



**Health and
Disability Ethics
Committees**

**Southern Health and Disability
Ethics Committee**

**Annual Report
2023**

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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 2022 – 30 June 2023. 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

With respect to this annual report of the Southern HDEC for the year ending 30 June 2023, I note that I was not formally appointed Chair of the southern HDEC until 3 July 2023, albeit I have been Acting Chair since the resignation of the former chair (Anthony Fallon) in late 2022.

It has been a busy year for our committee having reviewed a total of 117 new applications. 77 were reviewed at full committee meetings, while 40 new applications were reviewed through the expedited (low risk) pathway. The committee has been light on numbers for a large part of this year, and we have been lucky to have the support of the other HDECs when it comes to co-opting their members to satisfy quorum requirements and/or lighten the workload on the committee members.

Our committee has a broad range of experience, and we have made real progress with a number of research organisations in respect of compliance with ethical standards and in particular how the NEAC standards apply to their studies. However, there does remain a broad lack of understanding and/or knowledge of the HDEC website and templates available for researchers to assist with their applications. In addition, there are definite improvements that can be made to the online application form and process.

Finally, thanks to the Secretariat staff also who have as always been a huge help in terms of liaising with the researchers, taking meeting minutes and providing ad hoc advice during online meetings. And, from a technical point of view, there is a real willingness to make changes to the process in order to enable us to function effectively.

Nga mihi nui,

Dominic Fitchett

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 at first review	0
No. of applications approved subject to conditions / pending at first review (Non-standard conditions or NSC)	21
No. of applications deferred (provisionally approved) at first review and subsequently approved	38
No. of applications deferred as at time of report	13
No. of applications that were declined (in part) because of no/insufficient consultation with appropriate Māori/whānau/iwi/hāpu	0
No. of applications that were declined 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/whānau/iwi/hāpu/cultural group.)	3
<i>No. of applications which do not require ethics committee approval (across all four Committees, expedited and full combined)</i>	<i>676</i>
No. of studies withdrawn by researcher during the reporting period	2
No. of studies terminated by sponsor	0
No. of studies transferred to another EC	0
Total number of applications received by full EC	77

Summary of applications received under expedited / low risk review

No. of applications approved	4
No. of applications approved subject to conditions	7
No. of applications deferred and subsequently approved	19
No. of applications deferred as at time of report	9
<i>No. of applications referred for full committee review</i>	<i>0</i>
No. of applications declined	1
No. of studies withdrawn by researcher	0
Total number of applications received under expedited / low risk review	40

Total number of applications received:

117

Complaints and overdue application summary

This section outlines complaints about decisions made by the Committee during 2023.

Complaints received

Complaint one

Type of complaint: Adverse Event of Participant

Review date: 27 June 2023

Complaint received: 27 April 2023

Nature of complaint:

A participant experienced an adverse event that reportedly caused lasting medical issues (respiratory) after exposure to ozone as part of the study and was concerned the side effects were not adequately explained and that they may not resolve within the window given in the participant information. In addition, the complainant was under the same employ as the investigators and felt pressure to not push their complaint directly to the investigators.

Actions taken:

The Chair and non-lay Deputy Chair were consulted, and they had concerns and follow-up questions they wished the coordinating-investigator (CI) to address. Permission was then sought from complainant to follow up with investigator as they due to the nature of the complaint they could be identified. The complainant was happy for selected information to be shared. A description of the complaint and the queries/concerns raised by Chair and Deputy Chair were provided to the CI. The CI responded to each point queried, including providing assurance that all medical expenses as a result of this adverse event have been reimbursed, and any further ones will also be reimbursed. The study team were asked to provide more information to participants, specifically that for some people any side effects may not resolve within the anticipated window, as well as reporting further COI management when recruiting from those under their employ, and for the updates to be provided in the next annual report.

Outcome:

The complainant reported satisfaction with the resolution, and the Committee was satisfied with the responsiveness of the research team in addressing the matter.

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 31 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 33 days for full applications. Target timeframe for full applications is 35 days. ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 54-59).

The average review time for expedited applications was over the targeted timeframe.

The reason for these delays is due to the Acting Chair (then newly appointed Chair) covering when the previous Chair resigned and required additional training and time in order to review when they were new to online work.

Appendix 1: Details of applications reviewed¹

Applications reviewed by full committee

Reference no.	Protocol title	Name of principal investigator	Date received	Date of first review	Outcome of first review	Status at time of report	Date of final outcome	Locality	Local funder	Global funder (if any)
2022 EXP 11210	A Case Report of Acquired Haemophilia in Chronic Myelomonocytic Leukaemia	Dr Jian Li	9/10/2022	25/10/2022	Provisionally Approved	Approved	26/10/2022			
2023 FULL 13857	A computational pathology framework to improve outcome prediction for oestrogen receptor positive breast cancer	Dr Gavin Harris	27/06/2023	11/07/2023	Approved	Approved	17/07/2023	Te Whatu Ora locality, Tertiary Education Institution	Te Whatu Ora Waitaha	
2022 FULL 13560	A First-in-Human, Randomized, Double-Blind, Placebo-Controlled, Phase 1 Single and Multiple Ascending Dose Study to Assess the Safety and Pharmacokinetics of RBN-3143 in Healthy Subjects and as Open-Label in Patients with Atopic Dermatitis	Principal Investigator Alexandra Cole	8/11/2022	23/11/2022	Provisionally Approved	Approved	24/11/2022	Private Organisation	Novotech (New Zealand) Limited c/o Novotech (Australia) Pty	Ribon Therapeutics, Inc.
2023 EXP 15624	A Minimal Intervention to Support Motivation for Pre-Arthroplasty Physical Activity Behaviour	Ms Jessica Calverley	28/06/2023	25/07/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality		
2022 FULL 13123	A multicenter, randomized, double-blind, parallel group, placebo-controlled study to assess safety, tolerability,	Dr Nick Cross	26/07/2022	9/08/2022	Approved NSC	Approved	16/08/2022	Private Organisation, Te Whatu Ora locality	Boehringer Ingelheim Pty Ltd.	Boehringer Ingelheim Pharma GmbH

