



**Health and
Disability Ethics
Committees**

**Northern A 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 Northern A 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 Northern A 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 Northern A 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 Northern A HDEC is registered (number IRB00008714) 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

As the Chair of Northern A HDEC for the year ending June 2023, I am pleased to present this Annual Report summarising the work of the Committee. The Committee reviewed a total of 89 applications at full committee meetings. 253 submissions for amendment to previously approved studies were processed through the expedited pathway. In addition, any applications that were reviewed at extra full meetings arranged for high volumes of submissions were assigned to the Northern A HDEC for post-approval monitoring.

Northern A has functioned in accordance with the HRCEC's expectations for proper process and membership, the Guidelines for the Approval of Ethics Committees, and HDECs Standard Operating Procedures.

Over the past reporting year, Northern A has enjoyed full membership and consistently good attendance, co-opting members from other committees when required. Northern A members have supported the other HDECs by regularly providing member support for meetings. While in my experience there are benefits in participating in a different committee, it does pose a burden on the Secretariat and those who are co-opted and maintaining a full complement of members is important. Fortunately, the Chairs are seldom unavailable, but this arises from a concerted effort to attend given the desire not to burden other Chairs and the inability to internally co-opt a member to assume the role for whole or part of a meeting. Provision for this would be helpful.

All Northern A meetings are held by Zoom. Applicants attend for a pre-determined half-hour slot, allowing for some flexibility for investigators with clinical commitments to request a time. This generally works smoothly, and remote meetings enable representatives of international sponsors to attend, which is increasingly common. There is some room for improvement with how the committees are to manage the situation where a researcher does not respond to requests to confirm attendance or simply does not join the meeting at their allotted time. When this occurs, there is little flexibility for the Committee to rearrange other applications; it would be helpful to be able to treat non-responders as inevitably to be dealt with on the papers, and slotted into the agenda accordingly. I would certainly encourage attendance as the standard expectation.

The number of applications considered at each meeting fluctuates; any more than eight is difficult particularly by Zoom but that number is exceeded from time to time. The filing of applications with very extensive documentation for review is becoming more prevalent (a recent example is three applications with each having in excess of 90 documents for review). Work may be done on further streamlining the process of what documents are required for review and how these can be presented to best respect the time of Committee members.

The Committee would be assisted by improved sharing of information by other committees that operate in parallel (in particular SCOTT, GTAC) given the significance of their decision making and any recommendations made.

The Chairs continue to meet by Zoom regularly, and these discussions are valuable for highlighting common issues, potential developments and areas for vigilance, sharing guidance on non-study specific matters. These meetings are also a valuable forum for sharing current literature or developments in the ethics space. It would be a positive step if the importance of maintaining and improving skills in this area was factored into the ability to claim rather than for time spent on specific studies.

After a hiatus, in-person training is scheduled for December 2023 which will be a highly valuable experience for all members, both in terms of the education and training content, and personal connections.

The Secretariat continues to provide excellent support. The ERM platform is well and truly bedded in, with amendments made responsively when possible. Liaison by the

Secretariat between researchers and Chairs appears to be positive, and efforts are made for practical and ethical outcomes to issues raised.

I express my gratitude to all members and staff of the HDEC Secretariat for their hard work and support of me in my capacity as Chair, to non-lay members of other Committees who regularly assist me with post approval reviews. It is my pleasure to serve as the Chair of Northern A and I look forward to the coming year.

Catherine Garvey

Chair – Northern A 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	1
No. of applications approved subject to conditions / pending at first review (Non-standard conditions or NSC)	29
No. of applications deferred (provisionally approved) at first review and subsequently approved	28
No. of applications deferred as at time of report	12
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.)	17
<i>No. of applications which do not require ethics committee approval (across all four Committees, expedited and full combined)</i>	676
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	89

The Northern A Committee does not currently review Expedited applications.

Total number of applications received:

89

Complaints and overdue application summary

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

Complaints received

No complaints were received during the reporting period regarding any Northern A 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.

Target timeframe for expedited applications is 15 calendar days. ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 9-102). The Secretariat notes that due to member availability, the Northern A Committee does not perform expedited review of applications.

