



**Health and
Disability Ethics
Committees**

**Northern B 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 B 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 B 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 B 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 B HDEC is registered (number IRB00008715) 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 my privilege to present this Annual Report of the work of Northern B HDEC (NTB) over the last year. In the year ending June 2023, the committee reviewed a total of 189 new applications. 97 were reviewed at full committee meetings, while 92 new applications were reviewed through the expedited (lower ethical risk) pathway. 362 applications for Substantial Amendments to previously approved studies were reviewed, along with 293 Annual Reports and 58 reports of Protocol Deviations.

I am happy to confirm that NTB has operated effectively over the reporting period, and in accordance with the HRCEC's expectations of efficient processes and fit-for-purpose ethical review. A delay in appointment processes reported previously was resolved for NTB in 2022, and our new members have settled in well and already have considerable experience. Although we don't currently have a medical professional member it is hoped that a targeted appointment can be made after the election.

My sincere thanks go to all staff of the HDEC Secretariat under the leadership of Nic Aagaard, for ensuring that the committees' function smoothly. I am particularly thankful for the dedication and expertise of Dr Devonie Waaka (seconded from Southern HDEC) who joins me on the review of expedited applications, amendments, and protocol deviations. The volume of new health research through HDECs has not yet returned fully to its pre-pandemic heights, while quality has improved notably as career researchers renew their efforts post-pandemic, and as the HDEC Advisors now routinely implement a quality/ completeness screen before assigning applications to meeting agendas.

This last year has seen the beginnings of research uses of AI or machine learning, typically aimed at the use of algorithms for diagnosis or predicting treatment outcomes. Whilst this is still an emerging and fluid ethical area, we note that these uses of health data (without consent) present unique challenges for ethical review. These go beyond the conditions of safe data and the regular justifications for waiver of consent. Therefore, we have agreed that such applications will routinely receive review at a Full Committee and are developing a template form which will supplement a submission, and draw out more fully the social, ethical and legal implications of AI research. I expect this to be operational in 2024.

At the start of 2023, an improvement in the ERM submission form clarified that all Co-ordinating Investigators who are university staff or student, require sign-off from their institution as Local Sponsor. This will ensure that institutional governance policies apply to each study with HDEC approval. It should be clear to each researcher what their own internal institutional policy and procedure for obtaining Local Sponsor authorisation is.

In terms of the wider context, we are presently in a relatively stable period, but are expecting some amendment to operations as the review of the (NEAC) National Ethical Standards is complete by the end of the 2024, and as the regulatory functions of the Therapeutic Products Act (2023) come into effect mid-2026. This latter will necessitate that all components of the health research review and regulatory system, (from HDECs, Localities, Māori consultative groups, and Local Sponsors, to the scientific review panels of clinical trials, gene and reproductive technologies) work in concert, both transparently and highly effectively. I remain confident that Northern B HDEC can continue to do its important work of assessing whether health and disability research meets the ethical standards expected and thereby contribute positively to the whole health research infrastructure of New Zealand.

Kate O'Connor

Chair – Northern B 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	2
No. of applications approved subject to conditions / pending at first review (Non-standard conditions or NSC)	23
No. of applications deferred (provisionally approved) at first review and subsequently approved	56
No. of applications deferred as at time of report	4
No. of applications that were declined (in part) because of no/insufficient consultation with appropriate Māori/whānau/iwi/hāpu	3
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.)	7
No. of applications which do not require ethics committee approval (across all four Committees, expedited and full combined)	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	97

Summary of applications received under expedited / low risk review

No. of applications approved	6
No. of applications approved subject to conditions	20
No. of applications deferred and subsequently approved	49
No. of applications deferred as at time of report	10
<i>No. of applications referred for full committee review</i>	2
No. of applications declined	7
No. of studies withdrawn by researcher	0
Total number of applications received under expedited / low risk review	92

Total number of applications received:

189

Complaints and overdue application summary

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

Complaints received

Complaint one

Type of complaint: Breach of Ethical Standards

Review date: Resolved 1 December 2022

Complaint received: 19 November 2022

Nature of complaint:

A concerned member of the public associated with an advocacy group complained about the HDEC's approval of a study where children under five were able to provide their own assent, querying the point of the assent and the study as a whole. The study in question involved child participants that are part of the community the advocacy group represents. It was noted that the advocacy group as a whole was involved in the study, and the complaint received was from an individual.

Actions taken:

The HDECs confirmed that all cases of consent to participate will be given by the parents for both themselves and on behalf of the children – though it was maintained that where assent is possible, it should be obtained in a way that is appropriate and child centered. It is the responsibility of the researcher to determine the capacity of the child participant and whether assent would be appropriate on a case-by-case basis and the committee found that researchers in this study had the expertise to determine capacity and whether assent was appropriate. Although, as the complainant noted, in this study this would be unlikely for the child participants to be able to provide their own assent, which was acknowledged.

Due to existing relationships between the parties, the HDECs referred the complainant to send enquiries to the study team.

The Secretariat also reached out to the study team to advise them of this complaint (keeping the complainant anonymous) and our response. The coordinating investigator (CI) of the study responded that in practice, the current assent process is appropriate but would review the process in light of the complaint and consult with the advocacy group further.

Outcome:

The complainant was provided with a summary of the discussion with the CI on the responsiveness of the study, and the rationale outlined as per the National Ethical Standards. The HDEC has taken no further action.

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 14 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).

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)
2022 FULL 1322 1	A 52-week, open-label, randomised, multi-centre, parallel group, phase III, controlled trial in patients age 5 to 11 years with mild, moderate and severe asthma, evaluating the efficacy and safety of Budesonide-formoterol (Symbicort Turbuhaler®) maintenance and/or reliever therapy compared with standard therapy: Budesonide (Pulmicort Turbuhaler®) maintenance or Budesonide-formoterol (Symbicort Turbuhaler®) maintenance, both with Terbutaline (Bricanyl Turbuhaler®) reliever.	Professor Richard Beasley	22/09/2022	4/10/2022	Provisionally Approved	Approved	6/10/2022	Private Organisation	Medical Research Institute of New Zealand	
2023 EXP 13376	A clinical prediction model to risk-stratify children at paediatric ED triage	Dr Zhenqiang Wu	29/06/2023	16/07/2023	Approved NSC	Approved	17/07/2023		The University of Auckland	
2022 EXP 12136	A Clinicians and Patients Survey to Examine PreventS App Usability for Primary Stroke Prevention	Prof. Valery Feigin	11/08/2022	15/08/2022	Provisionally Approved	Approved	17/08/2022	Te Whatu Ora locality	AUT University Research Office	
2023 FULL 1321 3	A comparison of the pressures inside paediatric endotracheal cuffs filled with air or saline during aeromedical transport	Dr Chris Hands	23/01/2023	24/01/2023	Provisionally Approved	Approved	25/01/2023	Te Whatu Ora locality		
2022 EXP 12583	A Narrative Inquiry Exploring the Experiences of Survivors and Support People of Long-term ICU	Miss Amy Best	31/08/2022	8/09/2022	Provisionally Approved	Approved	9/09/2022	Te Whatu Ora locality	Massey University	
2023 EXP 17884	A national, multi-centre study of post-endoscopy colorectal and	Dr Christopher Harmston	2/06/2023	7/06/2023	Provisionally Approved	Approved	7/06/2023			

