A Trifocal Intraocular Lens | Dr Dean Corbett | 27/06/2019 | 26/07/2019 | Approve | 27/08/2019 | Auckland Eye | medical device company |
| 19/STH/12 | AROAPOC31001: Study of ARO-APOC3 in Adult Healthy Volunteers as well as in Severely Hypertriglyceridemic Patients and Patients with Familial Chylomicronemia Syndrome | Doctor Christian Schwabe | 17/01/2019 |  | Approve | 8/02/2019 | ACS | pharmaceutical company |
| 19/STH/120 | BD EEG | Mr Matthew Hall | 25/06/2019 | 10/07/2019 | Approve | 25/07/2019 |  | no sponsor |
| 19/STH/121 | Midodrine as an Adjunctive VasoprEssor for Refractory Hypotension in Intensive Care (MAVERIC) Study | Dr Paul Young | 27/06/2019 |  | Approve | 26/07/2019 | Capoital Coast District Health Board | no sponsor |
| 19/STH/122 | Perceptions of psychedelic-assisted psychological intervention | Dr Lisa Reynolds | 25/06/2019 | 10/07/2019 | Approve | 2/08/2019 | The University of Auckland | academic institution |
| 19/STH/123 | ACTICCA-1 | Dr Amanda Ashley | 27/06/2019 |  | Approve | 26/07/2019 | Cancer & Blood Service | academic institution, collaborative research |
| 19/STH/124 | Comparison of the blood levels of two forms of oxycodone/naloxone tablets under fasting conditions. | Dr Noelyn Hung | 27/06/2019 | 26/07/2019 | Approve | 8/08/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/STH/125 | Comparison of the blood levels of two forms of oxycodone/naloxone tablets under fed conditions. | Dr Noelyn Hung | 27/06/2019 | 26/07/2019 | Approve | 8/08/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/STH/126 | Comparison of the blood levels of two forms of oxycodone/naloxone tablets under steady state conditions. | Dr Noelyn Hung | 27/06/2019 | 26/07/2019 | Approve | 8/08/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/STH/127 | BRII-179-001: Safety and activity of BRII-179 in CHB | Dr Tien-Huey Lim | 27/06/2019 | 26/07/2019 | Approve | 26/08/2019 | Middlemore Hospital and Middlemore Clinical Trials | pharmaceutical company |
| 19/STH/128 | Long-term safety and efficacy of Bimatoprost SR | Professor Anthony Wells | 27/06/2019 |  | Decline | 26/07/2019 | Capital Eye Specialists | pharmaceutical company |
| 19/STH/129 | Effect of wholegrain structure on metabolism and breath volatile organic compounds | Mr Caleb Robinson | 26/06/2019 | 18/07/2019 | Approve | 25/07/2019 | University of Otago | no sponsor |
| 19/STH/18 | A study comparing the trial drug AVT02 and Humira®, in healthy adults. | Dr Chris Wynne | 17/01/2019 |  | Approve | 8/02/2019 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 19/STH/21 | Validating a novel MRI method to measure blood-brain barrier function | Dr Catherine Morgan | 17/01/2019 |  | Approve | 18/02/2019 | University of Auckland | academic institution |
| 19/STH/22 | Mobility skills programme for children with cerebral palsy | Mrs Gaela Kilgour | 17/01/2019 |  | Approve | 8/02/2019 | Australian Catholic University | academic institution |
| 19/STH/23 | Emerging Sources and Pathways for Leptospirosis - a paradigm shift | Dr Shahista Nisa | 17/01/2019 |  | Decline | 8/02/2019 | Massey University | academic institution, other |
| 19/STH/26 | Low Intensity CBT with Māori | Dr Paul Merrick | 23/01/2019 | 21/02/2019 | Approve | 20/03/2019 | Massey University | academic institution |
| 19/STH/27 | New Zealand resident Tongan health and illness beliefs about cough and access to healthcare | Dr Sarah Mooney | 24/01/2019 |  | Approve | 15/02/2019 | Counties Manukau Health | other |
| 19/STH/3 | BEDROC-1 Study | Professor Paul Glue | 17/01/2019 | 8/02/2019 | Approve | 16/04/2019 | University of Otago | pharmaceutical company |
| 19/STH/30 | The influence of gender and the oral contraceptive pill on acute protein induced thermogenesis. | Miss Julia Cree | 25/01/2019 | 19/02/2019 | Approve | 19/03/2019 | University of Auckland | academic institution |