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

	pharmacokinetics and pharmacodynamics of BI 764198 administered orally once daily for 12 weeks in patients with focal segmental glomerulosclerosis.									
2022 FULL 13371	A PHASE 1 STUDY EVALUATING THE EFFECTS OF ARO-RAGE INJECTION FOR SUBCUTANEOUS ADMINISTRATION IN HEALTHY SUBJECTS	Dr Mark O'Carroll	31/08/2022	13/09/2022	Approved NSC	Approved	29/09/2022	Private Organisation	Novotech (New Zealand) Limited	Arrowhead Pharmaceuticals, Inc.
2022 FULL 13249	A Phase 1, Placebo-Controlled, Single/Multiple Ascending Dose Study of DNTH103 Safety, Tolerability, Pharmacokinetics and Pharmacodynamics, Following Intravenous and Subcutaneous Administration in Healthy Volunteers	Dr Mark Marshall	30/08/2022	13/09/2022	Approved NSC	Approved	29/09/2022	Private Organisation	Infinity Consulting Ltd	Dianthus Therapeutics, Inc.
2023 FULL 18186	A Phase 2, Double-Blind, Randomized, Active-Control, Parallel Group Study to Assess the Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Safety of INBRX-101 Compared to Plasma Derived Alpha1-Proteinase Inhibitor (A1PI) Augmentation Therapy in Adults with Alpha-1 Antitrypsin Deficiency (AATD) Emphysema	Dr Michelle Baker	26/06/2023	11/07/2023	Provisionally Approved	Provisionally Approved		Private Organisation, Te Whatu Ora locality	PPD Global Limited, part of TMF Group	Inhibrx, Inc.
2023 FULL 15247	A Phase 2, Randomized, Double-Blind, Multicenter, Placebo-Controlled Study to Evaluate the Safety and	Dr Lutz Beckert	11/04/2023	19/04/2023	Provisionally Approved	Approved	28/04/2023	Te Whatu Ora locality, Tertiary	PPD- part of Thermo Fisher Scientific	Insmad Incorporated

	Tolerability of Treprostinil Palmitil Inhalation Powder in Participants with Pulmonary Hypertension Associated with Interstitial Lung Disease							Education Institution		
2023 FULL 13521	A PHASE 2A, RANDOMIZED, PLACEBO-CONTROLLED, DOSE-RANGING STUDY TO EVALUATE THE SAFETY AND EFFICACY OF PTC518 IN SUBJECTS WITH HUNTINGTON'S DISEASE	Prof Tim Anderson	24/04/2023	9/05/2023	Approved NSC	Approved	29/05/2023	Other	Pharmaceutical Solutions Ltd.	PTC THERAPEUTICS, INC
2022 FULL 13274	A Phase 2a/2b Randomized, Placebo-Controlled Clinical Study to Evaluate the Safety and Efficacy of MK-1942 as Adjunctive Therapy in Participants with Mild to Moderate Alzheimer's Disease (AD) Dementia.	Doctor Nigel Gilchrist	1/09/2022	13/09/2022	Approved NSC	Approved	29/09/2022	Private Organisation	Merck Sharp & Dohme (Australia) Pty Ltd, Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD)	Merck Sharp & Dohme (MSD) a subsidiary of Merck & Co., Inc., Rahway, NJ, USA
2023 FULL 17941	A Phase 3 Program to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Moderately to Severely Active Systemic Lupus Erythematosus.	Dr Mark Sapsford	30/05/2023	13/06/2023	Provisionally Approved	Declined	4/09/2023	Te Whatu Ora locality	Abbvie	Abbvie
2022 FULL 12896	A Phase 3, Multicentre, Randomised, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy, Safety and, Tolerability of CBD Capsules in Adults with Sleep Disturbance.	Dr Michael Williams	6/07/2022	1/08/2022	Provisionally Approved	Approved	1/08/2022	Private Organisation	Avance Clinical	Cann Group Limited

2023 FULL 13542	A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of VX-121 Combination Therapy in Subjects With Cystic Fibrosis (VX20-121-104)	Dr Mark O'Carroll	14/02/2023	24/02/2023	Provisionally Approved	Approved	24/02/2023	Te Whatu Ora locality	Adjutor Healthcare (NZ) Limited	Vertex Pharmaceuticals Australia Pty Ltd
2022 FULL 13130	A Phase 3, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with Rituximab and Lenalidomide (R2) compared to R2 in Subjects with Relapsed or Refractory Follicular Lymphoma (EPCOREâ„¢ FL-1)	Dr Samar Issa	15/09/2022	29/09/2022	Provisionally Approved	Approved	3/10/2022	Private Organisation, Te Whatu Ora locality		AbbVie Pty Ltd
2022 FULL 13686	A Phase 3, Randomized, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with R-CHOP Compared to R-CHOP in Subjects with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)	Dr Peter Ganly	5/12/2022	9/01/2023	Provisionally Approved	Approved	10/01/2023	Te Whatu Ora locality		Abbvie Ltd
2022 FULL 13160	A Phase Ic, Randomized, Double-blind, Placebo-controlled, Multiple Dose-Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of HB0034 in Adult Healthy Subjects.	Doctor Christian Schwabe	26/07/2022	9/08/2022	Approved NSC	Approved	16/08/2022	Private Organisation	Syneos Health New Zealand Ltd.	Shanghai Huaota Biopharmaceutical Co., Ltd
2023 FULL 13797	A PHASE II, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSE-FINDING STUDY TO EVALUATE THE SAFETY,	Professor Tim Anderson	28/02/2023	5/03/2023	Provisionally Approved	Approved	21/03/2023	Te Whatu Ora locality		Roche Products (New Zealand) Ltd.