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

	upper gastrointestinal cancers in Aotearoa New Zealand									
2023 FULL 1388 4	A non-randomized, open label, multi-country, cohort study to describe the safety of study participants who received RSVPreF3 maternal vaccination (any dose) or controls from previous RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-010, RSV MAT-011, RSV MAT-009, RSV MAT-012 and RSV MAT-039) during any pregnancy conceived post vaccination/control.	Dr Rebecca Griffith	11/01/2023	8/02/2023	Provisionally Approved	Approved	13/02/2023	Private Organisation, Te Whatu Ora locality		GlixoSmithKline (GSK)
2022 FULL 1318 7	A Phase 1 Safety and Dose Finding Study of 131I -TLX101 Plus Standard of Care in Patients with Newly Diagnosed Glioblastoma	Dr Andrew Henderson	15/08/2022	28/09/2022	Provisionally Approved	Approved	28/09/2022	Private Organisation	Telix Pharmaceuticals (NZ) Ltd	Telix Pharmaceuticals (NZ) Ltd
2023 FULL 1540 7	A Phase 1 Study in Healthy Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous and Intramuscular Lenacapavir	Dr Christian Schwabe	13/04/2023	2/05/2023	Provisionally Approved	Approved	11/05/2023	Private Organisation	Gilead (New Zealand)	Gilead Sciences, Inc.
2023 FULL 1814 6	A Phase 1 Study Investigating the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of HPK1 Inhibitor BGB-26808 alone or in Combination with Anti-PD-1 Monoclonal Antibody Tislelizumab in Patients with Advanced Solid Tumors.	Dr Sanjeev Deva	21/06/2023	4/07/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	BeiGene	
2023 FULL 1523 7	A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Ascending Doses of TLC-6740 in Healthy Subjects	Professor Edward Gane	22/02/2023	7/03/2023	Approved NSC	Approved	14/03/2023	Private Organisation	Infinity Consulting Ltd	OrsoBio, Inc.
2022 FULL 1383 9	A PHASE 1, RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED, SINGLE ASCENDING DOSE STUDY TO EVALUATE THE SAFETY AND	Principal Investigator Paul Hamilton	17/11/2022	6/12/2022	Approved NSC	Approved	23/12/2022	Private Organisation	PPD, Part of Thermo Fisher Scientific	ReCode Therapeutics, Inc.

	TOLERABILITY OF RCT1100 IN HEALTHY PARTICIPANTS									
2023 FULL 1787 8	A PHASE 1, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF SINGLE ASCENDING DOSES OF REGN7544, AN ANTAGONISTIC MONOCLONAL ANTIBODY TO NPR1, IN HEALTHY ADULTS	Dr Chris Wynne	24/05/2023	6/06/2023	Approved NSC	Approved	15/06/2023	Private Organisation	ICON Clinical Research (New Zealand) Ltd	Regeneron Pharmaceuticals
2022 FULL 1384 2	A Phase 1, Single and Multiple Ascending Dose Study of NEU-723 Administered Orally to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Subjects	Principal Investigator Chris Wynne	17/11/2022	6/12/2022	Approved NSC	Approved	23/12/2022	Private Organisation	PPD, Part of Thermo Fisher Scientific	Neuron23, Inc.
2022 FULL 1334 4	A Phase 1/1b, Double-Blind, Randomized, Placebo-Controlled, First-in-Human Study of Subcutaneously Administered ALG-125755 to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics After Single Ascending Doses in Healthy Volunteers (Part 1) and Subjects with Chronic Hepatitis B (Part 2), and Multiple Doses in Subjects with Chronic Hepatitis B (Part 3)	Professor Ed Gane	24/08/2022	6/09/2022	Approved NSC	Approved	15/09/2022	Private Organisation	Novotech (New Zealand) Limited	Aligos Therapeutics Inc.
2023 FULL 1666 8	A Phase 1/2 First-in-Human Study of the Safety and Efficacy of IMC-F106C as a Single Agent and in Combination with Checkpoint Inhibitors in HLA-A*02:01-Positive Participants with Advanced PRAME-Positive Cancers	Doctor Catherine Han	13/04/2023	2/05/2023	Approved NSC	Approved	11/05/2023	Private Organisation	IQVIA RDS Pty Limited	Immunocore, Limited
2023 FULL 1529 1	A Phase 1/2, Open-label, Multicenter, Dose Escalation and Expansion Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of HM43239 in Patients with Relapsed or	Dr Lauren Child	8/06/2023	25/06/2023	Provisionally Approved	Approved	27/06/2023	Te Whatu Ora locality	Labcorp New Zealand Limited	Aptose BioSciences, Inc.

	Refractory Acute Myeloid Leukemia (AML)									
2023 FULL 1522 5	A Phase 1b Multi-Center, Open-Label, Dose-Escalation, Prime and Boost Vaccination Evaluation of Two Chimpanzee Adenoviral Vectors in Adult Participants With Chronic HBV Infection Who Are Currently Receiving HBV Nucleos(t)ide Reverse Transcriptase Inhibitors	Professor Edward Gane	4/05/2023	10/05/2023	Provisionally Approved	Approved	18/05/2023	Private Organisation	New Zealand	Virion Therapeutics, LLC
2023 FULL 1531 9	A Phase 1B, Open-Label, Multicenter Dose-Expansion Study Evaluating the Safety, Pharmacokinetics, and Activity of RO7496353 in Combination with a Checkpoint Inhibitor with or without Standard of Care Chemotherapy in Patients with Locally Advance or Metastatic Solid Tumors.	Dr Peter Fong	25/05/2023	6/06/2023	Provisionally Approved	Approved	16/08/2023	Te Whatu Ora locality	PPD Part of Thermo Fisher	gRED Clinical Operations, Genentech, Inc.
2023 FULL 1666 3	A Phase 2 basket study of an Aromatase inhibitor plus PI3KCA inhibitor or CDK4/6 inhibitor in women with hormone receptor positive recurrent/metastatic Gynaecological Neoplasms (PARAGON-2)	Dr Michelle Wilson	25/05/2023	6/06/2023	Approved NSC	Approved	16/06/2023	Te Whatu Ora locality		University of Sydney, University of Sydney
2023 FULL 1545 1	A Phase 2 Study Evaluating INCB099280 in Participants With Advanced Cutaneous Squamous Cell Carcinoma	Associate Professor Michael Jameson	29/05/2023	29/05/2023	Provisionally Approved	Approved	2/06/2023	Te Whatu Ora locality	Iqvia	Incyte Corporation
2022 FULL 1248 4	A Phase 2, Randomized, Open-Label, Allopurinol-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of AR882 Alone or in Combination with Allopurinol in Tophaceous Gout Patients	Professor Nicola Dalbeth	13/07/2022	18/07/2022	Provisionally Approved	Approved	19/07/2022	Te Whatu Ora locality, Tertiary Education Institution	Novotech (New Zealand) Limited	Arthrosi Therapeutics Inc.
2023 FULL 1355 6	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	Dr Di (Caroline) Jiang	29/03/2023	21/04/2023	Provisionally Approved	Approved	28/04/2023	Te Whatu Ora locality		Janssen-Cilag

	Moderately to Severely Active Ulcerative Colitis									
2022 FULL 12653	A Phase 3 Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Daily Subcutaneous Injections of Elamipretide in Subjects with Primary Mitochondrial Disease Resulting from Pathogenic Nuclear DNA Mutations (nPMD)	A/Prof Richard Roxburgh	3/08/2022	6/09/2022	Approved NSC	Approved	15/09/2022	Private Organisation, Te Whatu Ora locality	Syneos Health New Zealand Limited	Stealth BioTherapeutics Inc
2023 FULL 15382	A Phase 3 Study Evaluating the Pharmacokinetics, Safety, and Tolerability of VX121/Tezacaftor/Deutivacaftor Triple Combination Therapy in Cystic Fibrosis Subjects 1 through 11 Years of Age (Protocol Number: VX21-121-105)	Professor Catherine Byrnes	24/05/2023	26/06/2023	Provisionally Approved	Approved	27/06/2023	Te Whatu Ora locality	Adjutor Healthcare (NZ) Limited	Vertex Pharmaceuticals Australia Pty Ltd
2023 FULL 15290	A Phase 3b, Randomized, Open-Label, Double Crossover Study Comparing Treatment Preference Between Oral Decitabine/Cedazuridine and Azacitidine in Adult Patients with IPSS-R Intermediate Myelodysplastic Syndrome, Low-Blast Acute Myeloid Leukemia, IPSS Intermediate-2 or High-Risk Myelodysplastic Syndrome or Chronic Myelomonocytic Leukemia	Dr Anna Elinder-Camburn	27/06/2023	4/07/2023	Provisionally Approved	Approved	5/07/2023	Primary Health Care Centre, Private Organisation	IQVIA RDS Pty Limited	Otsuka Australia Pharmaceutical Pty. Ltd.
2023 FULL 15137	A PHASE I STUDY TO INVESTIGATE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF RO7565020 IN HEALTHY PARTICIPANTS AND IN PARTICIPANTS WITH CHRONIC HEPATITIS B VIRUS INFECTION	Prof. Edward Gane	24/01/2023	7/02/2023	Approved NSC	Approved	10/02/2023	Private Organisation	LabCorp New Zealand Limited	F. Hoffmann-La Roche Ltd
2022 FULL 13329	A Phase II, randomised, placebo-controlled, double-blind, parallel-group, efficacy and safety study of at least 48 weeks of oral BI 685509 treatment in adults with	Dr Kamal Solanki	28/09/2022	10/10/2022	Provisionally Approved	Approved	11/10/2022	Te Whatu Ora locality		Boehringer Ingelheim Pty Ltd