Average review time was 20 days for full applications. Target timeframe for full applications is 35 days. ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 54-59)

Appendix 1: Details of applications reviewed¹

Applications reviewed by the 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)
2023 FULL 13403	A feasibility study of non-invasive auricular vagus nerve stimulation in people with rheumatoid arthritis.	Mr Ankit Parimal Parikh	1/05/2023	16/05/2023	Declined	Declined	30/05/2023	Te Whatu Ora locality	Exsurgo Ltd	
2022 FULL 12102	A Multicenter, Single-Arm, Open-Label, Extension, Rollover Study To Evaluate The Long-Term Safety and Efficacy of Ocrelizumab In Patients With Multiple Sclerosis	Doctor Kurien Koshy	26/07/2022	1/08/2022	Provisionally Approved	Approved	4/08/2022	Te Whatu Ora locality		IQVIA RDS PTY LTD
2022 FULL 12656	A Non-randomised Comparative Phase II Trial To Determine The Benefit Of Continuous Positive Airway Pressure (CPAP)-Assisted Radiotherapy Vs Deep Inspiration Breath Hold (DIBH) In Breast Cancer And In Lung & Liver Stereotactic Ablative Body Radiotherapy (SABR)	Dr Ken Rantshilane	31/10/2022	1/01/2023	Provisionally Approved	Approved	10/01/2023	Te Whatu Ora locality		
2022 FULL 13049	A Phase 1 Randomized, Double Blinded, Placebo Controlled, Ascending Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of Single Doses of ARCT-	Principal Investigator Mark Marshall	24/11/2022	8/12/2022	Approved NSC	Approved	16/12/2022	Private Organisation	Novotech	Arcturus Therapeutics, Inc.

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

	032 in Healthy Adult Subjects									
2022 FULL 13295	A Phase 1, Blinded, Placebo-controlled Study of the Safety, Tolerability, and Pharmacokinetics of Single- and Multiple-Ascending Doses of ABI-4334 in Healthy Subjects	Prof. Edward Gane	5/09/2022	20/09/2022	Approved NSC	Approved	30/09/2022	Private Organisation	PPD	Assembly Biosciences, Inc
2023 FULL 15637	A phase 1, prospective study to compare safety, tolerability, biodistribution and pharmacokinetics of a single dose of 89Zr-DFO- girentuximab with the antibody produced by ADRM-free adapted cell lines or original cell lines in patients with indeterminate renal masses.	Dr Andrew Williams	30/03/2023	18/04/2023	Approved NSC	Approved	8/05/2023	Private Organisation	Telix Pharmaceuticals (NZ) Ltd	Telix International Pty Ltd
2023 FULL 13992	A Phase 1, Randomized, Double-blind, Placebo-controlled, Single Ascending Dose Study of Subcutaneously and Intravenously Administered ALXN1920 in Healthy Adult Participants	Principal Investigator Christian Schwabe	3/02/2023	21/02/2023	Approved NSC	Approved	8/03/2023	Private Organisation	Parexel International, Decentralised	Alexion Pharmaceuticals, Inc.
2023 FULL 15408	A Phase 1, Single and Multiple Ascending Dose and Food Effect Study of NEU-411 Administered Orally to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Subjects	Principal Investigator Christopher John Wynne	7/03/2023	21/03/2023	Approved NSC	Approved	3/04/2023	Private Organisation	PPD, Part of Thermo Fisher Scientific	Neuron23, Inc.
2022 FULL 13730	A Phase 1/2a, Randomized, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of BJT-	Prof. Edward Gane	2/11/2022	15/11/2022	Approved NSC	Approved	18/11/2022	Private Organisation	Novotech (New Zealand) Limited	Bluejay Therapeutics

	778 in Healthy Volunteers and in Subjects With Chronic Hepatitis B Infection, Including Subjects With Chronic Hepatitis D Infection									
2022 FULL 13504	A Phase 1a/1b Study to Evaluate the Safety and Tolerability of Repeated Doses of Nonreplicating Arenavirus Vector Therapeutic Vaccines GS-2829 and GS-6779 in Healthy Participants and Participants With Chronic Hepatitis B (CHB)	Professor Edward Gane	5/10/2022	18/10/2022	Approved NSC	Approved	3/11/2022	Private Organisation	Gilead Sciences (Australia)	Gilead Sciences
2022 FULL 13875	A Phase 2a Study Evaluating the Safety, Tolerability, and Efficacy of TLC-3595 in Subjects with Insulin Resistance	Professor Russell Scott	24/11/2022	8/12/2022	Approved NSC	Approved	16/12/2022	Private Organisation	Infinity Consulting Ltd	OrsoBio, Inc.
2023 FULL 13557	A Phase 2b Randomized, Double-blind, Active- and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Induction and Maintenance Combination Therapy with Guselkumab and Golimumab in Participants with Moderately to Severely Active Crohn's Disease	Dr Di Jiang	9/06/2023	3/07/2023	Provisionally Approved	Approved	5/07/2023	Te Whatu Ora locality		Parexel International
2022 FULL 13898	A Phase 3, Randomized, Double-blind, Active Comparator-controlled Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in Pneumococcal Vaccine-naïve Adults 18 to 64 years of Age	Dr Jackie Kamerbeek	21/12/2022	9/01/2023	Provisionally Approved	Approved	10/01/2023	Private Organisation	Merck Sharp & Dohme (New Zealand) Ltd a subsidiary of Merck & Co., Inc., Rahway, NJ, USA	

