



**Health and
Disability Ethics
Committees**

**Southern Health and Disability
Ethics Committee**

**Annual Report
2022**

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About this report

This report is a summary of the activities of the Southern Health and Disability Ethics Committees (HDEC) for the period of 01 July 2021 – 30 June 2022. It includes a summary of the applications reviewed during the year, details of any complaints received (and how they were resolved), and a list of new applications submitted.

About the committee

The Southern Health and Disability Ethics Committees (HDEC) is a Ministerial committee established under section 87 of the [Pae Ora \(Healthy Futures\) Act 2022](#). 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 by checking that it meets or exceeds established [ethical standards](#).

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](#).

The Southern HDEC is registered (number IRB00008713) with the United States' [Office for Human Research Protections](#). This registration enables the committee to review research conducted or supported by the US Department of Health and Human Services.

Chairperson's report

It is with much pleasure I present the annual report of the Southern HDEC for the year ending 30 June 2022 and my first such report as Chair. It has been a busy year for our committee having reviewed a total of 156 new applications. 97 were reviewed at full committee meetings, while 59 new applications were reviewed through the expedited (low risk) pathway. The committee has been fortunate to have the support of the other HDECs and we are particularly indebted to Helen Walker QSM for her support prior to my appointment as Acting Chair.

Our committee has a depth of experience, and we have appreciated the willingness of the researchers to engage in discussion on their applications and to accept advice and direction on how to improve future applications. The NEAC standards are a minimum standard for ethical research, and we applaud the research teams that go over this threshold in their design. While workloads have been consistently high for the most part, the committee has managed to respond in a prompt fashion to all queries and within timeframes.

I would like to extend thanks to the Secretariat staff also who have done an exceptional job in responding to all the researchers, juggling committee queries and researching advice during meetings online, you have made the SHDEC able to respond as it has.

Nga mihi nui,

Anthony Fallon

Chair – Southern HDEC

Applications reviewed

Summary of applications received by full EC

The Secretariat notes that HDEC cannot defer, however they can provisionally approve. We have answered as if defer is a provisional approval.

No. of applications approved	0
No. of applications approved subject to conditions (minor, non-standard conditions)	27
No. of applications deferred and subsequently approved (provisionally approved before approval)	56
No. of applications deferred as at time of report (provisionally approved)	1
No. of applications that were declined in part because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu	0
No. of applications that were declined in part because of no/insufficient consultation with appropriate cultural group	0
No. of applications declined (this <u>excludes</u> those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group)	11
No. of applications which were invalidated for incompleteness	0
<i>No. of applications which do not require ethics committee approval (applications submitted to all Committees that were out of scope (total across Committees))</i> <i>Note: this number is greatly increased from prior reports due to the new Ethics Review Manager automatic scope check process</i>	382
No. of studies withdrawn by researcher (none made to meetings or reviewed)	2
No. of studies terminated by sponsor	0
No. of studies transferred to another EC	0
Total number of applications received by full EC	97

Summary of applications received under expedited / low risk review

No. of applications approved	3
No. of applications approved subject to conditions	11
No. of applications deferred and subsequently approved	30
No. of applications deferred as at time of report	4
No. of applications which do not require ethics committee approval (applications submitted to Committee that were incomplete or out of scope)	0
<i>No. of applications referred for full committee review</i>	4
No. of applications declined	11
No. of studies withdrawn by researcher	0
Total number of applications received under expedited / low risk review	59

Total number of applications received:

156

Complaints and overdue application summary

This section outlines complaints about decisions made by the Committee during 2022.

Complaints received

No complaints were received during the reporting period regarding any Southern HDEC matters.

Overdue review

Average review times consider 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. ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 9-102).

Average review time was 44 days for full applications. Target timeframe for full applications is 35 days. ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 54-59).

In both review pathways, the clock days went over. This appears to be primarily due to the changeover of review system the HDECs were using partway through the reporting period, causing delays as a result of committee members, secretariat and researchers becoming more familiar with the system and able to respond in a timely manner.