	early progressive diffuse system sclerosis.									
2023 FULL 1679 1	A Phase III Open-Label Extension Study to Evaluate the Long-Term Safety of Astegolimab in Patients with Chronic Obstructive Pulmonary Disease (COPD)	Dr Michael Epton	21/06/2023	4/07/2023	Approved NSC	Approved	18/07/2023	Private Organisation, Te Whatu Ora locality	PPD, part of ThermoFisher Scientific	F. Hoffmann-La Roche Ltd
2022 FULL 1247 1	A Phase III, adjudicator-blinded, randomised study to evaluate the efficacy and safety of treatment with olorofim versus treatment with AmBisome® followed by standard of care (SOC) in patients with invasive fungal disease (IFD) caused by Aspergillus species	Dr Olivia Bupha-Intr	5/10/2022	10/11/2022	Provisionally Approved	Approved	15/11/2022	Te Whatu Ora locality	IQVIA RDS Pty Limited	F2G
2022 EXP 12727	A pilot dose duration-response study using Advantan® ointment (Leo Pharma Pty Ltd, Australia) to determine the appropriate dose duration (ED50) for use in a pivotal in vivo bioequivalence study and using 12 participants who demonstrate adequate vasoconstriction to topical steroids.	Dr Noelyn Hung	8/09/2022	14/09/2022	Approved NSC	Approved	21/09/2022	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd
2023 EXP 13771	A pilot trial into the effect of feeding on MitoQ absorption	Dr Christopher Hedges	8/05/2023	10/05/2023	Provisionally Approved	Approved	11/05/2023	Tertiary Education Institution	University of Auckland	
2023 FULL 1375 1	A randomised, placebo-controlled, double-blind, multi-centre, phase III trial to assess the efficacy and safety of trimodulin (BT588) in adult hospitalised subjects with severe community-acquired pneumonia (sCAP)	Dr. Colin McArthur	12/01/2023	7/02/2023	Provisionally Approved	Approved	27/07/2023	Te Whatu Ora locality		Biotech AG
2023 FULL 1550 4	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO ASSESS THE EFFICACY AND SAFETY OF RIFAXIMIN SOLUBLE SOLID DISPERSION (SSD) TABLETS FOR THE DELAY OF ENCEPHALOPATHY DECOMPENSATION IN CIRRHOSIS (RED-C)	Dr Hannah Giles	20/06/2023	5/07/2023	Provisionally Approved	Approved	7/07/2023	Te Whatu Ora locality		Salix Pharmaceuticals, Inc. an affiliate of Bausch Health US, LLC

2023 FULL 13720	A Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Zilebesiran Used as Add-on Therapy in Patients with Hypertension Not Adequately Controlled by a Standard of Care Antihypertensive Medication	Dr. Claire Thurlow	17/02/2023	29/03/2023	Provisionally Approved	Approved	29/03/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	IQVIA RDS Pty. Limited	Alnylam Pharmaceutical
2023 FULL 13485	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	17/01/2023	21/02/2023	Provisionally Approved	Approved	21/02/2023	Private Organisation, Te Whatu Ora locality	PPD, Part of Thermo Fisher Scientific	United Therapeutics Corp.
2022 FULL 13095	A Randomized, Positive- and Placebo-Controlled Study to Evaluate the Effects of ONC201 on Cardiac Repolarization in Healthy Participants	Principal Investigator Alexandra Cole	20/07/2022	2/08/2022	Approved NSC	Approved	8/08/2022	Private Organisation	Infinity Consulting Ltd (on behalf of Avance Clinical)	Chimerix, Inc.
2023 FULL 13714	A sector analysis of the needs of transgender adults, youth and parents of transgender children within primary healthcare services	Dr. Katie McMennamin	6/04/2023	2/05/2023	Provisionally Approved	Provisionally Approved		Other, Primary Health Care Centre		
2023 FULL 16681	A Self-compassion Chatbot to Improve the Wellbeing of Adolescents with Type 1 Diabetes (T1D): a Feasibility Study	Senior Lecturer in Health Psychology Anna Serlachius	19/05/2023	27/05/2023	Provisionally Approved	Approved	2/06/2023	Te Whatu Ora locality	University of Auckland	
2023 EXP 16744	A study to validate use of a novel ultrasound device in early detection of gingivitis	Prof Warwick Duncan	11/05/2023	12/05/2023	Provisionally Approved	Approved	15/05/2023	Tertiary Education Institution	WNT Ventures	
2023 FULL 15336	A Two-cohort, Phase II, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating the Efficacy and Safety of Vixarelimab compared with Placebo in Patients with Idiopathic Pulmonary Fibrosis and in Patients with System Sclerosis-Associated Interstitial Lung Disease	Dr Henry Gallagher	12/06/2023	20/06/2023	Provisionally Approved	Approved	20/06/2023	Te Whatu Ora locality	PPD, part of ThermoFisher Scientific	Genentech, Inc.
2023 EXP 16688	Accepted, declined or outsourced to private: a retrospective review of patient characteristics and waiting	Dr Christine Zhang	28/04/2023	2/05/2023	Provisionally Approved	Approved	3/05/2023			

	times in those receiving a hip or knee joint replacement in New Zealand									
2023 EXP 15593	Adapting an Autism Support Program for a Lower Financially Resourced Family: A Case Study	Mrs. Carla Wallace-Watkin	15/05/2023	18/05/2023	Provisionally Approved	Approved	19/05/2023	Other, Tertiary Education Institution	Human Ethics Committee, Victoria University of Wellington	
2023 FULL 1534 5	Adherence to myopia control spectacle wear in children aged 7 to 12: a comparison of two lens designs.	Miss Emily Benefer	9/06/2023	4/07/2023	Provisionally Approved	Approved	24/08/2023	Tertiary Education Institution	The University of Auckland	
2023 EXP 11604	Adolescent accounts of emotions and self-harm and risky behaviours	Ms. Megan Lenny	12/01/2023	17/01/2023	Provisionally Approved	Approved	17/01/2023	Primary Health Care Centre, Private Organisation	University of Waikato	
2023 FULL 1537 3	Advancing Interleukin 1 Receptor Antagonist to Prevent Inflammatory Disease in Preterm Infants	Dr Gergely Toldi	28/04/2023	1/05/2023	Provisionally Approved	Approved	3/05/2023	Te Whatu Ora locality	University of Auckland	Monash University
2022 FULL 1380 2	Advancing Palliative Care among Pacific Children	Associate Professor Sunia Foliaki	11/11/2022	6/12/2022	Declined	Declined	23/12/2022	Other, Te Whatu Ora locality		
2023 FULL 1805 5	Ageing Well through Eating, Sleepoing, Socialising and Mobility (AWESSOM care Home Project;	Dr Kathy Peri	16/06/2023	4/07/2023	Declined	Declined	18/07/2023	Private Organisation	Ministry of Business, Innovation & Employment	
2022 EXP 13226	Alternative and complementary medicine as a pathway to care for New Zealand military Veterans experiencing pain and distress.	Associate Professor David McBride	21/07/2022	2/08/2022	Declined	Declined	8/08/2022	Private Organisation	University of Otago	
2022 EXP 13431	Alternative and complementary medicine as a pathway to care for New Zealand military Veterans experiencing pain and distress.	Associate Professor David McBride	25/08/2022	6/09/2022	Approved NSC	Approved	15/09/2022	Private Organisation	University of Otago	
2023 FULL 1508 9	An Open-Label Extension Study of Olezarsen (ISIS 678354) Administered Subcutaneously to Patients with Severe Hypertriglyceridemia (SHTG)	Dr Jocelyne Benatar	16/03/2023	4/04/2023	Approved	Approved	26/04/2023	Te Whatu Ora locality	CARSL Consulting (Clinical and Regulatory Services)	Ionis Pharmaceuticals, Inc.