	BIOMARKERS, AND EFFICACY OF TOMINERSEN IN INDIVIDUALS WITH PRODROMAL AND EARLY MANIFEST HUNTINGTONâ€™S DISEASE									
2022 FULL 13207	A Phase III randomised, placebo-controlled, double-blind, multi-centre, clinical trial to determine the efficacy and safety of Presendin in idiopathic intracranial hypertension	Prof. Helen Danesh-Meyer	11/10/2022	18/10/2022	Provisionally Approved	Approved	19/10/2022	Private Organisation	Premier Research	Invex Therapeutics, Ltd.
2023 FULL 15347	A Phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Astegolimab in patients with chronic obstructive pulmonary disease	Mr Andrew Edwards	23/06/2023	6/07/2023	Provisionally Approved	Approved	10/07/2023	Private Organisation, Te Whatu Ora locality	PPD, part of Thermo Fisher	Roche Product Pty Limited
2022 EXP 11277	A prospective randomised pilot study of biofeedback training with â€œContrainâ€• in patients with major LARS and faecal incontinence symptoms after anterior resection for rectal cancer.	DR John Woodfield	15/07/2022	23/07/2022	Provisionally Approved	Approved	26/07/2022	Te Whatu Ora locality, Tertiary Education Institution	Research and Enterprise Office, University of Otago	
2022 FULL 11763	A prospective Study Examining the Diagnostic of USPIO Enhanced MRI Scans in Patients with Glioblastoma and Brain Metastases	Mr Ahmad Taha	6/11/2022	12/12/2022	Provisionally Approved	Approved	21/12/2022	Te Whatu Ora locality, Tertiary Education Institution	Southern District Health Board	
2023 FULL 14037	A randomised multi-arm trial evaluating the role of antibiotic therapy or immunoglobulin to prevent infection in patients with acquired hypogammaglobulinemia	Dr Robert Weinkove	19/06/2023	11/07/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality		Monash University

	secondary to haematological malignancies.									
2023 FULL 16649	A randomised, open-label study to compare the bioavailability of 1 x 6.3 mg rosuvastatin orally disintegrating tablet (ODT) taken sublingually (Aspen) versus 1 x 10 mg Crestor® oral tablet (Menarini, Australia) in healthy participants under fasting conditions.	Dr Noelyn Hung	25/05/2023	13/06/2023	Provisionally Approved	Provisionally Approved		Private Organisation	Zenith Technology Corporation Limited	Aspen Pharmacare Australia Pty Ltd
2022 FULL 12932	A randomized, double-blind, multicenter phase III study to evaluate the long-term efficacy and safety of ABX464 25 mg or 50 mg once daily as a maintenance therapy in subjects with moderately to severely active ulcerative colitis	Dr Vivek Tharayil	8/12/2022	6/02/2023	Provisionally Approved	Approved	8/02/2023	Te Whatu Ora locality	Iqvia	Abivax
2022 FULL 13953	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF AHB-137 WITH SINGLE ASCENDING DOSES AND MULTIPLE ASCENDING DOSES IN HEALTHY VOLUNTEERS AND CHRONIC HEPATITIS B PATIENTS	Professor Ed Gane	28/11/2022	13/12/2022	Approved NSC	Approved	23/12/2022	Private Organisation	Novotech (New Zealand) Limited	Ausper Biopharma Co., Ltd.
2023 FULL 15150	A Randomized, Double-blind, Placebo-controlled, Dose-finding Study to Evaluate the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of	Dr Nigel Gilchrist	17/04/2023	18/05/2023	Provisionally Approved	Approved	19/05/2023	Te Whatu Ora locality		Abbvie Ltd

	ABBV-552 in Participants with Mild Alzheimer's Disease									
2022 FULL 13016	A Randomized, Double-blind, Placebo-Controlled, Dose-Ranging Multicenter Study to Evaluate the Efficacy and Safety of ALN-AGT01 in Patients with Mild-to-Moderate Hypertension	Dr Milan Radojevic	8/09/2022	13/09/2022	Provisionally Approved	Approved	20/09/2022	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	IQVIA RDS PTY Ltd	Alnylam Pharmaceuticals, Inc.
2023 FULL 17954	A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of SPR001 (Tildacerfont) in Adult Subjects with Classic Congenital Adrenal Hyperplasia (SPR001-203)	Doctor Simon Young	31/05/2023	13/06/2023	Provisionally Approved	Withdrawn by Researcher		Te Whatu Ora locality	Clinical and Regulatory Services (CARLS) Consulting	Spruce Biosciences, Inc
2022 FULL 12865	A randomized, double-blind, placebo-controlled, multicenter phase III study to evaluate the efficacy and safety of ABX464 once daily for induction treatment in subjects with moderately to severely active ulcerative colitis	Dr Vivek Tharayil	5/12/2022	13/12/2022	Provisionally Approved	Approved	21/12/2022	Te Whatu Ora locality	Iqvia	Abivax
2022 FULL 11822	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Guselkumab Subcutaneous Induction Therapy in Participants With Moderately to Severely Active Crohn's Disease	Dr David Rowbotham	10/11/2022	12/12/2022	Provisionally Approved	Approved	13/12/2022	Te Whatu Ora locality	Janssen-Cilag	Janssen Research & Development, LLC