| 19/STH/31 | ABI-H0731-211: A Long-term Extension Study of ABI-H0731 + Nucleos(t)ide as Finite Treatment for Chronic Hepatitis B Patients | Professor Edward Gane | 31/01/2019 |  | Approve | 19/02/2019 | Auckland City Hospital | pharmaceutical company |
| 19/STH/32 | KEYNOTE-913 | Dr Ben Lawrence | 31/01/2019 |  | Approve | 19/02/2019 | Auckland City Hospital | pharmaceutical company |
| 19/STH/34 | The impact of Plusoptix type autorefraction screening on amblyopia | Mrs Sandi French | 31/01/2019 |  | Decline | 21/03/2019 | Hauora Tairawhiti | no sponsor |
| 19/STH/35 | Histological subtype of renal cell carcinoma by ethnicity in New Zealand | Dr Katherine Hulme | 26/01/2019 | 6/03/2019 | Approve | 20/03/2019 | Canterbury Health Laboratories | no sponsor |
| 19/STH/36 | Evaluating the IR experiences of young people in hospital | Dr Hiran Thabrew | 31/01/2019 |  | Decline | 19/02/2019 | ADHB | no sponsor |
| 19/STH/37 | Prognostic significance of Computed Tomography (CT) defined sarcopenia in patients presenting with acute rib fractures. | Dr Tsan Yue Siu | 1/02/2019 | 8/03/2019 | Approve | 2/04/2019 | Counties Manukau District Health Board | no sponsor |
| 19/STH/38 | Vitamin C for skin health | Professor Margreet Vissers | 31/01/2019 | 21/02/2019 | Approve | 6/03/2019 | UNIVERSITY OF OTAGO, CHRISTCHURCH | no sponsor |
| 19/STH/39 | Vitamin C for endometrial cancer | Associate Professor Peter Sykes | 31/01/2019 |  | Approve | 19/02/2019 | University of Otago, Christchurch | no sponsor |
| 19/STH/4 | KCAD Psych Study | Dr Chanel Prestidge | 17/01/2019 |  | Decline | 8/02/2019 |  | academic institution, collaborative research |
| 19/STH/41 | Phase 1b study to determine the safety, tolerability and pharmacokinetics of RTB101 and sirolimus alone or in combination in patients with Parkinson's Disease. | Prof Tim Anderson | 31/01/2019 | 19/02/2019 | Approve | 18/03/2019 | New Zealand Brain Research Institute | pharmaceutical company |
| 19/STH/42 | A Phase 3 Study of Pemetrexed + Platinum Chemotherapy + Pembrolizumab with or without Lenvatinib in Participants with NSCLC | Dr Richard North | 31/01/2019 |  | Approve | 19/02/2019 | Bay of Plenty District Health Board | pharmaceutical company |
| 19/STH/43 | Routine defunctioning in Low Anterior Resections | Mr Jasen Ly | 1/02/2019 |  | Approve | 21/02/2019 | Waikato District Health Board | no sponsor |
| 19/STH/44 | The COAST pilot initiative | Dr Amanda Sommerfeldt | 28/02/2019 | 21/03/2019 | Approve | 11/04/2019 | Hospice Southland | district health board (DHB), non-governmental organisation (NGO) |
| 19/STH/45 | Deep learning to determine outcome following stroke clot retrieval | Professor P. Alan Barber | 25/02/2019 |  | Approve | 8/03/2019 | University of Auckland and Auckland City Hospital | no sponsor |
| 19/STH/46 | CBP-201AU002: Study of the Safety and Effect of CBP-201 in Adults with Atopic Dermatitis | Assoc. Prof Marius Rademaker | 28/02/2019 |  | Decline | 21/03/2019 | Clinical Trials New Zealand Ltd | pharmaceutical company |
| 19/STH/47 | Developing Potential New Treatments for Epidermolysis Bullosa | Dr Hilary Sheppard | 28/02/2019 | 9/04/2019 | Approve | 21/03/2019 | Universtiy of Auckland | academic institution, non-governmental organisation (NGO) |
| 19/STH/5 | Comparison study of methylprednisolone aceponate fatty ointment applied to the skin in healthy male and female volunteers. | Dr Noelyn Hung | 17/01/2019 | 8/02/2019 | Approve | 10/04/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/STH/52 | M16-011 | Dr Marina Sew-Hoy | 28/02/2019 | 21/03/2019 | Approve | 20/05/2019 | CGM Research Trust | pharmaceutical company |
| 19/STH/53 | M15-998 | Dr Marina Sew Hoy | 28/02/2019 | 21/03/2019 | Approve | 20/05/2019 | CGM Research Trust | pharmaceutical company |
| 19/STH/54 | SAGE-ANZ | A/Prof Rachael Parke | 28/02/2019 | 28/02/2019 | Approve |  | Auckland District Health Board | no sponsor |