2023 FULL 1796 9	An open-label, Phase 2 study to assess the safety and efficacy of EQ101 in adult subjects with moderate to severe alopecia areata	Dr Penny Montgomery	19/05/2023	6/06/2023	Approved NSC	Approved	16/06/2023	Private Organisation	Avance Clinical (Representative, CRO)	Equillium AUS Pty Ltd
2022 FULL 1341 5	Aotearoa New Zealand, Paramedic Care Collection (ANZPaCC)	Associate Professor Bridget Dicker	29/08/2022	12/09/2022	Approved NSC	Approved	21/09/2022	Other		
2023 FULL 1535 9	Application of artificial intelligence in defecating proctogram interpretation	Dr Chris Varghese	20/02/2023	7/03/2023	Declined	Declined	14/03/2023	Private Organisation, Te Whatu Ora locality		
2023 EXP 15377	Assessing the application of an equity readiness assessment tool and an equity-focused implementation science framework in a Lung Cancer Screening intervention.	Professor Sue Crengle	9/05/2023	15/05/2023	Approved NSC	Approved	18/05/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	University of Otago	
2022 EXP 12276	Assessment of anti viral effect of probiotic bacterium Streptococcus salivarius from a powder format to the oral cavity.	Professor Emeritus John Tagg	6/07/2022	27/07/2022	Provisionally Approved	Approved	28/07/2022	Private Organisation	Blis Technologies	
2023 EXP 15172	Assessment of colonization and skin quality parameter improvement by probiotic Micrococcus luteus Q24 serum in healthy adults (2023)	Dr John Tagg	28/02/2023	7/03/2023	Provisionally Approved	Approved	17/03/2023	Other	Blis Technologies	
2023 EXP 12672	Atypical Parkinsonian Disorder Network Database (APND)	Prof Tim Anderson	14/04/2023	18/04/2023	Provisionally Approved	Approved	20/04/2023	Private Organisation, Te Whatu Ora locality		
2022 FULL 1389 9	Being active, feeling good: People with learning disabilitiesâ€™ perspectives about sport and physical activity	Associate Professor Brigit Mirfin-Veitch	15/11/2022	6/12/2022	Approved NSC	Approved	23/12/2022	Other, Private Organisation	Special Olympics New Zealand	
2023 FULL 1510 3	Biologic Therapy Responders in Inflammatory Bowel Diseases - impact on epithelium and immune responses	Prof Michael Schultz	18/06/2023	26/06/2023	Approved	Approved	28/06/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Otago, Research and Enterprise Office	
2022 FULL 1243 8	BonE and Joint infections â€” Simplifying Treatment in children trial (BEST)	Associate professor Tony Walls	12/07/2022	10/09/2022	Provisionally Approved	Approved	12/09/2022	Te Whatu Ora locality		

2023 EXP 11136	BUMP Study: Characterization of Placental Blood Flow in Univentricular Fontan Maternal Physiology and Implications for Maternofetal Outcomes	Dr Clare O'Donnell	14/06/2023	19/06/2023	Approved NSC	Approved	27/06/2023	Te Whatu Ora locality		
2022 FULL 13147	Caffeine to improve neurodevelopmental outcomes in babies born late preterm: the Latte Trial	Associate Professor Jane Alsweiler	25/09/2022	4/10/2022	Approved NSC	Approved	10/10/2022	Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland	
2022 FULL 13305	Caudal, High flow oxygen and light intravenous anaesthesia for inguinal hernia surgery in infants – a feasibility project.	Dr Ben Van Der Griend	19/09/2022	27/10/2022	Provisionally Approved	Approved	2/11/2022	Te Whatu Ora locality		
2022 EXP 13065	Characterising inflammation in coronary artery disease (CAD): a study of participants receiving coronary angiography	Dr. Kathryn Hally	4/11/2022	14/11/2022	Approved NSC	Approved	16/11/2022	Te Whatu Ora locality, Tertiary Education Institution		
2023 FULL 15583	Characteristics of Spontaneous Venous Pulsation (SVP) and its relationship to other physiological parameters.	Dr Kelechi Ogbuehi	20/05/2023	6/06/2023	Declined	Declined	16/06/2023	Te Whatu Ora locality	ODOCS Eye Care	
2022 EXP 13741	Characteristics, management, outcomes and costs of systemic lupus erythematosus in New Zealand	Dr Chunhuan Lao	31/10/2022	9/11/2022	Approved	Approved	14/11/2022			
2023 EXP 12736	Chronic lithium-induced neurotoxicity: a cross-sectional study in the Wellington region.	Dr David Bourke	16/11/2022	27/01/2023	Provisionally Approved	Approved	30/01/2023	Te Whatu Ora locality		
2022 EXP 13637	Colonisation efficacy of a direct compressed (lozenge) probiotic chewing gum	Professor Emeritus John Tagg	31/10/2022	5/11/2022	Provisionally Approved	Approved	7/11/2022	Private Organisation	Blis Technologies	
2023 EXP 13385	Comparison of rates of diagnosis of sexually transmitted infections and blood borne viruses in a cohort of Auckland sex workers with diagnosis rates in Auckland Sexual health Service general clinic attendees	Dr Sunita Azariah	29/05/2023	6/06/2023	Provisionally Approved	Approved	7/06/2023			
2022 EXP 13617	Computed Tomography Coronary Angiography allows safe discharge of undifferentiated patients with	Dr Ashley Cheung	16/10/2022	27/10/2022	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality		