Appendix 1: Details of applications reviewed¹

Applications reviewed by full committee

Review reference	Project title	Coordinating investigator	Review date received	Date of first review	Outcome of first review	Review status	Date of final outcome	Coordinating investigator organisation	Sponsor organisation
21/STH/212	(duplicate) Pharmacokinetics of Dexmedetomidine administered by Jet Injection- The DexJet Trial	Dr Nicola Whittle	30/07/2021	7/10/2021	Approved	Approved	7/10/2021	University of Auckland	University of Auckland
21/STH/166	208833 (STAPH AUREUS BIOCONJ-001 STG)	Dr Renate Koops	30/06/2021	21/07/2021	Approved	Approved	21/07/2021	Middlemore Clinical Trials	GlaxoSmithKline
21/STH/187	73763989PAHPB1006(Osprey) Combination of siRNA, DNA vaccine and Nucleoside Analogue for Chronic Hepatitis B	Professor Edward Gane	21/07/2021	2/11/2021	Approved	Approved	2/11/2021	Auckland Clinical Studies	Janssen-Cilag Pty Ltd
2022 FULL 11650	A clinical trial in Familial Chylomicronemia Syndrome (FCS)	Dr John Baker	10/02/2022	22/12/2021	Provisionally Approve	Approved	30/03/2022	Middlemore Clinical Trials	Arrowhead Pharmaceuticals, Inc, CARSL Consulting
2022 FULL 12988	A comparison of the safety and efficacy of bimagrumab with semaglutide in adults who are overweight or obese	Dr Penny Montgomery	23/06/2022	14/07/2022	Approved	Approved	14/07/2022	Optimal Clinical Trials.	Versanis Bio, Inc., Pharmaceutical Solutions Ltd.
2022 FULL 13074	A feasibility study of Psychedelic Microdosing-Assisted Meaning Centred Psychotherapy in advanced stage cancer patients (PAM Trial)	Dr Lisa Reynolds	28/06/2022	14/07/2022	Approved	Approved	14/07/2022	University of Auckland	University of Auckland
2022 EXP 12941	A pathway to care for NZ veterans revision 1	Associate Professor David McBride	1/06/2022	28/06/2022	Decline	Declined	28/06/2022	Otago University	Otago University
2022 FULL 12158	A Phase 1 study to evaluate the effect of renal impairment on the pharmacokinetics of ONC201	Principal Investigator Dr Nicholas Cross	22/02/2022	29/03/2022	Approved	Approved	29/03/2022	New Zealand Clinical	Chimerix, Inc., Infinity Consulting Ltd
2022 FULL 12482	A PHASE 1/2A STUDY EVALUATING THE EFFECTS OF ARO-MUC5AC INHALATION SOLUTION IN HEALTHY PARTICIPANTS AND PATIENTS WITH ASTHMA	Dr Mark O'Carroll	2/05/2022	28/04/2022	Provisionally Approve	Approved	12/05/2022	New Zealand Clinical Research Ltd Inc	Arrowhead Pharmaceuticals Inc, Novotech (New Zealand) Limited

¹ Data is directly reported from the online system. Any errors in spelling is reflected due to errors made by the applicant.

2022 FULL 11901	A Phase 3 study evaluating the safety and efficacy of VX-121 triple combination therapy in Cystic Fibrosis (VX20-121-102)	Dr Mark O'Carroll	23/03/2022	28/04/2022	Approved	Approved	28/04/2022	Auckland City Hospital and Green Lane Clinical Centre	Vertex Pharmaceuticals Australia Pty Ltd, Adjutor Healthcare (NZ) Limited
2022 FULL 12083	A phase 3 study evaluating the safety and efficacy of VX121 triple combination therapy in Cystic Fibrosis (VX20-121-103)	Dr Mark O'Carroll	23/03/2022	28/04/2022	Approved	Approved	28/04/2022	Auckland City Hospital and Green Lane Clinical Centre	Vertex Pharmaceuticals Australia Pty Ltd, Adjutor Healthcare (NZ) Limited
21/STH/228	A pilot study of contralesional motor cortex facilitation in chronic stroke	Professor Cathy Stinear	20/08/2021	7/10/2021	Provisionally Approve	Approved	10/03/2022	University of Auckland	University of Auckland
2022 EXP 11570	A primary care-led weight management intervention: DiRECT to Aotearoa New Zealand	Dr Kim Ma'ia'i	18/02/2022	2/12/2021	Provisionally Approve	Approved	8/03/2022	Te Kāika Caversham	Ōtākou Health Limited
2021 FULL 11336	A study investigating a new ocular implant, PA5346 Latanoprost FA SR Ocular Implant.	Prof Anthony Wells	13/12/2021	26/11/2021	Provisionally Approve	Approved	26/01/2022	Capital Eye Specialists	PolyActiva Pty Ltd, Avance Clinical
21/STH/189	A study of Odevixibat in patients with Alagille Syndrome	Dr Helen Evans	21/07/2021	7/10/2021	Provisionally Approve	Approved	29/11/2021	Auckland DHB	Syneos Health New Zealand Limited
2021 EXP 11143	A study of Pacific infant care practices	Mrs Amio Matenga Ikihele	10/11/2021	21/10/2021	Provisionally Approve	Approved	30/11/2021	Moana Research	University of Auckland
2022 FULL 11233	A study of safety, reactogenicity and immune response of the repeat vaccination against RSV when given to female participants of 18- 49 years of age during their subsequent uncomplicated pregnancy.	Dr Rebecca Griffith	10/01/2022	24/11/2021	Provisionally Approve	Approved	29/03/2022	Optimal Clinical Trials	GlaxoSmithKline Biologicals SA, GlaxoSmithKline
2021 FULL 11060	A Study to Evaluate the Efficacy and Safety of Astegolimab in Patients with Chronic Obstructive Pulmonary Disease (COPD)	Doctor Andrew Veale	8/12/2021	8/11/2021	Provisionally Approve	Approved	28/01/2022	New Zealand Respiratory and Sleep Institute	PPD
2021 FULL 11246	A Study to Treat Small to Medium Sized Abdominal Aneurysms	Associate Professor Andrew Holden	21/09/2021	8/11/2021	Approved	Approved	8/11/2021	Auckland District Health Board	Nectero Medical, Inc.
2021 FULL 11026	Adenovirus Type 7 Infection in Children	Dr Alana Ainsworth	1/09/2021	7/10/2021	Approved	Approved	7/10/2021	Counties Manukau Health	Counties Manukau Health
2022 EXP 11151	ADHB Postnatal Kete	Ms Alex Woodley	1/02/2022	24/11/2021	Provisionally Approve	Approved	18/02/2022	Point and Associates	Waitematā and Auckland DHB
2022 FULL 10996	AG10-304: Extension Study and Safety Monitoring of Acoramidis (AG10) in Participants with Transthyretin Amyloid Cardiomyopathy (ATTR-CM)	Dr Hugh Goodman	11/01/2022	26/11/2021	Provisionally Approve	Approved	11/02/2022	Waikato Hospital, Cardiology Clinical Trials Unit	Eidos Therapeutics, Inc., Pharmaceutical Research Associates New Zealand Limited