2022 FULL 12984	A randomized, double-blind, single-dose, parallel-group design, 3 arm study to investigate the pharmacokinetic similarity, safety, tolerability, immunogenicity, and pharmacodynamics of subcutaneous AVT05, US licensed SimponiÂ®, and EU approved SimponiÂ® in healthy adult participants.	Principal Investigator Chris Wynne	11/10/2022	25/10/2022	Provisionally Approved	Approved	26/10/2022	Private Organisation	IQVIA RDS Pty Limited	Alvotech Swiss AG
2022 FULL 12217	A randomized, two-arm, placebo-controlled, participant, investigator and sponsor-blinded, proof-of-concept study investigating the efficacy, safety and tolerability of QUC398 in patients with symptomatic knee osteoarthritis.	Dr Nigel Gilchrist	27/10/2022	23/11/2022	Provisionally Approved	Approved	24/11/2022	Private Organisation		Novartis Pharmaceuticals Australia Pty Limited
2022 EXP 13620	A review of early stage gastrointestinal cancer in New Zealand.	Doctor Cameron Schauer	19/10/2022	15/11/2022	Approved NSC	Approved	15/11/2022			
2023 FULL 16764	A soft pressure-sensitive skin to measure lymphoedema treatment efficiency.	Dr Anna Rolleston	27/04/2023	9/05/2023	Provisionally Approved	Approved	31/08/2023	Private Organisation		
2022 FULL 13067	Abortion services in Aotearoa New Zealand: The voices of wāhine on improving access.	Doctor Melanie Gibson	30/08/2022	13/09/2022	Approved NSC	Approved	29/09/2022	Other, Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	Dean of the Faculty of Health, Te Herenga Waka - Victoria University of Wellington	
2023 EXP 15472	Acute hospitalisations in patients with Systemic Sclerosis in Waikato	Dr Philippa van Dantzig	26/04/2023	11/05/2023	Provisionally Approved	Approved	12/05/2023		Rheumatology Research Department	
2022 EXP 13353	Acute maxillofacial fractures and infection: Ten-year retrospective	Dr Belinda Liu	29/12/2022	26/01/2023	Provisionally Approved	Approved	27/01/2023			

	review at Auckland hospitals									
2023 EXP 18047	Advancing Palliative Care among Pacific Children	Associate Professor Sunia Foliaki	28/06/2023	11/07/2023	Approved NSC	Approved	24/07/2023	Primary Health Care Centre, Te Whatu Ora locality, Tertiary Education Institution	Massey University	
2023 FULL 15140	Advancing Palliative Care among Pacific Children	Associate Professor Sunia Foliaki	26/01/2023	14/02/2023	Declined	Declined	2/03/2023	Other, Primary Health Care Centre, Te Whatu Ora locality	Massey University	
2023 FULL 15203	Aged Care in a Changing World; Flourishing with care	Joyce Cook Chair in Ageing Well Ngaire Kerse	28/01/2023	14/02/2023	Approved NSC	Approved	2/03/2023	Private Organisation, Te Whatu Ora locality		
2022 FULL 12285	Ageing Well through Eating, Sleeping, Socialising and Mobility (AWESSOM) Care Home Project: Oral Health	Dr Moira Smith	27/09/2022	7/11/2022	Provisionally Approved	Approved	8/11/2022	Private Organisation	Ministry of Business, Innovation & Employment	
2023 FULL 13960	ALLIANCE: Safety and Effectiveness of Balloon-Expandable Bioprosthetic SAPIEN X4 Transcatheter Heart Valve	Dr James Blake	28/06/2023	11/07/2023	Approved NSC	Approved	24/07/2023	Te Whatu Ora locality	Edwards Lifesciences (New Zealand) Ltd	Edwards Lifesciences LLC
2023 EXP 11368	An Investigation into the Frequency Spectrum of the Lung	Mrs. Sarla Kumari	16/05/2023	7/06/2023	Provisionally Approved	Declined	9/06/2023	Tertiary Education Institution		
2023 FULL 15441	An Open-Label Extension Study to Assess the Safety, Tolerability, and Effectiveness of the Long-Term use of Treprostinil Palmitil Inhalation Powder in Participants with Pulmonary Hypertension	Dr. Lutz Beckert	11/04/2023	19/04/2023	Provisionally Approved	Approved	24/04/2023	Te Whatu Ora locality, Tertiary Education Institution	PPD part of Thermo Fisher Scientific	Insmed Incorporated