	Acute Chest Pain Syndromes – a 4-year outcome study									
2023 EXP 13370	COVID-19 Rapid Antigen Testing - Exploring Public use in New Zealand. Behaviour and attitude of rapid antigen test general use in New Zealand: A Survey	Dr Gabby Shortt	8/05/2023	15/05/2023	Approved NSC	Approved	15/05/2023	Private Organisation		
2023 FULL 13948	De-Escalation of adjuvant ChemotheRapy in HER2-positive, EStrogen reCEptor-negative, Node-negative early breast cancer patients who achieved pathological complete response after neoadjuvant chemotherapy and Dual HER2 bIOckade	Dr David Porter	20/03/2023	4/04/2023	Approved NSC	Approved	26/04/2023	Te Whatu Ora locality		Breast Cancer Trials
2023 EXP 15087	Describing care pathways for patients with delirium discharged from hospital - qualitative.	Doctor Engelina Groenewald	9/03/2023	18/03/2023	Provisionally Approved	Approved	20/03/2023	Te Whatu Ora locality	Te Whatu Ora - Counties Manukau	
2023 EXP 15403	Determination of an Indigenous Māori ethnic weighting within the PCLOm2012 risk prediction model for lung cancer screening by comparison between Māori and European participants in New Zealand	Professor Sue Crengle	24/04/2023	2/05/2023	Provisionally Approved	Approved	3/05/2023	Other, Primary Health Care Centre, Te Whatu Ora locality	Te Whatu Ora Waitemata	
2023 EXP 15224	Diagnostic pathways of oral cavity squamous cell carcinoma in Aotearoa/New Zealand	Associate Professor James Stanley	20/02/2023	24/02/2023	Approved NSC	Approved	27/02/2023		University of Otago	
2023 FULL 15093	Do injuries to the brain affect how people think in the longer term? A study of people who have and have not experienced injuries to the brain in Corrections	Professor Alice Theadom	24/01/2023	7/02/2023	Approved NSC	Approved	10/02/2023	Other	Auckland University of Technology	
2022 EXP 11503	EEG recording in patients with bipolar disorder	Professor Paul Glue	15/11/2022	17/11/2022	Provisionally Approved	Archived		Te Whatu Ora locality	University of Otago	
2023 EXP 15464	Effective engagement for immunisation of pŌpi Māori in primary care	Dr Amber Young	17/05/2023	22/05/2023	Provisionally Approved	Approved	23/05/2023	Other, Tertiary Education Institution	University of Auckland	
2022 FULL 11460	Effects of Lithium and Fampridine on Electroencephalography Profiles in Healthy Volunteers	Professor Paul Glue	18/08/2022	27/10/2022	Provisionally Approved	Approved	27/10/2022	Te Whatu Ora locality	University of Otago	

2022 EXP 12840	Electrochemical quantification of non transferrin bound iron (NTBI) in human blood plasma	Dr Manisha Sharma	26/07/2022	8/08/2022	Approved NSC	Approved	11/08/2022	Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland	
2023 EXP 16701	Estimating induction time from intraoperative records of physiological signals	Dr David Cummin	22/05/2023	24/05/2023	Provisionally Approved	Declined	29/05/2023		University of Auckland	
2023 FULL 1366 2	Estimating the burden of leptospirosis in Taranaki	Prof Jackie Benschop	3/03/2023	7/03/2023	Provisionally Approved	Approved	20/03/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	Health Research Council (HRC) of New Zealand	
2023 FULL 1799 9	Evaluating glucose control using a next generation automated insulin delivery algorithm in patients with type 1 and type 2 diabetes	A/Prof. Martin de Bock	21/06/2023	2/07/2023	Provisionally Approved	Approved	3/07/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Otago	Insulet Corporation
2022 EXP 12268	Evaluation of bioavailability and antioxidant effects of phytochemicals presented in 'Monty's Surprise' apple puree in healthy adults.	Miss Linda Nezbedova	30/06/2022	8/07/2022	Provisionally Approved	Approved	14/07/2022	Tertiary Education Institution	TE OHU RANGAHAU KAI-AgResearch and the Riddet Institute	
2022 FULL 1298 0	Exploring a twin-track approach to violence elimination for disabled women	Assoc. Prof Brigit Mirfin-Veitch	24/08/2022	6/09/2022	Approved NSC	Approved	15/09/2022	Other, Private Organisation	Health Research Council of New Zealand	
2023 EXP 13643	Exploring task challenge from the perspective of people with stroke and therapists in stroke rehabilitation using video-reflexive ethnography.	Associate Professor Nada Signal	22/05/2023	6/06/2023	Provisionally Approved	Approved	28/07/2023	Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	Auckland University of Technology	
2023 EXP 13974	Exploring the social frailty in Aotearoa New Zealand	Dr Ruth Teh	21/04/2023	27/04/2023	Provisionally Approved	Approved	1/05/2023	Other	University of Otago, National Health Science Challenge Ageing Well	

2023 FULL 1362 4	Fibrinogen Concentrate vs. Cryoprecipitate in Traumatic Haemorrhage: A Multi-centre Randomised Controlled Trial	Dr James Moore	5/05/2023	6/06/2023	Provisionally Approved	Approved	28/07/2023	Te Whatu Ora locality		Monash University
2023 FULL 1318 9	Follow up of early medical abortion: a multicentre randomised controlled trial	Associate Professor Michelle Wise	25/05/2023	6/06/2023	Approved NSC	Approved	15/06/2023	Primary Health Care Centre, Te Whatu Ora locality	University of Auckland	
2022 EXP 12945	From clinical research to clinical practice: In vivo confocal microscopy of the human cornea	Dr Stuti Misra	24/11/2022	10/01/2023	Provisionally Approved	Approved	12/01/2023	Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland	
2022 EXP 12750	Genetics of pituitary tumours - GWAS study	Dr Marianne Elston	25/08/2022	8/09/2022	Provisionally Approved	Approved	9/09/2022	Te Whatu Ora locality		Queen Mary University of London
2023 EXP 13768	Hīnātore: Māori perspectives on perinatal mental health distress	Ms Cara Meredith	9/02/2023	13/02/2023	Provisionally Approved	Approved	17/02/2023	Other	University of Otago, Christchurch	
2023 FULL 1391 0	High-definition transcranial grey noise stimulation (HD-tGNS) for the treatment of generalized anxiety disorder: A proof of concept study	Professor Dirk De Ridder	8/01/2023	8/02/2023	Provisionally Approved	Approved	13/02/2023	Tertiary Education Institution	University of Otago	
2023 FULL 1542 9	Hypermobile Ehlers-Danlos Syndrome and Hypermobility Spectrum Disorder - Assessing Criteria and Their Modification in Clinical Practice.	Dr Fraser Burling	7/04/2023	15/04/2023	Provisionally Approved	Approved	28/04/2023	Private Organisation		The Ehlers-Danlos Society
2022 EXP 13276	iACT4IBD: Testing an online intervention for IBD patients	Dr. Anna Serlachius	28/11/2022	30/11/2022	Provisionally Approved	Approved	2/12/2022	Te Whatu Ora locality, Tertiary Education Institution	University of Auckland	
2022 FULL 1240 5	Identifying the therapeutic potential of zinc in autism by examining cellular mechanisms in human neurons differentiated from induced pluripotent stem cells.	Associate Professor Johanna Montgomery	19/10/2022	27/10/2022	Provisionally Approved	Approved	2/11/2022	Te Whatu Ora locality, Tertiary Education Institution	University of Auckland	

2022 FULL 1273 4	Impact of mānuka honey on symptoms and quality of life in patients with functional dyspepsia: a feasibility study	Dr Jody Miller	22/08/2022	29/08/2022	Provisionally Approved	Approved	31/08/2022	Tertiary Education Institution	University of Otago	
2023 FULL 1254 4	Implementation of Metformin therapy to Ease Decline of kidney function in Polycystic Kidney Disease (IMPEDE-PKD) Randomised Placebo-Controlled Trial	Professor Suetonia Palmer	3/05/2023	25/06/2023	Provisionally Approved	Approved	26/06/2023	Te Whatu Ora locality	University of Otago	
2023 EXP 13107	Improving Equity and Access to Intervention for Tamariki with Tube Dependency	Dr Sarah Leadley	12/05/2023	17/05/2023	Provisionally Approved	Approved	29/05/2023	Te Whatu Ora locality	University of Auckland	
2023 FULL 1675 7	Improving health services for people with musculoskeletal chest pain - a randomised controlled feasibility trial	Dr Ewan Kennedy	15/05/2023	6/06/2023	Provisionally Approved	Provisionally Approved		Other, Te Whatu Ora locality, Tertiary Education Institution		
2022 EXP 11091	Incapacitated and unable to provide informed consent for surgery- A survey of elective and emergent New Zealand adult surgical patients on whom they would prefer to consent for them if they do not have an Enduring Power of Attorney.	Dr Tin Lun Chiu	21/10/2022	26/10/2022	Provisionally Approved	Approved	27/10/2022	Te Whatu Ora locality	Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland	
2023 EXP 18040	Incidence and outcomes of splenic injuries in Aotearoa New Zealand	Dr Matthew McGuinness	29/05/2023	9/06/2023	Approved NSC	Approved	13/06/2023			
2022 EXP 13602	Inflammatory Bowel Disease- Lifestyle, Food, and Exercise (IBD-LiFE) study : A randomised controlled trial to assess the effectiveness of a personalised nutrition and exercise intervention for people with inflammatory bowel disease in Aotearoa, New Zealand	Professor Michael Schultz	12/10/2022	19/10/2022	Provisionally Approved	Approved	21/11/2022	Te Whatu Ora locality, Tertiary Education Institution	Gut Health Network	
2023 EXP 13755	Interval Oesophageal Adenocarcinoma (OA) after Oesophago-gastro-duodenoscopy (OGD) in Auckland	Dr seong shin	19/10/2022	26/10/2022	Provisionally Approved	Approved	13/01/2023			
2022 EXP 13815	Investigating the metabolic conversion of crab apple-derived ascorbyl 2-beta-glucoside	Ms Halina Stoklosinski	17/11/2022	21/11/2022	Provisionally Approved	Approved	12/12/2022	Other	Th New Zealand Institute for	