21/STH/236	AML18	Dr Claire Hemmaway	21/08/2021	7/10/2021	Provisionally Approve	Approved	8/11/2021	Auckland City Hospital	Cardiff University
2021 EXP 10974	An investigation of government agency support provided to surviving family members for the immediate family or whanau of a family violence deceased	Dr Pauline Gulliver	1/12/2021	21/09/2021	Provisionally Approve	Approved	6/12/2021	Health Quality & Safety Commission	Health Quality & Safety Commission
2021 EXP 11637	Aneurysmal SAH in Māori and European New Zealanders	Dr. Ben Smith	28/10/2021	24/11/2021	Approved	Approved	24/11/2021	Capital & Coast DHB	Capital & Coast DHB
2021 FULL 11045	ANZ-SCAD REGISTRY	Dr Aniket Puri	18/11/2021	7/10/2021	Provisionally Approve	Approved	2/12/2021	Canterbury District Health Board	Canterbury District Health Board
2022 FULL 12480	APL-101-03: A Study Comparing two different capsule formulations of APL-101 and PLB-1001 in Healthy Chinese and Caucasian Participants	Dr Paul Hamilton	29/04/2022	28/04/2022	Provisionally Approve	Approved	13/05/2022	New Zealand Clinical Research	Apollomics Inc, LabCorp
2022 FULL 12829	BD Veritor,® At-Home COVID-19 & Flu Test and BD Veritor,® System for Rapid Detection of COVID-19 & Flu	Dr Penny Montgomery	30/06/2022	28/06/2022	Provisionally Approve	Approved	20/07/2022	Optimal Clinical Trials	Becton Dickinson Limited
21/STH/191	BO42864: A Study of Pralsetinib Versus Standard of Care for Patients with RET Fusion-Positive Metastatic Non-Small Cell Lung Cancer	Dr. Rajiv Kumar	27/07/2021	11/10/2021	Approved	Approved	11/10/2021	Auckland Clinical Studies	Roche Products (New Zealand) Limited
21/STH/202	CaPTO study:Part 2	Dr. Ramya Nagarajan	29/07/2021	7/10/2021	Decline	Declined	7/10/2021	University of Auckland	
21/STH/168	CD3 Negative Hepatosplenic T Cell Lymphoma - A Case Report	Dr Jian Li	30/06/2021	16/07/2021	Approved	Approved	16/07/2021	New Zealand Blood Service	
2022 EXP 12341	Cerebral Venous Thrombosis (CVT) in New Zealand	Dr. Josh Faulkner	14/06/2022	10/06/2022	Provisionally Approve	Approved	17/06/2022	Te Herenga Waka - Victoria University of Wellington	Te Herenga Waka - Victoria University of Wellington
2022 EXP 11049	Characterisation of voice and swallowing in individuals with chronic cough	Miss Elizabeth Cross	8/02/2022	3/03/2022	Approved	Approved	3/03/2022	University of Canterbury Rose Centre for Stroke Recovery and Research	
2022 EXP 13009	Characterization of immune cells in human skin	Dr Olivier Gasser	17/06/2022	6/07/2022	Approved	Approved	6/07/2022	Malaghan Institute of Medical Research	Malaghan Institute of Medical Research
21/STH/221	Combination T4/T3 trial for hypothyroidism	Dr Mark Bolland	13/08/2021	7/10/2021	Provisionally Approve	Approved	6/12/2021	University of Auckland	University of Auckland