	Associated with Interstitial Lung Disease									
2023 FULL 13872	Approach: A Phase 2b, Multicenter, Double-Blind, Randomized, Placebo-controlled Trial evaluating Efficacy and Safety of Subcutaneous Doses of TransCon CNP Administered Once Weekly for 52 Weeks in Children with Achondroplasia followed by an Open Label Extension period	Dr. Paul Hofman	16/02/2023	23/02/2023	Provisionally Approved	Approved	24/02/2023	Private Organisation, Tertiary Education Institution	Pharmaceutical Solutions Ltd	Ascendis Pharma Growth Disorders
2022 FULL 13536	Assessing the effects of LSD microdosing in patients with major depressive disorder (LSDDEP)	Associate Professor Suresh Muthukumaraswamy	15/11/2022	6/12/2022	Provisionally Approved	Approved	14/12/2022	Tertiary Education Institution	The University of Auckland	
2023 EXP 13772	Assessment of colonization and skin quality parameter improvement by probiotic Micrococcus luteus Q24 balm in healthy adults.	Dr Rohit Jain	2/02/2023	3/02/2023	Provisionally Approved	Approved	7/02/2023	Private Organisation	Blis Technologies	
2022 FULL 12766	B9991046 (Sub-Study B9991001C) AN OPEN-LABEL STUDY FOR CONTINUED TREATMENT ACCESS FOR	Dr Peter Fong	26/07/2022	9/08/2022	Approved NSC	Approved	16/08/2022	Te Whatu Ora locality	Pfizer Australia Pty Ltd	Pfizer Italia srl
2022 FULL 13318	BIO CONCEPT.Amvia Study - First in Human study for the Amvia/Solvia pacemaker family	Cardiologist Ian Crozier	7/11/2022	12/12/2022	Provisionally Approved	Approved	14/12/2022	Te Whatu Ora locality		Biotronik Australia Pty Ltd
2023 FULL 13541	Biophysical and environmental predictors of asthma exacerbations: a prospective observational study	Dr Amy Chan	27/01/2023	8/02/2023	Provisionally Approved	Approved	13/02/2023	Primary Health Care Centre, Te Whatu Ora locality	The University of Auckland	
2023 FULL 14014	C4781004 - A PHASE 3, RANDOMIZED, OBSERVER-BLINDED	Dr Claire Thurlow	12/01/2023	14/02/2023	Approved NSC	Approved	2/03/2023	Other, Private Organisation	Pfizer New Zealand Limited	Pfizer Inc.

	STUDY TO EVALUATE THE EFFICACY, SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF A MODIFIED RNA VACCINE AGAINST INFLUENZA COMPARED TO LICENSED INACTIVATED INFLUENZA VACCINE IN HEALTHY ADULTS 18 YEARS OF AGE OR OLDER									
2023 FULL 15361	Casting a long shadow: H. pylori prevalence in Aotearoa New Zealand	Associate Professor James Stanley	1/06/2023	6/06/2023	Provisionally Approved	Approved	13/06/2023	Other	University of Otago	
2023 EXP 18068	Clinical and histological diversity in hyperkeratotic flexural erythema "beyond granular parakeratosis?"	Dr Anna Luo	23/06/2023	17/07/2023	Provisionally Approved	Declined	7/08/2023			
2022 FULL 12829	Clinical Evaluation of The BD Veritor [®] At-Home COVID-19 & Flu Test and BD Veritor [®] System for Rapid Detection of SARS-CoV-2 & Flu A+B Assay	Dr Penny Montgomery	30/06/2022	20/07/2022	Provisionally Approved	Approved	20/07/2022	Private Organisation		Becton Dickinson Limited, Becton Dickinson Limited
2022 FULL 13418	Comparative evaluation of pain among the patient treated with different available external splintage device for simple wrist fracture during the first two week of splintage	Dr Pranesh Kumar	30/08/2022	13/09/2022	Declined	Declined	29/09/2022	Primary Health Care Centre		
2022 EXP 13063	Conceptualising factors contributing to positive relationships between Disabled Support Workers and Disabled People in Canterbury	Dr John Bourke	16/09/2022	22/09/2022	Provisionally Approved	Approved	29/09/2022	Other		

2022 FULL 12683	Counting Ourselves 2022: The Aotearoa New Zealand Trans and Non-Binary Health Survey	Dr Jaimie Veale	31/07/2022	15/08/2022	Provisionally Approved	Approved	15/08/2022	Other		
2023 FULL 15177	Decreasing Postoperative Blood Loss by Topical vs. Intravenous Tranexamic Acid in Open Cardiac Surgery (DEPOSITION) Trial	Dr Shay McGuinness	15/05/2023	18/05/2023	Provisionally Approved	Approved	19/05/2023	Te Whatu Ora locality		Hamilton Health Sciences Corporation
2022 FULL 12612	Defining the auditory and vestibular phenotype of a novel COCH gene variant.	Dr Rachael Taylor	24/08/2022	7/09/2022	Provisionally Approved	Approved	8/09/2022	Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland Department of Ethics and Integrity	
2022 FULL 12931	Diabetes in pregnancy: Routine screening for placental insufficiency using the sFlt-1/PIGF ratio	Dr Ruth Hughes	6/07/2022	13/07/2022	Provisionally Approved	Approved	14/07/2022	Te Whatu Ora locality		
2023 EXP 15196	Effect of asymmetric nasal high flow therapy on nasal patency in healthy adults	Dr Matthew Barnes	22/06/2023	5/07/2023	Provisionally Approved	Approved	5/07/2023	Tertiary Education Institution	Massey University	
2022 EXP 12905	Effect of Curcumin-Fortified Whey Protein Beverage and Strength Training on Physical Performance in Older Adults	Miss Krutika Nanavati	20/07/2022	23/07/2022	Provisionally Approved	Approved	26/07/2022	Other		
2022 EXP 11720	Effect of Curcumin-Fortified Whey Protein Beverage on Antioxidant Capacity and Exercise-Induced Muscle Damage in Older Adults	Miss Krutika Nanavati	15/08/2022	26/08/2022	Provisionally Approved	Approved	31/08/2022	Tertiary Education Institution		
2023 FULL 13944	Effectiveness of intensive, app-based swallowing skill rehabilitation vs. usual dysphagia management for post-stroke dysphagia	PhD student Ruth FLYNN	23/06/2023	11/07/2023	Provisionally Approved	Provisionally Approved		Primary Health Care Centre, Te Whatu Ora locality	The University of Canterbury Rose Centre for Stroke Recovery and Research	