	(AA2βG)) to Vitamin C by characterising the bioavailability of Vitamin C after consuming a single dose of crab apple juice in healthy individuals								Plant and Food Research Ltd.	
2023 EXP 15600	Investigation into the nutritional response to chyme reinfusion in patients with Type 2 Intestinal Failure - a pilot study	Professor Rozanne Kruger	23/03/2023	4/04/2023	Approved NSC	Approved	26/04/2023	Te Whatu Ora locality, Tertiary Education Institution	Massey University	
2023 FULL 1285 2	LOGGIC/FIREFLY-2: A Phase 3, Randomized, International Multicenter Trial of DAY101 Monotherapy Versus Standard of Care Chemotherapy in Patients with Pediatric Low-Grade Glioma Harboring an Activating RAF Alteration Requiring First-Line Systemic Therapy. Protocol Number: DAY101-102	Dr Karen Tsui	10/01/2023	7/02/2023	Provisionally Approved	Approved	10/02/2023	Te Whatu Ora locality	Pharmaceutical Research Associates New Zealand Limited	Day One Biopharmaceuticals
2023 FULL 1400 1	Long-Term Open-Label Study to Assess the Safety and Efficacy of Vatiquinone in Patients With Friedreich Ataxia	Professor Richard Roxburgh	31/01/2023	7/03/2023	Provisionally Approved	Approved	3/05/2023	Tertiary Education Institution	Pharmaceutical Solutions Ltd.	PTC Therapeutics, Inc.
2023 FULL 1515 2	Mastery of breathlessness in Chronic Obstructive Pulmonary Disease after an eight-week mindful breathing intervention. A feasibility study	Mrs Shirley Harris	3/04/2023	11/04/2023	Approved NSC	Approved	14/04/2023	Te Whatu Ora locality	University of Otago	
2023 EXP 12288	Morphologic study of the cervical spinal cord in a New Zealand population	Associate Professor Joe Baker	28/02/2023	16/03/2023	Approved	Approved	17/03/2023			
2023 EXP 15204	Mo'ui Ma'a Tonga: A pilot study to reduce cardiometabolic risk in Tongan men living in Auckland	Dr Stacey Reading	27/02/2023	15/03/2023	Approved NSC	Approved	16/03/2023	Tertiary Education Institution	University of Auckland	
2023 EXP 16742	Myocarditis and pericarditis association studies. Observational studies to assess the risk of adverse events of special interest following COVID-19 and mpox / smallpox vaccines in Aotearoa New Zealand – A gold standard approach.	Associate Professor Helen Petousis Harris	25/05/2023	31/05/2023	Approved	Approved	31/05/2023		The University of Auckland	

2023 EXP 15318	Myocarditis and pericarditis association studies. Observational studies to assess the risk of adverse events of special interest following COVID-19, and mpox (smallpox), vaccines in Aotearoa New Zealand – A gold standard approach.	Associate Professor Helen Petousis Harris	9/03/2023	4/04/2023	Declined	Declined	26/04/2023		The University of Auckland	
2023 EXP 14061	Neonatal & Paediatric Chyme Reinfusion - Retrospective study	Dr. Celia KEANE	20/02/2023	24/02/2023	Approved NSC	Approved	27/02/2023		The Insides Company	
2022 EXP 13106	New Zealand Parkinson's Progression Programme (NZP3)	Prof Tim Anderson	18/11/2022	25/11/2022	Provisionally Approved	Approved	16/01/2023	Other		
2023 FULL 1554 2	Newborn genomics - Te Ira oo Te Arai	Professor Justin O'Sullivan	6/04/2023	2/05/2023	Approved NSC	Approved	11/05/2023	Te Whatu Ora locality	Ethics and Integrity Manager Research Strategy and Integrity, The University of Auckland	
2023 FULL 1363 3	Nutritional response to chyme reinfusion therapy in patients with Type 2 Intestinal Failure in New Zealand	Professor Rozanne Kruger	26/01/2023	7/02/2023	Declined	Declined	10/02/2023	Te Whatu Ora locality	Massey University	
2023 EXP 15100	Ocular Melanotic Lesions – a review on the current status of ocular melanoma in New Zealand	Professor Charles McGhee	10/02/2023	23/01/2023	Provisionally Approved	Approved	17/02/2023			
2022 EXP 13416	Older informal caregiver experiences following the COVID-19 pandemic in Aotearoa	Dr. Shinya Uekusa	4/10/2022	19/09/2022	Provisionally Approved	Approved	7/10/2022	Other	Research & Innovation, University of Canterbury	
2023 FULL 1404 4	Optimising recurrence risk assessment for patients undergoing meningioma resection in Auckland.	Dr Clinton Turner	10/04/2023	2/05/2023	Approved	Approved	11/05/2023	Te Whatu Ora locality		
2023 EXP 13780	Outcomes in patients with high risk intramucosal cancer and superficial submucosal oesophageal adenocarcinoma managed initially with endoscopic local resection – a multi-centre retrospective study	Dr Ravindar Ogra	15/05/2023	23/05/2023	Provisionally Approved	Approved	7/07/2023		Middlemore Hospital	

2023 EXP 13656	Outcomes of subsequent pregnancies for women with an OASIS tear in their first pregnancy	Dr Rachel Goodwin	7/05/2023	24/04/2023	Provisionally Approved	Approved	15/05/2023			
2022 EXP 13925	Outcomes of treatment of acute cholangitis in Maori and Pacific Islander patients as compared to non-Maoris and non-Pacific Islanders	Dr Andrei Belyaev	17/11/2022	21/11/2022	Declined	Declined	24/11/2022			
2022 EXP 13981	Outcomes of treatment of acute cholangitis in Maori and Pacific Islander patients as compared to other ethnic groups in New Zealand	Dr Andrei Belyaev	27/11/2022	6/12/2022	Provisionally Approved	Provisionally Approved				
2022 EXP 13607	Pacific Health and Social Care Providers - A Sector Stocktake	Dr Debbie Ryan	8/12/2022	5/01/2023	Approved	Approved	10/01/2023	Primary Health Care Centre	Pacific Perspectives Limited	
2023 FULL 1370 2	Pacific peoples' vaccination beliefs and behaviours including Covid-19 and Well Child immunisations	Mrs Jacinta Fa'alili-Fidow	23/01/2023	1/02/2023	Approved NSC	Approved	2/02/2023	Other		
2023 EXP 13601	Pae Ora - Collaborations in Action	Dr Lis Ellison-Loschmann	19/01/2023	17/11/2022	Provisionally Approved	Approved	24/01/2023	Other, Private Organisation		
2023 EXP 13856	Paediatric Cervical Spine Morphology in a NZ cohort: A retrospective computed tomography analysis	Dr Ampili Mathews	5/04/2023	2/02/2023	Provisionally Approved	Approved	14/04/2023			
2023 FULL 1513 4	Paediatric Eye Health Services in New Zealand - An investigation into the prevalence of visual conditions in New Zealand 7 year olds	Dr Rebecca Findlay	24/05/2023	6/06/2023	Provisionally Approved	Approved	27/07/2023	Other	University of Auckland	
2022 FULL 1303 7	Palmerston North Interventional Rapid Avastin Treat & Extend (PIRATE) Study	Dr. Antoine Bonnet	26/09/2022	30/09/2022	Provisionally Approved	Approved	3/10/2022	Te Whatu Ora locality		
2023 FULL 1780 6	Parent Perceptions of Augmented Input Using A Speech-Generating Device for Autistic Children	Ms Siobhan Gardiner	21/06/2023	4/07/2023	Provisionally Approved	Provisionally Approved		Tertiary Education Institution	Human Ethics Committee, Victoria University of Wellington	
2023 FULL 1369 0	Parental Emotional Engagement with Preterm Infants Study	Professor of Child Developmental Psychology	6/03/2023	6/12/2022	Provisionally Approved	Approved	21/03/2023	Te Whatu Ora locality, Tertiary	University of Canterbury	