| 19/STH/55 | The New Zealand National Stroke Registry | A/Prof Annemarei Ranta | 28/02/2019 |  | Approve | 21/03/2019 |  | no sponsor |
| 19/STH/57 | Financial Evaluation of EDDI (Early Detection Decision Information) | Dr David Cumin | 28/02/2019 | 24/04/2019 | Approve | 16/05/2019 |  | medical device company |
| 19/STH/58 | Study Evaluating AZR-MD-001 in Patients with Meibomian Gland Dysfunction (MGD) and Evaporative Dry Eye Disease (DED) | Dr Dean Corbett | 28/02/2019 | 21/03/2019 | Approve | 21/05/2019 | Auckland Eye | pharmaceutical company |
| 19/STH/59 | Delta | Dr Dean Corbett | 28/02/2019 | 21/03/2019 | Approve | 13/05/2019 | Auckland Eye | pharmaceutical company, medical device company |
| 19/STH/6 | NHFO2: Algorithm 2 | Dr James Harper | 17/01/2019 |  | Approve | 8/02/2019 | Medical Research Institute New Zealand | medical device company |
| 19/STH/60 | GA41024. A study of the trial asthma drug GDC-4379 in healthy participants and in adults with mild asthma. | Dr Chris Wynne | 28/02/2019 |  | Approve | 21/03/2019 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 19/STH/64 | Vibration exercise in peripheral artery disease | Dr Darryl Cochrane | 13/03/2019 |  | Decline | 3/04/2019 | Massey University | no sponsor |
| 19/STH/65 | Alcohol screening for older adults in primary care | Dr David Newcombe | 12/03/2019 | 10/04/2019 | Approve | 28/06/2019 |  | academic institution |
| 19/STH/66 | Perioperative oxygen therapy - A prospective audit of practice | Dr Daniel Frei | 14/03/2019 |  | Approve | 16/04/2019 | Capital and Coast District Health Board | no sponsor |
| 19/STH/67 | Trial of Exenatide in Acute Ischaemic Stroke (TEXAIS) | Dr Teddy WU | 28/03/2019 |  | Approve | 29/04/2019 | Canterbury District Health Board | collaborative research |
| 19/STH/68 | Micronutrients and traumatic brain injury: case studies | Prof Julia Rucklidge | 28/03/2019 | 29/04/2019 | Decline | 20/06/2019 | University of Canterbury | no sponsor |
| 19/STH/69 | ENABLE (Engaging Toll-like Receptor Signalling for B-cell Lymphoma Chimeric Antigen Receptor T-cell Therapy) | Dr Robert Weinkove | 28/03/2019 | 29/04/2019 | Approve | 21/06/2019 | Malaghan Institute of Medical Research | academic institution |
| 19/STH/7 | Centre for Brain Research Neurogenetic Research Clinic (CBR - NRC) | A/Prof Richard Roxburgh | 25/01/2019 | 21/02/2019 | Approve | 6/03/2019 | Auckland District Health Board | no sponsor |
| 19/STH/72 | MK-7339-010: Phase 3 Study of Pembrolizumab Plus Olaparib Versus Abiraterone Acetate or Enzalutamide in mCRPC | Dr Peter Fong | 28/03/2019 |  | Approve | 29/04/2019 | Auckland District Health Board | pharmaceutical company |
| 19/STH/73 | CA209-8FC: A Study to Compare Nivolumab Drug Product Process D to Nivolumab Drug Product Process C in Participants with Stage IIIa/b/c/d or Stage IV Melanoma after Complete Resection | Dr Gareth Rivalland | 28/03/2019 | 29/04/2019 | Approve | 20/05/2019 | Auckland City Hospital | pharmaceutical company |
| 19/STH/74 | Survivors of medically serious suicide attempts | Dr Sarah Fortune | 28/03/2019 | 29/04/2019 | Approve | 1/07/2019 | University of Otago | no sponsor |
| 19/STH/75 | The integrated intervention of Whakatupu Ora | Dr. D. Bianca Sava | 29/03/2019 | 16/04/2019 | Provisionally approve |  |  | no sponsor |
| 19/STH/78 | CBP-201AU002: Study of the Safety and Effect of CBP-201 in Adults with Atopic Dermatitis | Assoc. Prof Marius Rademaker | 28/03/2019 |  | Approve | 29/04/2019 | Clinical Trials New Zealand Ltd | pharmaceutical company |
| 19/STH/8 | Synbiotics and liver transplantation | Associate Professor Lindsay Plank | 17/01/2019 |  | Decline | 8/02/2019 | University of Auckland | no sponsor |
| 19/STH/80 | Emerging Sources and Pathways for Leptospirosis - a paradigm shift | Dr Shahista Nisa | 29/03/2019 |  | Approve | 16/04/2019 | Massey University | academic institution, other |