	in hospital and community settings: A Randomized Controlled Trial.									
2023 FULL 15109	Endoscopic Anti-Reflux Mucosal Ablation versus Nissen Fundoplication for Refractory Reflux: a blinded randomised control trial	Doctor Cameron Schauer	1/04/2023	26/04/2023	Provisionally Approved	Approved	28/04/2023	Te Whatu Ora locality	Te Whatu Ora	
2023 EXP 15339	Epidemiology of invasive Streptococcus pneumoniae, Neisseria meningitidis, Staphylococcus aureus, and Streptococcus pyogenes in tamariki and rangatahi under 25 years in Aotearoa New Zealand, 2016-2023	Dr Cameron Burton	24/05/2023	16/06/2023	Approved NSC	Approved	16/06/2023		Head of Department of Paediatrics	
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	12/07/2022	Approved NSC	Approved	14/07/2022	Te Whatu Ora locality		W. L. Gore & Associates, Inc.
2022 FULL 12924	Fatigue after Infusion or Transfusion (FIT) Pilot Trial and Feasibility Study	Associate Professor Katie Groom	5/08/2022	26/08/2022	Provisionally Approved	Approved	29/08/2022	Te Whatu Ora locality	Liggins Institute, University of Auckland	
2023 EXP 18255	Feel Good Study - Effects of increased fruit and vegetable intake on mental well-being and cognitive function in children: A pilot/feasibility Study.	Dr Nicola Gillies	22/06/2023	11/07/2023	Approved NSC	Approved	24/07/2023	Other	University of Auckland, Ethics and Integrity Department	
2023 EXP 16642	Function of lactic acid bacteria to support health study.	Dr Rebecca Slykerman	17/05/2023	24/05/2023	Provisionally Approved	Approved	28/05/2023	Other	The University of Auckland	
2023 EXP 17955	GLOBE: Effects of a glucoraphanin-containing vegetable soup on the	Dr Farha Ramzan	22/05/2023	20/06/2023	Provisionally Approved	Approved	31/07/2023	Tertiary Education Institution	University of Auckland	

	composition and functional activities of blood extracellular vesicles									
2022 EXP 11434	Hauora Manawa mō ngā• Kaumātua me Wānau/Heart Health in Kaumātua and Whānau	Dr Andree Pearson	10/11/2022	13/12/2022	Approved NSC	Approved	23/12/2022	Other, Tertiary Education Institution	Research and Enterprise, University of Otago	
2022 EXP 12827	HPV Technology Validation study for processing self-collected swab samples	Dr Margaret Sage	5/10/2022	11/10/2022	Provisionally Approved	Approved	11/10/2022	Private Organisation, Te Whatu Ora locality	NCSP	
2023 FULL 13807	Improving Care in Rural and URgent care centres for patients with possible Acute coronary syndrome using the Latest Point-of-Care technology	Dr Rory Miller	28/04/2023	13/06/2023	Approved NSC	Approved	30/06/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	University of Otago	
2022 FULL 13343	Improving Genomic Diagnosis for Tamariki	Professor Stephen Robertson	29/09/2022	11/10/2022	Provisionally Approved	Approved	21/12/2022	Te Whatu Ora locality	University of Otago	
2023 EXP 17867	Improving nutrition delivery in acute and chronic diseases: A pilot volunteer study	Professor John Windsor	22/05/2023	19/06/2023	Provisionally Approved	Declined	31/07/2023	Tertiary Education Institution	The University of Auckland	
2023 EXP 13982	Improving Psychosocial Outcomes for Adolescents and Young Adults with Type 1 Diabetes: A Feasibility Study of the LIFT App	Senior Lecturer in Health Psychology Anna Serlachius	8/03/2023	3/04/2023	Provisionally Approved	Approved	24/04/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Auckland	
2023 EXP 16691	Improving the engagement of patients with low back pain to education and exercise advice to reduce recurrence	Dr Paul Marshall	26/06/2023	19/07/2023	Provisionally Approved	Approved	11/08/2023	Private Organisation	NZ Chiropractic College	
2023 EXP 15266	Incidence and outcomes of all-terrain vehicles injuries in Aotearoa New Zealand	Mr Nejo Joseph	22/04/2023	11/05/2023	Approved	Approved	12/05/2023			
2023 EXP 15582	Intergenerational Conflict in immigrant Chinese families in New Zealand:	Dr Richard Yu	24/04/2023	9/05/2023	Provisionally Approved	Provisionally Approved		Primary Health Care Centre, Te		