		and Te Lianne Woodward						Education Institution		
2023 FULL 1362 1	Patient Reported Outcome and Experience Measures Among ICU Survivors and Whanau (ANZICS-PROEMs)	Prof Paul Young	25/01/2023	6/12/2022	Provisionally Approved	Approved	10/02/2023	Te Whatu Ora locality		
2022 EXP 11155	Patient reported outcomes after mesh and non mesh complications of pelvic floor surgery	Doctor Eva Fong	18/09/2022	28/09/2022	Declined	Declined	29/09/2022			
2022 EXP 13825	Patient reported outcomes after mesh and non mesh complications of pelvic floor surgery	Doctor Eva Fong	17/11/2022	9/11/2022	Provisionally Approved	Approved	21/11/2022	Te Whatu Ora locality		
2023 EXP 18237	Percutaneous Surgical Fixation of the Lisfranc Injury: a Cohort Review	Dr Matthew D'Arcy	17/06/2023	22/06/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Te Whatu Ora Counties Manukau	
2023 EXP 15450	Percutaneous Surgical Fixation of the Lisfranc Injury: a Retrospective Cohort Review	Dr Matthew D'Arcy	1/04/2023	9/04/2023	Declined	Declined	14/04/2023	Te Whatu Ora locality		
2022 EXP 13178	Phenotypes of Inflammatory Bowel Disease in the Maori Population	Dr David Law	9/08/2022	22/08/2022	Provisionally Approved	Approved	29/09/2022			
2023 FULL 1531 1	Point of care mapping of oxidative stress in patients undergoing gastrointestinal surgery	Mr Wal Baraza	12/04/2023	2/05/2023	Provisionally Approved	Approved	13/06/2023	Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland	
2022 EXP 13561	Positive Participatory Organisational Intervention to Reduce Burnout in New Zealand Emergency Department Staff â€” Multisite study	Dr Gordon Michael (Mike) Nicholls	8/12/2022	5/01/2023	Declined	Declined	11/01/2023	Te Whatu Ora locality		
2023 EXP 15332	Positive Participatory Organisational Intervention to Reduce Burnout in New Zealand Emergency Department Staff â€” Multisite study	Dr Gordon Michael (Mike) Nicholls	8/02/2023	21/02/2023	Provisionally Approved	Approved	9/03/2023	Te Whatu Ora locality		
2023 EXP 13810	Predicting influenza disease burden in New Zealand and informing strategies to manage future disease burden	Professor Cameron Grant	9/05/2023	15/05/2023	Provisionally Approved	Approved	18/08/2023		University of Auckland	
2023 EXP 13938	Prospective study on pseudocellulitis in adults at North Shore Hospital	Dr Hasan Bhally	27/01/2023	3/02/2023	Declined	Declined	13/02/2023	Te Whatu Ora locality		

2022 EXP 13852	Qualitative examination of experiences of early psychosis care services in New Zealand	Dr Rebecca Grattan	4/11/2022	14/11/2022	Approved NSC	Approved	16/11/2022	Te Whatu Ora locality		
2022 FULL 1237 2	Resection of central mesenteric small intestine neuroendocrine tumour (NET) lymph node mass: novel surgical technique and outcomes	Dr Rachel Robertson	19/08/2022	30/08/2022	Provisionally Approved	Approved	21/11/2022	Te Whatu Ora locality		
2023 EXP 12842	Residual tumor volume: stratification of survival after surgery for glioblastoma	Dr. Joyce Antony	14/01/2023	24/01/2023	Provisionally Approved	Approved	1/05/2023			
2022 EXP 13716	Return to bowel function after right versus extended right hemicolectomy: a retrospective analysis	Doctor Zak Maas	10/10/2022	17/10/2022	Provisionally Approved	Approved	8/11/2022			
2022 EXP 13795	Return to work after non-operatively versus operatively managed humeral shaft fractures	Mr Steve McChesney	6/12/2022	5/01/2023	Approved	Approved	10/01/2023			
2023 FULL 1374 0	Safety and Efficacy of the Alleviant System for No-Implant Interatrial Shunt Creation in Patients with Chronic Heart Failure.	Professor Gerard Thomas Wilkins	21/03/2023	4/04/2023	Provisionally Approved	Approved	30/06/2023	Private Organisation, Te Whatu Ora locality		Alleviant Medical Inc.
2023 EXP 13727	Safety, tolerability and efficacy of the use of EvusHeld® as pre-exposure COVID-19 prophylaxis in kidney and simultaneous pancreas kidney transplant recipients – the Australia and New Zealand experience (SHIELD study)	Professor Helen Pilmore	19/10/2022	28/10/2022	Provisionally Approved	Approved	28/03/2023			
2023 FULL 1391 8	Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation – the STEPCARE trial	Prof Paul Young	16/11/2022	6/12/2022	Provisionally Approved	Approved	1/02/2023	Te Whatu Ora locality		
2023 FULL 1820 4	Services Your Way: Evaluating a Youthline national counselling program	Dr Jessica Stubbing	16/06/2023	4/07/2023	Approved NSC	Approved	18/07/2023	Private Organisation	CEO, Youthline	
2023 EXP 13971	Sexual function and early onset colorectal cancer. Functional outcomes and issues around communication.	Dr Oliver Waddell	7/02/2023	9/03/2023	Provisionally Approved	Approved	15/05/2023	Te Whatu Ora locality	University of Otago	
2023 FULL 1554 7	Sheep and Cow milk Complementary Food Effects on	Professor Clare Wall	23/03/2023	4/04/2023	Provisionally Approved	Approved	26/06/2023	Other	University of Auckland	