21/STH/222	Comparison of two clozapine oral suspensions.	Dr Noelyn Hung	13/08/2021	7/10/2021	Approved	Approved	7/10/2021	Zenith Technology Corporation Limited	Douglas Pharmaceuticals Ltd
2022 EXP 11039	Connecting Pathways	Dr Jesse Kokaua	6/05/2022	17/02/2022	Provisionally Approve	Approved	17/05/2022	University of Otago	University of Otago
2022 FULL 11557	Correlating molecular alterations in low grade ovarian serous carcinoma to patient outcomes in New Zealand	Dr Mak Sarwar	21/02/2022	24/11/2021	Provisionally Approve	Approved	5/05/2022	University of Otago	University of Otago
2021 FULL 11138	Cultural appropriateness of the use of Autism Diagnostic and Observation Schedule for Maori	mrs Meenakshi Panda	9/09/2021	7/10/2021	Decline	Declined	7/10/2021	Hutt Valley DHB	Child Development Service, Hutt Valley DHB
21/STH/225	DELTOID TAKEDOWN APPROACH - AN APPROACH TO COMPLEX GLENOID FRACTURES	Dr Natalie Hong	17/08/2021	8/10/2021	Decline	Declined	8/10/2021	WDHB	
2021 EXP 11664	DELTOID TAKEDOWN APPROACH - AN APPROACH TO COMPLEX GLENOID FRACTURES (2)	Dr Natalie Hong	4/12/2021	25/11/2021	Provisionally Approve	Approved	13/12/2021	Waikato District Health Board	Waikato District Health Board
2021 EXP 11774	Determining the clinical significance of the Monocyte Distribution Width (MDW) on the Sysmex XN-9000 haematology analyser in a cohort of patients with radiologically-proven pneumonia	Dr Julian Verran	6/12/2021	2/12/2021	Provisionally Approve	Approved	13/12/2021	Waikato District Health Board	Waikato District Health Board
2022 FULL 12721	Development of an ultrasound picture-based classification system to grade the degree of osteoarthritic change in the big toe joint_V2	Ms Prue Molyneux	3/06/2022	25/05/2022	Provisionally Approve	Approved	17/06/2022	Auckland University of Technology	Auckland University of Technology
2021 FULL 11430	Diabetes eye care services in Auckland and Counties Manukau	Associate Professor Jacqueline Ramke	29/11/2021	Not approved	Decline	Declined	22/12/2021	University of Auckland	University of Auckland
2022 FULL 12178	Diabetes eye care services in Auckland and Counties Manukau	Associate Professor Jacqueline Ramke	7/02/2022	29/03/2022	Approved	Approved	29/03/2022	University of Auckland	University of Auckland
2021 FULL 11615	ED Elderly Head Injury Outcomes, ED-EM-HI Study	Dr Devin Faragasso	25/10/2021	26/11/2021	Decline	Declined	26/11/2021	Taranaki District Health Board	Taranaki District Health Board
2022 FULL 11925	Emergency Department Elderly Head Injury Outcomes Study, ED-EM-HI (re-application)	Dr Devin Faragasso	14/04/2022	25/02/2022	Provisionally Approve	Approved	17/05/2022	Taranaki District Health Board	Taranaki District Health Board
2022 FULL 11866	ETERNAL€ A clinical trial comparing thrombolysis to standard care for ischaemic stroke presenting within 24 hours	Dr Teddy Wu	29/03/2022	25/02/2022	Provisionally Approve	Approved	12/04/2022	Canterbury District Health Board	University of Melbourne

2022 EXP 11507	Evaluating the clinical assessment of later termination of pregnancy and the role of psychiatrists following the NZ abortion law reform	Dr Te Kahui Tapsell	7/03/2022	5/04/2022	Decline	Declined	5/04/2022	CCDHB	CCDHB
2022 FULL 12705	Evaluation and validation of the body surface gastric mapping (BSGM) device for use with Young People aged 5-18 years with symptoms or a diagnosis of an Upper Gastrointestinal Functional Disorder	Ms Gayl Humphrey	30/05/2022	12/05/2022	Provisionally Approve	Approved	5/07/2022	University of Auckland	University of Auckland
2022 FULL 13034	Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction	Associate Professor Andrew Holden	30/06/2022	14/07/2022	Approved	Approved	14/07/2022	Auckland District Health Board	W. L. Gore & Associates, Inc.
2022 FULL 12479	Evaluation of Youth Primary Mental Health and Addiction Services - Access and Choice Initiative	Dr Adrian Field	30/06/2022	12/05/2022	Provisionally Approve	Approved	13/07/2022	Dovetail Consulting Ltd	Ministry of Health - Manatū Hauora
2021 FULL 11239	Exploring implementation of the F-words for Child Development with an organisation in Aotearoa New Zealand	Dr Margaret Anne Jones	8/12/2021	26/11/2021	Provisionally Approve	Approved	28/01/2022	Auckland University of Technology	Auckland University of Technology
2022 FULL 12212	Fanau ola manuia programme	Associate Professor Riz Firestone	1/06/2022	28/04/2022	Provisionally Approve	Approved	30/06/2022	Massey University	Massey University
2022 FULL 11628	Feasibility and acceptability of the Moves4LiMinds Programme.	Associate Professor Kelly Jones	15/03/2022	22/12/2021	Provisionally Approve	Approved	30/03/2022	National Institute for Stroke and Applied Neurosciences	Auckland University of Technology
21/STH/223	Feasibility Study of a Group Intervention for Youths Impacted by the March 15th Attacks	Dr Katherine Donovan	16/08/2021	7/10/2021	Provisionally Approve	Approved	28/01/2022	University of Otago	University of Otago
2022 FULL 11858	Feasible, safety and utility of Endoscopic ultrasound-guided PPG measurement (EUS-PPGM) in patients undergoing liver resection and major intra-abdominal surgeries.	Dr Frank Weilert	15/06/2022	12/05/2022	Provisionally Approve	Approved	28/06/2022	Waikato District Health Board	Waikato District Health Board
2022 FULL 11811	FINER - Phase III Fulvestrant and Ipatasertib for Advanced HER2-, ER+ Breast Cancer	Dr. Sheridan Wilson	12/04/2022	25/02/2022	Provisionally Approve	Approved	5/05/2022	Auckland District Health Board	Breast Cancer Trials
2022 EXP 12264	Fruit organic acids - glycaemia and laxation	Dr Suman Mishra	24/03/2022	20/04/2022	Approved	Approved	20/04/2022	Plant and Food Research	Plant and Food Research
2022 EXP 11833	Genes and exposures in PD	Dr Toni Pitcher	24/03/2022	25/02/2022	Provisionally Approve	Approved	30/03/2022	University of Otago	University of Otago
21/STH/185	GRIT Study	Dr Samantha Lee	20/07/2021	24/08/2021	Decline	Declined	24/08/2021	University of Canterbury	University of Canterbury
2021 FULL 11202	GRIT Study	Dr Samantha Lee	26/11/2021	8/11/2021	Provisionally Approve	Approved	28/01/2022	University of Canterbury	University of Canterbury