	With Increased Risk for Pneumococcal Disease									
2023 FULL 15351	A Phase 3, Randomized, Double-Blind, Double-Dummy, Parallel Group, Active-Controlled Study to Evaluate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, Versus Apixaban in Participants with Atrial Fibrillation LIBREXIA-AF	Dr Martin Stiles	7/06/2023	14/06/2023	Provisionally Approved	Approved	15/06/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	IQVIA RDS Pty Limited	IQVIA
2023 FULL 16790	A Phase 3, Randomized, Double-Blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With High-Risk Stage II-IV Melanoma	Dr Gareth Rivalland	11/05/2023	30/05/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Merck Sharp & Dohme (Australia) Pty Ltd (MSD), Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD)	Merck Sharp & Dohme (Australia) Pty Ltd (MSD)
2022 FULL 12179	A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study of Upifitamab Rilsodotin (XMT-1536) as Post-Platinum Maintenance Therapy for Participants with Recurrent, Platinum-Sensitive Ovarian Cancer (UP-NEXT)	Dr Michelle Wilson	3/11/2022	15/11/2022	Approved NSC	Approved	18/11/2022	Te Whatu Ora locality		Mersana Therapeutics
2023 FULL 13881	A Phase 3, 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	Dr Melissa Haines	12/01/2023	18/01/2023	Provisionally Approved	Approved	19/01/2023	Primary Health Care Centre, Private Organisation		Janssen Research & Development

	Severely Active Ulcerative Colitis									
2023 FULL 16773	A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Efficacy and Safety of Upadacitinib in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa Who Have Failed Anti-TNF Therapy	Dr Marius Rademaker	15/06/2023	8/07/2023	Provisionally Approved	Approved	10/07/2023	Private Organisation, Te Whatu Ora locality	AbbVie Ltd	AbbVie Ltd
2023 FULL 15596	A PHASE Ib/II, OPEN-LABEL, MULTICENTER, RANDOMIZED PLATFORM STUDY EVALUATING THE EFFICACY AND SAFETY OF NEOADJUVANT IMMUNOTHERAPY COMBINATIONS IN PATIENTS WITH SURGICALLY RESECTABLE HEPATOCELLULAR CARCINOMA (MORPHEUS-NEO HCC)	Professor Edward Gane	11/05/2023	30/05/2023	Provisionally Approved	Approved	20/07/2023	Te Whatu Ora locality	Labcorp New Zealand Limited	Genetech
2022 FULL 12644	A Phase IIb/III, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of cotadutide in participants with non-cirrhotic non-alcoholic steatohepatitis with fibrosis (PROXYMO-ADVANCE)	Dr David Orr	4/08/2022	22/08/2022	Provisionally Approved	Approved	22/08/2022	Private Organisation, Te Whatu Ora locality		AstraZeneca Pty Ltd
2023 FULL 15613	A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY EVALUATING ATEZOLIZUMAB AND BEVACIZUMAB, WITH OR WITHOUT	Professor Edward Gane	18/05/2023	30/05/2023	Approved NSC	Approved	13/06/2023	Te Whatu Ora locality		Roche Products (New Zealand) Limited

	TIRAGOLUMAB, IN PATIENTS WITH UNTREATED LOCALLY ADVANCED OR METASTATIC HEPATOCELLULAR CARCINOMA									
2022 FULL 12729	A pivotal in vivo bioequivalence study comparing methylprednisolone aceponate ointment (Nova Chem, Australia) to Advantan® ointment (Leo Pharma Pty Ltd, Australia), using the ED50 for Advantan® ointment calculated from the pilot dose duration-response study and using 90 responders with the expectation to have 40-60 subjects who meet the responder and detector criteria (â€œevaluableâ€•).	Dr Noelyn Hung	8/09/2022	20/09/2022	Approved NSC	Approved	30/09/2022	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd
2022 FULL 13020	A pivotal, prospective, multi-centre, randomised control, blinded study evaluating the efficacy of a dexamethasone eluting Slim Modiolar electrode (CI632D) in the reduction of fibrosis as compared to a standard Slim Modiolar electrode (CI632) in a newly implanted adult population with bilateral, post-linguistic, moderate to profound sensorineural hearing loss.	Associate Professor Holly Teagle	5/08/2022	18/08/2022	Provisionally Approved	Approved	22/08/2022	Private Organisation		Cochlear Limited
2022 FULL 13331	A randomised controlled trial of budesonide-formoterol vs terbutaline for symptom relief in adults with mild-moderate ASTHMA on	Professor Richard Beasley	5/10/2022	18/10/2022	Approved NSC	Approved	3/11/2022	Primary Health Care Centre, Private Organisation	Medical Research Institute of New Zealand	