	Gut Microbial Diversity _SMILEY Pilot Study									
2023 FULL 1672 1	Speech Therapy Delivered by Assistants: Outcomes and Effectiveness	Dr Toby Macrae	14/04/2023	2/05/2023	Provisionally Approved	Approved	2/06/2023	Other	University of Canterbury	
2022 EXP 12580	Steroid Hormones And DNA methylation in Endometriosis	Dr Anna Ponnampalam	29/07/2022	28/08/2022	Provisionally Approved	Provisionally Approved		Private Organisation, Te Whatu Ora locality		
2022 FULL 1347 8	Strategies to improve gout management in Aotearoa New Zealand - EASY-ALLO	Professor Lisa Stamp	23/09/2022	4/10/2022	Approved NSC	Approved	10/10/2022	Te Whatu Ora locality, Tertiary Education Institution	Director Research and Enterprise, University of Otago,	
2023 EXP 18006	Stroke in Paediatric Bacterial Meningitis in the Auckland Region	Dr Margot Price	15/05/2023	22/05/2023	Provisionally Approved	Approved	7/07/2023			
2022 FULL 1272 3	Study of the prevalence of previous and active hepatitis C infection in people who inject drugs using dried blood spot testing at pharmacies and needle exchange in the Northern Region	Dr Geoff Noller	17/08/2022	17/08/2022	Provisionally Approved	Approved	13/09/2022	Private Organisation	Northern Regional Alliance	
2023 EXP 18037	Studying cancer at the single cell level: in-depth analysis for Māori health	Dr Kirsty Danielson	22/05/2023	31/05/2023	Provisionally Approved	Approved	20/07/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Otago	
2022 EXP 13119	Survival after super-selective neck dissection for salvage treatment of mucosal HNSCC	Dr Chelsea Heaven	23/07/2022	27/07/2022	Provisionally Approved	Approved	5/08/2022			
2022 EXP 13688	Te Ara Poutama: Living Well With Heart Disease - Māori Heart Health Survey	Associate Professor Katrina Poppe	1/12/2022	22/12/2022	Approved NSC	Approved	23/12/2022	Other		
2023 EXP 18052	Te Pae Ora - Whā• nau Ora Navigation in Local Delivery of Oncology Care	Miss Maria Ngawati	1/06/2023	18/06/2023	Declined	Declined	27/06/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality		
2023 FULL 1391 2	The Agony & the Ecstasy of Trulicity for Pacific Islanders with Type 2 Diabetes Mellitus	Dr Denise Taylor	21/11/2022	28/11/2022	Provisionally Approved	Approved	22/03/2023	Private Organisation		

2022 EXP 13893	The Auckland Renal Cohort Study	Dr Kalpa Jayanatha	16/11/2022	22/11/2022	Approved NSC	Approved	24/11/2022	Te Whatu Ora locality		
2023 FULL 1797 2	The Australasian Malignant PLeural Effusion (AMPLE)-4 Trial: Topical Antibiotic Prophylaxis for Infections of Indwelling Pleural Catheters in Patients with Malignant Pleural Effusions	Dr Elaine Yap	15/06/2023	4/07/2023	Provisionally Approved	Approved	16/08/2023	Te Whatu Ora locality		Professor of Respiratory Medicine, University of Western Australia
2023 EXP 15097	The Burden of Long COVID in Aotearoa New Zealand: Establishing a Long COVID Registry	Professor Paula Lorgelly	17/05/2023	24/05/2023	Provisionally Approved	Approved	7/06/2023	Other	University of Auckland Waipapa Taumata Rau	
2022 FULL 1304 1	The Effect of Participating in the Let's Play Programme on Social Engagement and Interaction between Autistic Children and their Parents: A Between Groups, Randomised Controlled Trial	Associate Professor Laurie McLay	11/08/2022	6/09/2022	Provisionally Approved	Approved	6/10/2022	Tertiary Education Institution	University of Canterbury	
2023 EXP 13205	The effectiveness of RGM (RONNIE GARDINER METHOD) on cognitive function, quality of life, and physical abilities, in older persons and those with cognitive impairment	Dr Jaimie Wilkie	14/01/2023	7/02/2023	Declined	Declined	10/02/2023	Private Organisation	Summerset House	
2022 EXP 12655	The Effects of Brain Tumour on Cognition	Dr. Carolyn Wilshire	16/05/2022	13/06/2022	Provisionally Approved	Approved	25/08/2022	Te Whatu Ora locality	Te Herenga Waka - Victoria University of Wellington	
2022 FULL 1146 2	The effects of fampridine on EEG profiles in patients with bipolar disorder	Professor Paul Glue	18/08/2022	16/01/2023	Provisionally Approved	Approved	17/01/2023	Te Whatu Ora locality	University of Otago	
2022 FULL 1283 5	The First Responder Shock Trial (FIRST): A cluster randomised controlled trial of smartphone-activated first responders with ultraportable defibrillators in out-of-hospital cardiac arrest (OHCA).	Associate Professor Bridget Dicker	25/05/2022	13/06/2022	Provisionally Approved	Approved	5/08/2022	Other		
2022 EXP 13438	The impact of firm compared to soft coagulated protein-augmented bovine dairy gel on the appearance of amino acids in healthy female adults.	Dr Amber Milan	12/10/2022	18/10/2022	Approved NSC	Approved	21/10/2022	Tertiary Education Institution	Riddet Institute	
2022 EXP 12579	The outcomes of patients with Enterococcus faecalis endocarditis	Dr Simon Briggs	5/04/2022	9/05/2022	Provisionally Approved	Approved	19/07/2022	Te Whatu Ora locality		

	receiving treatment from an Outpatient Parenteral Antibiotic Therapy Service within the Northland, Auckland, Nelson and Christchurch regions July 2022 to June 2027; a prospective observational study of standard of care treatment.									
2022 EXP 13977	Tino Rangatiratanga during the COVID-19 Pandemic: A case study of two kaupapa Māori Bay of Plenty health providers and their COVID-19 community response.	Dr Anna Rolleston	1/12/2022	12/12/2022	Approved NSC	Approved	19/12/2022	Other, Primary Health Care Centre		
2023 FULL 11419	Ultra-Early, minimally invasive intraCerebral haemorrhage evacuation versus standard treatment (EVACUATE)	Dr. Martin Punter	24/01/2023	7/02/2023	Declined	Declined	10/02/2023	Te Whatu Ora locality		The University of Melbourne
2022 EXP 13535	Understanding the cognitive effects of TBI in Ara Poutama: An assessment of cognitive performance across several domains in a New Zealand offending population.	Professor Alice Theadom	8/11/2022	6/12/2022	Declined	Declined	23/12/2022	Other		
2022 EXP 13635	Understanding the Metabolism of Food	DR Serean Adams	29/09/2022	12/10/2022	Provisionally Approved	Provisionally Approved		Private Organisation	Remedius Bio	
2023 EXP 12662	Unravelling the protective effects of the MenZB ₄ vaccine against gonorrhoea in both immunologically primed and immunologically naïve adults.	Mr Jonathan Watts-Henwood	23/11/2022	6/12/2022	Provisionally Approved	Approved	3/03/2023	Tertiary Education Institution	The University of Auckland	
2022 FULL 13375	Using Patient Reported Outcome Measures to evaluate Current Cleft Team Treatment Pilot	Mr Kenny Ardouin	18/10/2022	26/10/2022	Provisionally Approved	Approved	13/12/2022	Te Whatu Ora locality	Dean of Postgraduate Research, UC Graduate School, University of Canterbury	
2022 EXP 13442	Vascular Risk Equity for Aotearoa NZ (VAREANZ)	Assoc Prof Sue Wells	5/10/2022	13/10/2022	Approved NSC	Approved	21/10/2022	Tertiary Education Institution		
2022 FULL 12690	Visual Function and Academic Outcomes in NZ children aged 5-7 years	Dr Rebecca Findlay	24/08/2022	6/09/2022	Provisionally Approved	Approved	2/11/2022	Other	University of Auckland	

2023 FULL 1554 6	What are the cognitive characteristics of men within the prison population?	Professor Alice Theadom	15/03/2023	4/04/2023	Provisionally Approved	Approved	11/05/2023	Other	Auckland University of Technology	
2022 EXP 12361	What are the factors influencing breastmilk feeding in moderate to late preterm infants in New Zealand neonatal care units?	Doctor Tanith Alexander	27/10/2022	9/11/2022	Provisionally Approved	Approved	8/12/2022	Te Whatu Ora locality	The University of Auckland	
2023 EXP 16690	What factors influence successful breastmilk feeding in very preterm pāpi (infants) in Aotearoa (New Zealand) neonatal intensive care units?	Doctor Barbara Cormack	12/06/2023	19/06/2023	Provisionally Approved	Approved	8/08/2023	Te Whatu Ora locality	Liggins Institute	
2023 EXP 16783	When Can I Drive After a Hip Replacement? A Pilot Study on Driving Reactions Following Right Sided Total Hip Replacement	Dr Tim Cheok	21/04/2023	11/05/2023	Provisionally Approved	Approved	22/05/2023	Te Whatu Ora locality		