2022 FULL 10999	GSN000350: A Phase 2b/3 Trial of Setanaxib with a 52-week Extension Phase in patients with PBC and Elevated Liver Stiffness	Dr Andrew Knox	11/01/2022	25/02/2022	Approved	Approved	25/02/2022	Auckland City Hospital	Genkyotex Suisse SA, Pharmaceutical Research Associates New Zealand Limited
2022 EXP 11574	HapÅ« Ora Experience Research	Dr. Susan Knox	20/05/2022	24/02/2022	Provisionally Approve	Approved	31/05/2022	AUT	AUT
21/STH/178	HeadSMART II	Prof William F Peacock	30/06/2021	24/08/2021	Declined	Declined	24/08/2021	Christchurch Hospital	BRAINBox Solutions, Inc.
21/STH/197	ICD codes in New Zealand children with epilepsy	Professor Lynette Sadleir	28/07/2021	18/11/2021	Approved	Approved	18/11/2021	University of Otago	University of Otago
21/STH/184	Identifying multi-omic markers(genomic,epigenomic,transcriptomic) to predict risk of prostate cancer in New Zealand men.	A/Prof Aniruddha Chatterjee	16/07/2021	14/10/2021	Approved	Approved	14/10/2021	University of Otago	University of Otago
2021 FULL 11191	Impact of Legionellosis in NZ - A Retrospective Analysis of Hospitalisations, 2000-2020	Ms Frances Graham	10/09/2021	7/10/2021	Decline	Declined	7/10/2021	University of Otago	University of Otago
2022 FULL 11658	Improving continence management for people with dementia in the community (PHASE 3)	Professor Vanessa Burholt	31/03/2022	28/04/2022	Approved	Approved	28/04/2022	The University of Auckland	The University of Auckland
2022 FULL 10993	Integrity Study - Glaukos infinite vs Hydrus to reduce eye pressure in patients with glaucoma	Dr Dean Corbett	14/01/2022	22/12/2021	Provisionally Approve	Approved	10/03/2022	Auckland Eye	Glaukos Corporation
21/STH/192	INTERCEPTevar	Dr Oliver Lyons	23/07/2021	14/12/2021	Approved	Approved	14/12/2021	Christchurch District Health Board	
2022 EXP 12300	Kawakawa and its impact on inflammatory markers	Dr Farha Ramzan	30/03/2022	21/03/2022	Provisionally Approve	Approved	12/04/2022	Liggins Institute	University of Auckland.
2022 FULL 12546	Let's screen for HPV (and prevent cervical cancer)	Associate Professor Peter Sykes	15/06/2022	25/05/2022	Provisionally Approve	Approved	1/07/2022	University of Otago	University of Otago
2022 FULL 11813	Low Dose Naltrexone To Help Treat Depression	Dr Joanne Lin	25/03/2022	28/04/2022	Decline	Declined	28/04/2022	The University of Auckland	The University of Auckland
2022 FULL 12781	Low-dose naltrexone to help treat depression	Dr Joanne Lin	30/05/2022	28/06/2022	Approved	Approved	28/06/2022	The University of Auckland	The University of Auckland
2021 FULL 11256	Lymphoma and Related Diseases Registry	Dr Leanne Berkahn	22/11/2021	22/12/2021	Decline	Declined	22/12/2021	Auckland City Hospital	Monash University
2022 FULL 12203	Lymphoma and Related Diseases Registry (LaRDR)	Dr Leanne Berkahn	14/02/2022	29/03/2022	Approved	Approved	29/03/2022	Auckland City Hospital	Monash University