	inhaled corticosteroid maintenance therapy									
2022 FULL 12486	A Randomised, double-blinded phase II study of gemcitabine and nab-paclitaxel with CEND-1 or placebo in patients with untreated metastatic pancreatic ductal adenocarcinoma	Dr Jane Yeojeong So	4/11/2022	17/11/2022	Provisionally Approved	Approved	18/11/2022	Te Whatu Ora locality		Australasian Gastro-Intestinal Trials Group
2023 FULL 12900	A Randomized Open-Label Phase 3 Study of XL092 + Atezolizumab vs Regorafenib in Subjects with Metastatic Colorectal Cancer	Dr Anne O'Donnell	3/03/2023	6/03/2023	Provisionally Approved	Approved	21/03/2023	Te Whatu Ora locality	Pharmaceutical Research Associates New Zealand Limited	Exelixis Inc
2022 FULL 13450	A randomized, cross-over, non-inferiority study comparing the Fisher and Paykel Airvo 3 non-invasive ventilator device to a commercially available device in patients with resolved acute hypercapnic respiratory failure.	Dr Louis Kirton	4/10/2022	18/10/2022	Approved NSC	Approved	2/11/2022	Te Whatu Ora locality	Fisher and Paykel Healthcare	
2022 FULL 13608	A RANDOMIZED, DOUBLE-BLIND, ACTIVE-CONTROLLED, PHASE I CLINICAL STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF A COVID-19 mRNA VACCINE (IN002.5.1) IN COMPARISON WITH AN APPROVED mRNA BOOSTER VACCINE FOR COVID-19 IN POPULATION ≥ 18 YEARS OF AGE	Dr Cory Sellwood	2/11/2022	15/11/2022	Approved NSC	Approved	18/11/2022	Private Organisation	Syneos Health	Shenzhen Shenxin Biotechnology Co., Ltd
2022 FULL 13452	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Phase III Efficacy and	Dr Benjamin Griffiths	8/09/2022	20/09/2022	Approved NSC	Approved	30/09/2022	Te Whatu Ora locality		AstraZeneca Pty Ltd

	Safety Study of Tezepelumab in Patients with Eosinophilic Esophagitis (CROSSING)									
2023 FULL 15313	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of SPR001 (Tildacerfont) in Reducing Supraphysiologic Glucocorticoid Use in Adult Subjects with Classic Congenital Adrenal Hyperplasia	Doctor Simon Young	31/03/2023	18/04/2023	Declined	Declined	8/05/2023	Te Whatu Ora locality	Clinical and Regulatory Services (CARSL) Consulting	Spruce Biosciences, Inc.
2023 FULL 15306	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	Doctor Simon Young	31/03/2023	18/04/2023	Declined	Declined	8/05/2023	Te Whatu Ora locality	Clinical and Regulatory Services (CARSL) Consulting	Spruce Biosciences, Inc.
2022 FULL 12565	A Randomized, Double-blind, Placebo-controlled, Multinational, Phase 3 Study of the Efficacy and Safety of Inhaled Treprostinil in Subjects with Idiopathic Pulmonary Fibrosis (TETON-2).	Dr Michael Epton	1/07/2022	19/07/2022	Declined	Declined	28/07/2022	Private Organisation, Te Whatu Ora locality	PPD, Part of Thermo Fisher Scientific	United Therapeutics Corp.
2023 FULL 16692	A single dose, double-blind, balanced, randomised, two-treatment, two period, two sequence, two-way crossover pilot study comparing 1 x 370 mg Iron Polymaltose tablet (equivalent to 100 mg of elemental iron) with 1 x 370 mg Maltofer® tablet (equivalent to 100 mg of elemental iron) in iron deficient participants	Dr Noelyn Hung	30/03/2023	18/04/2023	Approved NSC	Approved	8/05/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd

	under fed conditions with diet control.									
2022 FULL 13517	A single-centre, controlled, within-patient, multi-period study to assess the non-inferiority and safety of the Airvo 3 Junior device to deliver variable-flow CPAP to premature infants requiring respiratory support.	Dr Bronwyn Dixon	7/09/2022	20/09/2022	Approved NSC	Approved	30/09/2022	Te Whatu Ora locality	Fisher & Paykel Healthcare	
2022 FULL 13045	A single-dose, blinded, balanced, randomised, two-treatment, two-period, two-sequence, bioequivalence study comparing 1 x 2.5 mg felodipine extended release tablet (Arrotex, Australia) in a 2 way crossover comparison with 1 x 2.5 mg Plendil® ER tablet (AstraZeneca, Australia) in healthy participants under fasting conditions.	Dr Noelyn Hung	4/08/2022	16/08/2022	Approved NSC	Approved	25/08/2022	Private Organisation	Zenith Technology Corporation Limited	Arrotex Pharmaceuticals Pty Ltd
2022 FULL 13229	A Single-Group Treatment, Phase 2a, Open-label, Single-Arm Study to Assess the Safety, Tolerability, and Pharmacodynamic Effect of Oral BRN-002 in Adult Participants with Coronary Artery Disease	Dr Richard Stubbs	7/11/2022	18/11/2022	Provisionally Approved	Approved	18/11/2022	Private Organisation	PPD part of Thermo Fisher	Beren Therapeutics, P.B.C
2022 FULL 13508	Advanced automated insulin delivery in children and young adults with type 1 diabetes and high-risk glycaemic control	A/Prof Ben Wheeler	8/12/2022	8/01/2023	Provisionally Approved	Approved	10/01/2023	Te Whatu Ora locality	University of Otago	
2022 FULL 12863	Advanced MR Imaging at MĀ• tai	Dr Daniel Cornfeld	30/06/2022	19/07/2022	Declined	Declined	28/07/2022	Other		
2022 FULL 12983	An Open-label Extension Study to Evaluate Long-term Efficacy and Safety	Dr Helen Evans	29/08/2022	9/09/2022	Provisionally Approved	Approved	12/09/2022	Te Whatu Ora locality	Syneos Health	Albireo AB

	of Odevixibat (A4250) in Children with Biliary Atresia									
2023 FULL 13909	An Open-label Extension Trial to Evaluate the Long-term Safety of KVD900, an Oral Plasma Kallikrein Inhibitor, for On-demand Treatment of Angioedema Attacks in Adolescent and Adult Patients with Hereditary Angioedema Type I or II.	Dr Anthony Jordan	6/06/2023	18/06/2023	Provisionally Approved	Approved	27/06/2023	Te Whatu Ora locality	PPD, part of Thermo Fisher Scientific	Kalvista Pharmaceuticals Ltd
2022 FULL 11630	ARROW " Assessing the Reduction of Recurrent admissions with OM-85 for preschool Wheeze	Professor Cameron Grant	3/10/2022	12/10/2022	Provisionally Approved	Approved	17/10/2022	Te Whatu Ora locality	The University of Auckland	Barwon Health/Deakin University
2022 FULL 12534	ASSURE: An Open Label Long-Term Study to Evaluate the Safety and Tolerability of Seladelpar in Subjects with Primary Biliary Cholangitis (PBC)	Dr Steven Johnson	6/07/2022	20/07/2022	Provisionally Approved	Approved	4/08/2022	Te Whatu Ora locality	PPD, part of Thermo Fisher Scientific	CymaBay Therapeutics, Inc.
2022 FULL 12524	Australia and New Zealand Liver and Intestinal Transplant Registry (ANZLITR)	Professor Ed Gane	1/07/2022	19/07/2022	Approved NSC	Approved	28/07/2022	Te Whatu Ora locality		Victorian Liver Transplant Unit, Austin Hospital
2023 FULL 17811	Carcinoma Prostate Treatment Outcomes Part 2: Quality of Life	Dr. Kamran Zargar-Shoshtari	28/04/2023	16/05/2023	Declined	Declined	30/05/2023	Tertiary Education Institution	University of Auckland	
2023 FULL 13812	Cognitive Improvement by early Restoration of circadian rhythms in very preterm Infants through Environmental Modification: The CIRCA DIEM Study	Dr Maria Saito-Benz	6/06/2023	20/06/2023	Declined	Declined	29/06/2023	Te Whatu Ora locality, Tertiary Education Institution		Telethon Kids Institute
2022 FULL 12295	Comparative evaluation of pain among the patient treated with different available external splintage device for simple wrist fracture	Dr Pranesh Kumar	4/07/2022	19/07/2022	Declined	Declined	28/07/2022	Primary Health Care Centre, Private Organisation		