	A Qualitative Study of Mental Health Service Users							Whatu Ora locality		
2022 EXP 13381	Invasive non-Aspergillus mould (NAM) infections: a multi-centre observational study	Dr Rebekah Lane	18/09/2022	29/09/2022	Approved	Approved	3/10/2022			
2023 FULL 12591	Investigating Autoimmune Encephalitis in New Zealand	Dr Hannah Jones	19/09/2022	4/10/2022	Provisionally Approved	Approved	9/03/2023	Te Whatu Ora locality		
2023 EXP 14026	Investigating the differential effects between a blackcurrant oral-rinse and ingested juice on platelet MAO-B activity, circulating metabolites, cognition and mood.	Ms Nayer Ngametua	21/02/2023	22/03/2023	Provisionally Approved	Approved	3/05/2023	Other, Private Organisation, Tertiary Education Institution	The New Zealand Institute of Plant & Food Research Ltd.	
2023 FULL 13860	Investigating the effect of heat-inactivated Lactobacillus gasseri CP2305 on sleep, stress and gastrointestinal health in adults with insomnia and elevated stress levels: a randomised, controlled trial	Dr Jody Miller	29/11/2022	13/12/2022	Provisionally Approved	Approved	13/02/2023	Tertiary Education Institution		Asahi Quality and Innovations Ltd
2023 EXP 15505	Investigating the efficacy of supplementation with a proprietary dairy powder in supporting muscle recovery following exercise-induced muscle damage in healthy individuals	Dr Dominic Lomiwes	6/03/2023	27/03/2023	Provisionally Approved	Approved	24/04/2023	Other	The New Zealand Institute for Plant and Food Research Ltd.	
2022 FULL 13168	LATA-CS102: An open label, comparative, sequential-dose, multi-centre study involving intracameral administration of a PA5108 Latanoprost FA SR Ocular Implant into	Prof Anthony Wells	30/08/2022	13/09/2022	Provisionally Approved	Approved	14/12/2022	Private Organisation	Novotech (New Zealand) Limited	PolyActiva

	the eyes of patients with mild-moderate glaucoma.									
2022 EXP 12227	Māori and Pacific women's pre-diagnostic experiences of uterine cancer	Dr Georgina McPherson	20/07/2022	25/08/2022	Approved NSC	Approved	26/08/2022	Other, Primary Health Care Centre, Te Whatu Ora locality	Te Whatu Ora/Health New Zealand - Waitematā district	
2023 FULL 13454	Māori approaches to communication support: Living well with mate wareware (dementia)	Miss Megan Eustace	18/04/2023	9/05/2023	Provisionally Approved	Approved	17/08/2023	Other, Te Whatu Ora locality, Tertiary Education Institution	University of Canterbury (School of Psychology, Speech and Hearing)	
2023 EXP 16771	Measuring the skin metabolome to determine menopause status	Dr Geraldine McLeod	9/05/2023	31/05/2023	Provisionally Approved	Approved	18/08/2023	Private Organisation	Director Research and Enterprise	
2023 FULL 17925	MK-0616-017: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of MK-0616 in Adults With Heterozygous Familial Hypercholesterolemia	Dr Rosamund Carey	25/05/2023	13/06/2023	Provisionally Approved	Provisionally Approved		Private Organisation	Merck Sharp & Dohme (New Zealand) Ltd a subsidiary of Merck & Co., Inc., Rahway, NJ, USA	
2022 EXP 11759	National investigation of incidence, associations and implications of prolonged length of stay in the post anaesthetic care unit (PACU).	Dr Timothy Starkie	15/08/2022	7/09/2022	Approved	Approved	9/09/2022			
2022 FULL 13712	NEOLEV3: A Phase IIb Dose Escalation Study of Levetiracetam in the Treatment of Neonatal Seizures	Doctor Cynthia Sharpe	27/10/2022	8/11/2022	Approved NSC	Approved	15/11/2022	Te Whatu Ora locality		University of Minnesota School of Medicine
2023 FULL 13574	New Techniques to Understand the Development of Diabetic Kidney Disease Amongst Māori and Pasifika	Associate Professor John Baker	8/06/2023	11/07/2023	Provisionally Approved	Provisionally Approved		Tertiary Education Institution	Middlemore Hospital	
2023 FULL 13901	Novel approaches for the chemoprevention of high-risk breast cancer	Dr George Wiggins	27/06/2023	9/05/2023	Provisionally Approved	Approved	11/07/2023	Tertiary Education Institution	University of Otago	

2023 EXP 13401	Perioperative Management of New Antiplatelet Agents in patients presenting for Ophthalmic Surgery: a Retrospective Observational Cohort Study	Dr Phil Guise	3/05/2023	28/05/2023	Provisionally Approved	Provisionally Approved	25/08/2023		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland	
2022 FULL 13579	Phase 3 Multi-Center, Randomized, Double-Blind, Study to Assess the Efficacy and Safety of Treatment with Bepirovirsen in HBeAg negative Nucleos(t)ide Analogue treated Participants with Chronic Hepatitis B Virus (B-Well 2)	Professor Edward (Ed) Gane	28/09/2022	11/10/2022	Provisionally Approved	Approved	23/12/2022	Te Whatu Ora locality		GSK
2022 FULL 13814	Pilot Evaluation of the ENIVO System in Simple Unilateral Mastectomy	Dr Michelle Locke	29/11/2022	13/12/2022	Approved NSC	Approved	23/12/2022	Te Whatu Ora locality	Aroa Biosurgery Ltd	
2023 FULL 17890	Prophylaxis Against Early Ventilator Associated Lower Respiratory Tract Infection	Prof Paul Young	25/06/2023	11/07/2023	Provisionally Approved	Approved	24/07/2023	Te Whatu Ora locality	Medical Research Institute of New Zealand	
2023 EXP 15394	Quality of life and Experiences of Sarcoma Trajectories: A longitudinal cohort study that aims to gain insight into the diagnostic pathway for sarcoma patients in order to help improve this pathway and the outcomes for patients in the future.	Doctor Joanna Connor	23/03/2023	15/04/2023	Provisionally Approved	Approved	15/05/2023	Te Whatu Ora locality		Australia and New Zealand Sarcoma Association (ANZSA)
2023 FULL 18002	Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of SPR001 (Tildacerfont) in Reducing Supraphysiologic Glucocorticoid Use in Adult Subjects with	Dr Simon Young	31/05/2023	13/06/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Clinical and Regulatory Services (CARLS) Consulting	Spruce Biosciences, Inc