2021 FULL 11481	M20-371 Moderate to Severe Crohn's Disease: A Phase 2 Safety and Efficacy Study of ABBV-154	Dr. Benjamin Griffiths	21/12/2021	26/11/2021	Provisionally Approve	Approved	11/02/2022	CCDHB	Abbvie
2022 FULL 11279	M20-466 Moderate to Severe Rheumatoid Arthritis: A Phase 2b, Dose-Ranging, Safety and Efficacy Study of ABBV-154	Dr Douglas White	11/02/2022	26/11/2021	Provisionally Approve	Approved	28/02/2022	Waikato Hospital	AbbVie Pty Ltd
21/STH/179	Macrocytosis associated with the use of emtricitabine or lamivudine.	Dr Simon Briggs	8/07/2021	9/08/2021	Approved	Approved	9/08/2021	Auckland City Hospital	Auckland City Hospital
2021 EXP 10986	Manalagi Project	Dr Patrick Thomsen	1/12/2021	24/11/2021	Provisionally Approve	Approved	6/12/2021	The University of Auckland	The University of Auckland
2021 EXP 11367	Mindfulness Meditation and Brainwave Training for Pain Relief in Knee Osteoarthritis: A feasibility clinical trial.	Dr Ramakrishnan Mani	16/12/2021	24/11/2021	Provisionally Approve	Approved	11/01/2022	University of Otago	University of Otago
2021 FULL 11416	MK3475-B96 Pembrolizumab/placebo plus paclitaxel with or without bevacizumab for platinum-resistant recurrent ovarian cancer	Dr Michelle Wilson	23/11/2021	22/12/2021	Approved	Approved	22/12/2021	Auckland City Hospital	Merck Sharp & Dohme (Australia) Pty Limited
2022 FULL 12393	MT1002 in PCI	Dr Jithendra Somaratne	26/05/2022	28/04/2022	Provisionally Approve	Approved	8/06/2022	Auckland District Health Board	Merck Sharp & Dohme (Australia) Pty Limited
21/STH/213	Nasal High-Flow Oxygen Therapy After Cardiac Surgery (NOTACS) Study	A/Prof Rachael Parke	6/08/2021	12/10/2021	Approved	Approved	12/10/2021	Auckland District Health Board	Auckland District Health Board
21/STH/220	Neurobiology and biomarker discovery for neurodegenerative and psychiatric diseases	Professor Ping Liu	12/08/2021	19/11/2021	Approved	Approved	19/11/2021	University of Otago	A University of Otago
2022 EXP 12105	NOTORIOUS study; non-tuberculous mycobacteria skin and soft tissue infection	Dr Arthur Morris	25/03/2022	21/03/2022	Provisionally Approve	Approved	11/04/2022	Auckland City Hospital	University of Queensland Centre for Clinical Research
2021 EXP 11199	Opioid Prescriptions and usage after surgery	Dr Deborah Wright	9/11/2021	19/10/2021	Provisionally Approve	Approved	25/11/2021	The University of Otago	
2022 EXP 12392	Optimising heat therapy for treating high blood pressure	Dr Kate Thomas	16/05/2022	12/05/2022	Provisionally Approve	Approved	25/05/2022	University of Otago	University of Otago
2022 FULL 12118	Oral Lonafermin (LNF) for Treatment of Chronic Hepatitis D (delta)	Prof Ed Gane	13/04/2022	29/03/2022	Provisionally Approve	Approved	17/05/2022	Liver Research Unit	Liver Research Unit
2022 FULL 11192	Pacific Child Wellbeing	Dr Teuila Percival	8/04/2022	29/03/2022	Provisionally Approve	Approved	27/04/2022	Moana Research	Moana Research
21/STH/183	PaULVTE in cancer patients	Dr Laura Young	10/07/2021	17/08/2021	Approved	Approved	17/08/2021	Auckland DHB	Monash Health
21/STH/233	PD genes and exposures	Dr Toni Pitcher	20/08/2021	8/11/2021	Decline	Declined	8/11/2021	University of Otago	
2021 EXP 11088	Perceptions of perioperative brain complications	Dr Carolyn Deng	9/09/2021	20/09/2021	Approved	Approved	20/09/2021	Auckland District Health Board	Auckland District Health Board

2022 FULL 12280	Peripheral chemoreflex in hypertension: rest and exercise	Dr. James Fisher	28/03/2022	28/04/2022	Approved	Approved	28/04/2022	University of Auckland	University of Auckland
2022 EXP 11147	Pharmacokinetics of high dose quercetin	Dr Leon Yu-An Huang	21/03/2022	22/12/2021	Provisionally Approve	Approved	30/03/2022	Counties Manukau Health	Counties Manukau Health
2022 FULL 11982	Phase 1 study to assess safety, tolerability, and the immune response KJ103 in healthy adults	Principal Investigator Mark Marshall	8/03/2022	25/02/2022	Provisionally Approve	Approved	7/04/2022	New Zealand Clinical Research	Shanghai Bao Pharmaceuticals Co.,Ltd. , Infinity Consulting Ltd
2022 FULL 11944	Pilot study 177Lu-DOTA-Rosopitamab (TLX591) therapy in mCRPC patients failing PSMA small molecule ligands	Dr Andrew Henderson	26/06/2022	29/03/2022	Provisionally Approve	Approved	2/09/2022	Mercy Radiology	Mercy Radiology
21/STH/196	Polymyalgia Rheumatica (PMR) Dependent on Glucocorticoid Treatment: A Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Study of ABBV-154	Dr Mark Sapsford	28/07/2021	12/10/2021	Approved	Approved	12/10/2021	Middlemore Clinical Trials	AbbVie Pty Ltd
21/STH/182	Postnatal Care Kete	Ms Alex Woodley	9/07/2021	5/08/2021	Decline	Declined	5/08/2021	Point and Associates Aotearoa Ltd	
2022 FULL 12229	PREVISION First in Human Study	Dr Andrew Holden	31/03/2022	28/04/2022	Approved	Approved	28/04/2022	Auckland District Health Board	Becton, Dickinson and Company (BD)
21/STH/215	PRIME	Prof Valery L. Feigin	12/08/2021	17/09/2021	Decline	Declined	17/09/2021	AUT	
2022 EXP 12320	Rangoa Marori 3	MR/PROF JONATHAN KOEA	6/04/2022	30/03/2022	Provisionally Approve	Approved	27/04/2022	NORTH SHORE HOSPITAL	HRC
21/STH/230	Real-World Evidence Study of the Impact of Esketamine (Spravato) on the Quality of Life of Patients Living with Treatment Resistant Depression in Australia and New Zealand	Dr David Codyre	20/08/2021	7/10/2021	Provisionally Approve	Approved	9/12/2021	Tamaki Health	Janssen-Cilag
2022 EXP 11078	Recovery from Concussion	Dr Mangor Pedersen	13/01/2022	18/02/2022	Approved	Approved	18/02/2022	Auckland University of Technology (AUT)	Auckland University of Technology (AUT)
2022 FULL 11596	Rectal tissue concentrations of thioguanine in inflammatory bowel disease	Professor Murray Barclay	10/01/2022	25/02/2022	Decline	Declined	25/02/2022	Barclay Gastroenterology Ltd	Barclay Gastroenterology Ltd
2021 FULL 11166	Respiratory Health in Tamariki with Cerebral Palsy in New Zealand	Professor N. Susan Stott	13/11/2021	8/11/2021	Provisionally Approve	Approved	8/12/2021	Auckland District Health Board	Auckland District Health Board
2022 FULL 11766	Safety and Effectiveness of the Zenflow Spring System - A Minimally Invasive Treatment for LUTS associated with BPH - BREEZE study	Professor Peter Gilling	24/02/2022	22/12/2021	Provisionally Approve	Approved	18/03/2022	Tauranga Urology Research Limited	Zenflow Inc