	during the first two week of splintage									
2023 FULL 12788	Congenital Heart Alliance of Australia and New Zealand Congenital Heart Disease Registry and NZ Paediatric Heart Disease Registry	Dr Clare O'Donnell	23/03/2023	18/04/2023	Approved NSC	Approved	8/05/2023	Te Whatu Ora locality		
2022 FULL 12365	Does a marae-based clinic increase access to care for prevention of cervical cancer?	Dr Judy Ormandy	18/07/2022	26/07/2022	Provisionally Approved	Approved	1/08/2022	Te Whatu Ora locality	C&CDHB	
2022 FULL 12972	Early identification of children with disequilibrium	Dr Michael Maslin	29/07/2022	16/08/2022	Declined	Declined	25/08/2022	Other, Private Organisation, Te Whatu Ora locality	School of Psychology, Speech and Hearing, University of Canterbury	
2023 FULL 15406	Eat, Sleep, Play: Investigating nutrition and body composition in children with HĀ• kai Nukurangi - cerebral palsy	Dr Sian Williams	19/04/2023	8/05/2023	Provisionally Approved	Approved	11/05/2023	Te Whatu Ora locality	University of Auckland	
2023 FULL 15207	Equity in Employment: the (un)employment experiences of disabled people in Aotearoa New Zealand	Ms Angela Desmarais	1/05/2023	16/05/2023	Provisionally Approved	Provisionally Approved		Other, Private Organisation		
2022 FULL 13500	Examining Food Insecurity in a Regional New Zealand Emergency Department	Dr Stephanie Richling	11/10/2022	28/10/2022	Provisionally Approved	Approved	2/11/2022	Te Whatu Ora locality	Te Whatu Ora-Whangarei Hospital	
2023 FULL 15635	Feasibility Study of Electronic Implementation of Patient-Reported Outcome Measures (PROMs) in Routine Paediatric Diabetes Care	Assoc Prof Martin de Bock	29/06/2023	26/07/2023	Provisionally Approved	Approved	28/07/2023	Te Whatu Ora locality	The Clinician Ltd.	
2022 FULL 12190	Implementation of evidence-based, whaanau-focused care for acute rheumatic fever and chronic rheumatic	Dr Rachel Webb	6/07/2022	20/07/2022	Provisionally Approved	Approved	21/07/2022	Te Whatu Ora locality		

	heart disease in Counties Manukau									
2022 FULL 13240	Improved delivery of topical corticosteroid sprays	Prof Richard Douglas	17/11/2022	6/12/2022	Approved NSC	Approved	15/12/2022	Te Whatu Ora locality		
2023 FULL 13126	Ipilimumab and nivolumab combination therapy in patients with selected immunotherapy sensitive advanced rare cancers	Dr Jane So	25/05/2023	13/06/2023	Provisionally Approved	Approved	7/08/2023	Te Whatu Ora locality		Olivia Newton-John Cancer Research Institute
2022 FULL 12878	Modelling procalcitonin for bacterial infections in the intensive care	Dr Jacqueline Hannam	5/07/2022	19/07/2022	Declined	Declined	28/07/2022	Te Whatu Ora locality	The University of Auckland, Ethics and Integrity Department	
2022 FULL 13667	Modelling procalcitonin for bacterial infections in the intensive care - a retrospective study	Dr Jacqueline Hannam	10/10/2022	15/11/2022	Approved	Approved	18/11/2022	Te Whatu Ora locality	The University of Auckland, Ethics and Integrity Department	
2023 EXP 15277	Modulation of cough sensitivity using auricular stimulation in stroke: a randomised crossover trial	Associate Professor Yusuf Cakmak	1/03/2023	21/03/2023	Provisionally Approved	Approved	1/05/2023	Te Whatu Ora locality		
2023 FULL 13224	Neuflo Water Electrolysis System for the Treatment of Benign Prostatic Hyperplasia	Professor Peter Gilling	4/04/2023	18/04/2023	Provisionally Approved	Approved	2/06/2023	Te Whatu Ora locality		ProstaCare Pty Ltd., Sydney NSW 2000, Australia
2022 FULL 11919	New tests for invasive aspergillosis in immune compromised patients: Proof of principle studies. The ASPAG study	Professor Stephen Chambers	5/10/2022	18/10/2022	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Director, Research and Enterprise	
2023 FULL 13593	Novel white cap crowns for drill-free dental caries treatment in NZ children - Feasibility Study	Dr Joanne Jung Eun Choi	9/02/2023	21/03/2023	Provisionally Approved	Approved	28/07/2023	Te Whatu Ora locality	Te Whatu Ora Southern	
2022 FULL 13270	Novel white crowns for drill-free treatment of dental caries in NZ children - Feasibility Study	Dr Joanne Jung Eun Choi	25/07/2022	16/08/2022	Declined	Declined	25/08/2022	Te Whatu Ora locality		