| 19/STH/81 | Assessing changes to children's lives after fixing their teeth under general anaesthesia. | Dr Arun Natarajan | 2/05/2019 | 30/05/2019 | Approve | 20/08/2019 | Canterbury DHB | no sponsor |
| 19/STH/82 | M15-570: An Extension Study of ABBV-8E12 in Early Alzheimer's Disease | Dr Nigel Gilchrist | 2/05/2019 | 30/05/2019 | Approve | 13/06/2019 | CGM Research Trust | pharmaceutical company |
| 19/STH/83 | Phase 3 Ūloa Project | Dr Sione Vaka | 11/04/2019 | 6/05/2019 | Approve | 25/06/2019 | Massey University | non-governmental organisation (NGO) |
| 19/STH/85 | Cellular composition and healing capacity of adipose tissue in Caesarean section wounds. | Associate Professor Michael Stitely | 30/04/2019 |  | Approve | 7/05/2019 | University of Otago | no sponsor |
| 19/STH/86 | Scrotal and Core Temperature | Dr Marilyn Wong | 2/05/2019 |  | Decline | 30/05/2019 | Waikato Hospital | no sponsor |
| 19/STH/87 | Tenecteplase in wake-up Ischaemic Stroke Trial (TWIST) | Dr Teddy WU | 2/05/2019 |  | Approve | 30/05/2019 | Canterbury District Health Board | collaborative research |
| 19/STH/88 | An investigation into the clinical significance of Arcobacter species in New Zealand. | Miss Casey O'Byrne | 2/05/2019 |  | Approve | 30/05/2019 | Massey University and Wellington SCL Masterton | academic institution, other |
| 19/STH/89 | GS-US-402-4374: A study comparing how fast the trial drugs GS-9674 and GS-0976 are cleared from the body, in healthy adults and in adults with severely reduced kidney function. | Dr Richard Robson | 2/05/2019 | 30/05/2019 | Approve | 18/06/2019 | Christchurch Clinical Studies Trust Ltd | pharmaceutical company |
| 19/STH/90 | CA017-078 | Dr Peter Fong | 2/05/2019 | 30/05/2019 | Approve | 24/06/2019 | Auckland District Health Board | pharmaceutical company |
| 19/STH/91 | Microdosing LSD | Ass Prof Suresh Muthukumaraswamy | 2/05/2019 | 30/05/2019 | Provisionally approve |  |  | academic institution |
| 19/STH/92 | Food-Effect Study of 12 mg Tretinoin capsules in Healthy Male Subjects. | Dr Noelyn Hung | 2/05/2019 |  | Approve | 30/05/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/STH/93 | Comparison of Tretinoin capsules in Healthy Male Subjects. | Dr Noelyn Hung | 2/05/2019 |  | Approve | 30/05/2019 | Zenith Technology Corporation Limited | pharmaceutical company |
| 19/STH/94 | External Stimulators To Augment Rehabilitation Therapy (ESTART trial) | Associate Professor John Reynolds | 2/05/2019 | 30/05/2019 | Approve | 19/07/2019 | University of Otago | no sponsor |
| 19/STH/95 | Maxigesic IV Exposure Study | Dr. Simon Carson | 2/05/2019 |  | Decline | 30/05/2019 | Southern Clinical Trials | pharmaceutical company |
| 19/STH/97 | The Aotearoa New Zealand Genomic Variome Project | Professor Stephen Robertson | 2/05/2019 | 16/05/2019 | Approve | 27/05/2019 | University of Otago | academic institution |
| 19/STH/98 | Glycaemic index of kiwifruit | Dr John Monro | 7/05/2019 |  | Approve | 17/05/2019 | Plant and Food Research | other |
| 19/STH/99 | Te Uemairangi | Dr Cameron Lacey | 24/05/2019 | 6/06/2019 | Approve | 18/06/2019 | University of Otago | 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:** Dr Sarah Gunningham\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature: Date: 30** September 2019

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

**Name of EC: Central Health and Disability Ethics Committee**

**Name of organisation:** Ministry of Health

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

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

**Name:** Mr Rob McHawk

 Title First Name Last Name

**Position :** Manager – Ethics

**E-mail :** Rob.McHawk@health.govt.nz



**Signature: Date:** 30 September 2019

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)