	Classic Congenital Adrenal Hyperplasia (SPR001-204)									
2022 FULL 12929	Rapua te mea ngaro ka tau: Facilitating Strep A vaccine development for Aotearoa, New Zealand	Dr Anneka Anderson	6/07/2022	11/07/2022	Provisionally Approved	Approved	4/08/2022	Other, Primary Health Care Centre		
2023 EXP 14058	Remote or in-clinic: the effect of service delivery mode on hearing aid output: study protocol for a double-blinded, randomized trial of adults with slight to moderate sensorineural hearing loss.	Mr Craig Lett	13/04/2023	11/05/2023	Approved NSC	Approved	12/05/2023	Private Organisation, Tertiary Education Institution	University of Auckland	
2022 FULL 11306	SeaLAND: An ALLG phase 3 randomised trial of Selinexor and Lenalidomide versus Lenalidomide maintenance post Autologous Stem Cell Transplant for patients with Newly Diagnosed Multiple Myeloma	Dr Lauren Child	30/06/2022	12/07/2022	Approved NSC	Approved	14/07/2022	Te Whatu Ora locality		Australasian Leukaemia and Lymphoma Group
2022 FULL 13345	Study of Safety, Tolerability and Effects of CST-2032 and CST-107 on Cognition in Subjects with Mild Cognitive Impairment or Mild Dementia due to Parkinson's or Alzheimer's Disease	Prof Tim Anderson	29/08/2022	13/09/2022	Provisionally Approved	Approved	26/10/2022	Private Organisation	Research Associates Ltd	CuraSen Therapeutics, Inc
2023 EXP 16718	The Australia and New Zealand Multicentre Upper Gastrointestinal Endoscopic Tissue Resection Study	Dr Cameron Schauer	27/04/2023	21/05/2023	Approved NSC	Approved	22/05/2023	Te Whatu Ora locality	Te Whatu Ora - Waitemata	
2023 FULL 12278	The effectiveness of bioimpedance analysis in determining appropriate surgical antibiotic	A/Professor Joe Baker	28/02/2023	14/03/2023	Provisionally Approved	Approved	17/05/2023	Private Organisation, Te Whatu Ora locality		

	prophylactic dosing in cervical spine surgery									
2022 EXP 12243	The impact of geographical mobility on ethnic Chinese in accessing mental healthcare services in Aotearoa/New Zealand.	Dr Katherine Helen Hall	8/09/2022	14/09/2022	Approved NSC	Approved	20/09/2022	Other		
2022 EXP 11947	The Long-term Outcomes of Lidocaine Infusions for Post-Operative Pain Trial - The LOLIPOP Trial.	Dr Robyn Billing	7/11/2022	13/12/2022	Approved NSC	Approved	23/12/2022	Te Whatu Ora locality	ADHB	Monash University
2022 EXP 13234	Ultrasound assessment of the median nerve in carpal tunnel syndrome	Dr Luke Curwell	3/10/2022	5/11/2022	Provisionally Approved	Approved	21/11/2022	Te Whatu Ora locality	Waikato Hospital	
2023 EXP 15604	Understanding Measles Severity and Sequelae	Dr Emma Best	21/03/2023	12/04/2023	Approved NSC	Approved	14/04/2023			
2022 EXP 12337	Vaccine Barriers Assessment Tool â€” Phase II: Model and Test Items	Professor Nikki Turner	19/05/2022	17/06/2022	Provisionally Approved	Approved	26/07/2022	Other, Primary Health Care Centre		
2023 FULL 13996	Validation of Age and Stages ASQ: Ao: Aotearoa cultural and linguistic adaptation	Dr Alison Leversha	16/04/2023	9/05/2023	Provisionally Approved	Approved	13/06/2023	Te Whatu Ora locality		
2023 EXP 13310	Vestibular stimulation to enhance postural control in people with bilateral vestibulopathy	Professor Denise Taylor	11/05/2023	7/06/2023	Provisionally Approved	Approved	10/07/2023	Private Organisation, Tertiary Education Institution	Auckland University of Technology	
2023 EXP 13841	Whitu For Schools: Randomised controlled trial of an app for improving the well-being of high school students in Aotearoa	Dr Hiran Thabrew	30/11/2022	13/12/2022	Provisionally Approved	Declined	14/04/2023	Other	University of Auckland	
2023 EXP 17847	Whitu For Schools: Randomised controlled trial of an app for improving the well-being of high school students in Aotearoa	Dr Hiran Thabrew	27/04/2023	9/05/2023	Provisionally Approved	Approved	26/06/2023	Other	University of Auckland	

2022 FULL 12479	Youth Primary Mental Health and Addiction Services Value for Investment evaluation	Dr Adrian Field	25/04/2022	12/05/2022	Provisionally Approved	Approved	13/07/2022	Other, Private Organisation, Te Whatu Ora locality	Ministry of Health - Manat� Hauora	
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