2023 FULL 15343	Nutritional Intervention Preconception and During Pregnancy to Maintain Healthy Glucose Metabolism and Offspring Health	Professor Wayne Cutfield	14/03/2023	18/04/2023	Approved NSC	Approved	8/05/2023	Tertiary Education Institution	The University of Auckland	
2023 FULL 15420	OLX72021-01: A Multi-Centre, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Phase 1 Study to Evaluate the Safety, Tolerability and Pharmacokinetics of OLX72021 in Healthy Males with Androgenetic Alopecia.	Dr Simon Carson	24/03/2023	18/04/2023	Approved NSC	Approved	8/05/2023	Private Organisation		Olix Pharmaceuticals, Inc, Olix AU PTY LTD
2023 FULL 15233	OMS906-C3G-001: A Phase 1b Proof of Concept Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of OMS906 in Patients with C3 Glomerulopathy and Idiopathic Immune Complex-Mediated Glomerulonephritis	Dr Janak de Zoysa	7/03/2023	21/03/2023	Approved NSC	Approved	3/04/2023	Te Whatu Ora locality	Adjutor Healthcare (NZ) Limited	Omeros Corporation
2023 FULL 17829	Paediatric Influence of Cooling duration on Efficacy in Cardiac Arrest Patients (P-ICECAP)	Dr John Beca	7/06/2023	20/06/2023	Provisionally Approved	Approved	25/08/2023	Te Whatu Ora locality		The University of Michigan Medicine
2023 FULL 13962	Person-centred investigation of daylight environments for promoting dementia wellbeing while aging in place in New Zealand	Doctor Alessandro Premier	8/02/2023	21/02/2023	Declined	Declined	8/03/2023	Other, Private Organisation, Tertiary Education Institution	The University of Auckland	
2023 FULL 13153	Pilot Study- Assessment of FAPI PETCT in Castrate Resistant Prostate Carcinoma patients with discordant disease at FDG PETCT	Dr Andrew Henderson	8/03/2023	21/03/2023	Approved NSC	Approved	3/04/2023	Private Organisation	Prostate Cancer Foundation NZ	

2022 FULL 12742	PRECARE: An open-label Randomised Controlled Trial of as-needed budesonide-formoterol vs salbutamol reliever therapy in preschool children with mild asthma/recurrent wheeze	Professor Stuart Dalziel	2/10/2022	18/10/2022	Approved NSC	Approved	2/11/2022	Te Whatu Ora locality	University of Auckland	
2022 FULL 11309	PRoMPT Bolus: Balanced Fluid Resuscitation to Decrease Kidney Injury in Children with Septic Shock;	Professor Stuart Dalziel	25/01/2022	11/03/2022	Provisionally Approved	Approved	19/07/2022	Te Whatu Ora locality		
2022 FULL 13832	Randomised open label clinical trial examining the safety and efficacy of the Android Artificial Pancreas System (AAPS) with advanced bolus-free features in adults with type 1 diabetes	Dr Martin de Bock	21/11/2022	8/12/2022	Approved NSC	Approved	15/12/2022	Te Whatu Ora locality, Tertiary Education Institution	University of Otago	
2023 FULL 15066	Randomised, double-blind, placebo-controlled, Phase IIb/Phase III study to evaluate the efficacy and safety of spesolimab in patients with moderate to severe hidradenitis suppurativa.	Dr Marius Rademaker	9/02/2023	21/02/2023	Provisionally Approved	Approved	1/05/2023	Private Organisation	Boehringer Ingelheim (N.Z.) Limited	Boehringer Ingelheim Pty Ltd
2022 FULL 12899	Randomized, double-blind, placebo-controlled, parallel groups, multicenter pivotal study assessing the efficacy and safety of 15 mg twice a day (BID) of SER150 in well-controlled type 2 diabetic patients with diabetic kidney disease and macroalbuminuria in treatment with an angiotensin converting enzyme inhibitor or an	Dr Michael Williams	9/09/2022	20/09/2022	Provisionally Approved	Approved	3/11/2022	Primary Health Care Centre, Private Organisation	Avance Clinical	Serodus (AUS) Pty Ltd