2021 FULL 11094	SCIP RHD	Dr Julie Bennett	23/12/2021	22/12/2021	Provisionally Approve	Approved	31/01/2022	University of Otago	University of Otago
2022 FULL 11306	Selinexor and Lenalidomide post ASCT for Newly Diagnosed Myeloma (SeaLAND)	Dr Lauren Child	30/06/2022	14/07/2022	Approved	Approved	14/07/2022	Auckland City Hospital	Australasian Leukaemia and Lymphoma Group
2022 EXP 11552	Sepsis palliative care	Dr Katie Walland	11/04/2022	2/12/2021	Provisionally Approve	Approved	28/04/2022	Waikato DHB	Waikato DHB
2022 FULL 12187	SOTERIA - A Long Term Follow Up Study of Sotatercept for PAH Treatment	Dr Henry Gallagher	22/02/2022	29/03/2022	Approved	Approved	29/03/2022	Waikato Hospital/Waikato DHB	Acceleron Pharma Inc., PPD Global Limited
2021 FULL 11328	Study of ATH434 in Participants With Multiple System Atrophy	Prof. Tim Anderson	23/12/2021	25/02/2022	Approved	Approved	25/02/2022	University of Otago	Alterity Therapeutics Limited, Pharmaceutical Research Associates New Zealand Limited
2021 FULL 11162	Study of efficacy, safety, and tolerability of LNA043 in patients with symptomatic knee osteoarthritis.	Dr Nigel Gilchrist	20/12/2021	8/11/2021	Provisionally Approve	Approved	21/02/2022	CGM Research Trust Ltd	Novartis Pharmaceuticals Australia Pty Limited
2022 FULL 11098	Study of WVE-004 in Patients with C9orf72-associated ALS or FTD	Professor Tim Anderson	7/01/2022	26/11/2021	Provisionally Approve	Approved	11/02/2022	University of Otago	Wave Life Sciences UK Limited, CARSL Consulting
21/STH/177	Te Ao Marama (Phase 2)	Mrs Bernadette Jones	1/07/2021	23/03/2022	Decline	Declined	23/03/2022	University of Otago Wellington	
2022 EXP 12533	Te Ao Marama Wellbeing Survey (Phase 2)	Mrs Bernadette Jones	31/03/2022	4/05/2022	Approved	Approved	4/05/2022	University of Otago	University of Otago
21/STH/188	Te Ara Waiora	Prof Beverly Lawton	21/07/2021	30/09/2021	Approved	Approved	30/09/2021	Centre for Women's Health Research, Victoria University of Wellington	
2022 FULL 11386	TEMPO-2 €" A randomised clinical trial of tenecteplase thrombolysis versus standard treatment for minor stroke with brain artery occlusion	Dr Teddy Wu	21/01/2022	22/12/2021	Provisionally Approve	Approved	10/03/2022	Canterbury District Health Board	The University of Calgary
2022 EXP 12622	The effect of BerriQi boysenberry and apple drink on lung function following ozone exposure	Dr Odette Shaw	29/06/2022	14/07/2022	Approved	Approved	14/07/2022	The New Zealand Institute of Plant and Food Research Ltd	The New Zealand Institute for Plant and Food Research Ltd.