	angiotensin receptor antagonist									
2023 EXP 13668	Recovery associated outcomes: a 15-year longitudinal follow-up of the Schizophrenia: Outcomes, Psychosis, Experience (ScOPE) project.	Associate Professor Tess Patterson	2/03/2023	21/03/2023	Approved NSC	Approved	3/04/2023	Te Whatu Ora locality	Research & Enterprise, University of Otago	
2023 FULL 15417	Research to inform the FASD Action Plan Phase 2: Research on the whole-of-system response to young people aged 11-18 years with diagnosed and suspected Fetal Alcohol Spectrum Disorder (FASD) in Aotearoa New Zealand	Mrs Elizabeth Smith	27/04/2023	16/05/2023	Provisionally Approved	Approved	27/06/2023	Te Whatu Ora locality	Te Whatu Ora	
2022 FULL 13681	Responses to aerosol, intradermal and intramuscular administration of measles-mumps-rubella (MMR) vaccine in seronegative and to respiratory challenge with MMR vaccine in seropositive young adults given two doses of MMR in childhood	Professor Peter McIntyre	3/11/2022	15/11/2022	Provisionally Approved	Approved	10/01/2023	Tertiary Education Institution	Research & Enterprise Te Tari Rangahau me te Hinonga University of Otago Te Whare Wānanga o Otago	
2023 FULL 15192	Services Your Way: Evaluating a Youthline national counselling program	Dr Jessica Stubbing	15/05/2023	30/05/2023	Declined	Declined	13/06/2023	Private Organisation	CEO, Youthline	
2023 EXP 13822	TĀ«hauora: impact of different kawakawa dosing conditions on markers of metabolic health and inflammation in healthy human volunteers	Dr Farha Ramzan	31/10/2022	15/11/2022	Provisionally Approved	Approved	30/01/2023	Tertiary Education Institution	University of Auckland	
2023 FULL 15082	The BEAD Feasibility Study: Baby Head Elevation device at full	Dr. Jordon Wimsett	7/02/2023	21/02/2023	Declined	Declined	8/03/2023	Te Whatu Ora locality	University of Auckland	

	dilatation caesarean section									
2023 FULL 15526	The BEAD Feasibility Study: Baby Head Elevation device at full dilatation caesarean section	Dr. Jordon Wimsett	9/03/2023	18/04/2023	Approved NSC	Approved	8/05/2023	Te Whatu Ora locality	University of Auckland	
2022 FULL 12058	The Efficacy of Telehealth-delivered Play to Learn with and without ACTion in Caregiving on the Social Communication of Autistic Children and Caregiver Mental Health: A Multi-arm Parallel Group Randomised Clinical Trial	Associate Professor Laurie McLay	6/06/2022	8/07/2022	Provisionally Approved	Approved	1/08/2022	Tertiary Education Institution	University of Canterbury	
2023 FULL 18044	Three-dimensional human cancer models for drug discovery and therapeutic applications	Associate Professor Jaydee Cabral	6/06/2023	20/06/2023	Declined	Declined	29/06/2023	Tertiary Education Institution	University of Otago	
2023 FULL 15628	Understanding Child Abuse Victim, Caregiver and Clinician Trauma Focused Cognitive Behavioural Therapy (TF-CBT) Treatment Experience	Mrs Audrey Kusasira-Sutton	23/03/2023	18/04/2023	Provisionally Approved	Approved	7/08/2023	Private Organisation, Te Whatu Ora locality		
2023 FULL 15445	Understanding Policing Delivery: TĀ• kata Whaikaha, D/deaf and Disabled People	Associate Professor Brigit Mirfin-Veitch	3/05/2023	16/05/2023	Provisionally Approved	Approved	10/07/2023	Other, Private Organisation	Chief Advisor to the UPD Independent Panel (Understanding Policing Delivery Research Programme)	
2022 FULL 12101	Using A Digital Drawing Application (iTui) To Facilitate Communication With Patients In Paediatric Gateway Clinic: A Prospective Interventional Study	Mr Jonathan Lee	2/10/2022	18/10/2022	Declined	Declined	2/11/2022	Te Whatu Ora locality		

2023 EXP 17861	Zesty Kids Study - Effects of increased fruit and vegetable intake on children's mental and cognitive health: A pilot/feasibility study.	Dr Nicola Gillies	27/04/2023	30/05/2023	Declined	Declined	13/06/2023	Tertiary Education Institution	University of Auckland, Ethics and Integrity Department	
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