2022 EXP 11489	The effect of BerriQi® Boysenberry and apple drink on lung function following ozone exposure	Dr Odette Shaw	8/03/2022	24/11/2021	Provisionally Approve	Declined	22/03/2022	The New Zealand Institute for Plant and Food Research Ltd	The New Zealand Institute for Plant and Food Research Ltd.
2022 EXP 12491	The effect of diabetes drugs on the immune system	Dr Olivier Gasser	31/03/2022	20/04/2022	Approved	Approved	20/04/2022	Malaghan Institute of Medical Research	Malaghan Institute of Medical Research
2021 EXP 11065	The effect of heart rate variability biofeedback to improve mental health outcomes	DR Lynette Hodges	21/10/2021	24/11/2021	Decline	Declined	24/11/2021	Massey University	Massey University
21/STH/218	The effect of increased fibre intake on HbA1c and peripheral immune cells in diabetes	Dr Rosemary Hall	20/08/2021	8/10/2021	Approved	Approved	8/10/2021	Capital and Coast DHB	Malaghan Institute
2022 FULL 12531	The effect of positive pressure treadmill training in young people with cerebral palsy	Dr. Pablo Ortega-Auriol	24/03/2022	28/04/2022	Approved	Approved	28/04/2022	University of Auckland	University of Auckland
2022 EXP 12032	The FERDINAND study	Associate Professor Jennifer Miles-Chan	3/03/2022	17/02/2022	Provisionally Approve	Approved	16/03/2022	University of Auckland	University of Auckland
2022 EXP 12183	The Journey to HIV diagnosis	The Journey Taken to HIV Diagnosis James Rice-Davies	4/02/2022	8/03/2022	Decline	Declined	8/03/2022	CCDHB	CCDHB
2022 EXP 12079	The mechanistic role of the right atrium	Dr Jichao Zhao	28/02/2022	18/02/2022	Provisionally Approve	Approved	18/03/2022	The University of Auckland	The University of Auckland
21/STH/231	The New Zealand Food and Beverage Study (Synergy Sub-Study)	Dr Jennifer Miles-Chan	21/08/2021	13/12/2021	Approved	Approved	13/12/2021	University Of Auckland	University of Auckland
21/STH/181	The Topical Sevo Trial	Dr John Barnard	16/07/2021	7/10/2021	Approved	Approved	7/10/2021	Anaesthetic Research, Waikato District Health Board, Waikato Hospital.	Anaesthetic Research, Waikato District Health Board, Waikato Hospital.
2022 FULL 11228	Treatment-induced neuroplasticity in children who stutter	Mrs Fathiya Al'Amri	27/04/2022	25/02/2022	Provisionally Approve	Approved	9/05/2022	University of Canterbury	Canterbury Medical Research Foundation (CMRF)
21/STH/235	TRITON	Professor Anthony Wells	20/08/2021	7/10/2021	Decline	Declined	7/10/2021	Capital eye Specialists	Allergan Australia Pty Ltd

2021 FULL 11846	Tuning in to Teens in Aotearoa NZ	Ms Zara Mansoor	29/11/2021	22/12/2021	Approved	Approved	22/12/2021	University of Otago	University of Otago
21/STH/216	Tupuānuku	Dr Debbie Peterson	17/08/2021	18/11/2021	Approved	Approved	18/11/2021	University of Otago	University of Otago
2022 FULL 11790	Understanding Child Abuse Victims, their Caregivers and Clinicians Experience of Trauma Focused Cognitive Behavioural Therapy	Miss Audrey Kusasira	28/02/2022	22/12/2021	Provisionally Approve	Approved	24/03/2022	Auckland University of Technology (AUT)	Auckland University of Technology (AUT)
21/STH/217	Validating a model used to estimate free plasma penicillin concentrations.	Dr Simon Briggs	17/08/2021	17/01/2022	Approved	Approved	17/01/2022	Auckland City Hospital	Auckland District Health Board
2022 FULL 12095	Vectorcardiography	Doctor Jessica Wong	19/01/2022	25/02/2022	Decline	Declined	25/02/2022	Capital and Coast District Health Board	Capital and Coast District Health Board
2021 EXP 11142	Views of Women with prior GDM on Diet and Lifestyle Postpartum	Ms Tutangi Amataiti	11/11/2021	1/12/2021	Approved	Approved	1/12/2021	University of Otago	University of Otago
2022 FULL 11814	VT-1001: A Study of VERVE-101 in Patients with Heterozygous Familial Hypercholesterolemia, Atherosclerotic Cardiovascular Disease, and Uncontrolled Hypercholesterolemia	Dr. Patrick Gladding	28/04/2022	29/03/2022	Provisionally Approve	Approved	4/05/2022	New Zealand Clinical Research Ltd	Verve Therapeutics, IQVIA RDS Pty Limited
2021 EXP 11321	Weaving tikanga into practice for hapā ora	Dr Fiona Cram	23/09/2021	19/10/2021	Approved	Approved	19/10/2021	Katoa Ltd	Katoa Ltd
21/STH/229	Wholegrain structure in the blood glucose management of adults with type 2 diabetes	Dr Andrew Reynolds	20/08/2021	31/01/2022	Approved	Approved	31/01/2022	University of Otago	University of Otago
2022 FULL 12282	XL092-002 / STELLAR 002- Expansion Study of the Safety and Efficacy of XL092 in Combination with Immuno-Oncology Agents	Dr Simon Fu	28/06/2022	14/07/2022	Approved	Approved	14/07/2022	Auckland City Hospital	Exelixis Inc, Pharmaceutical Research Associates New Zealand Limited