



**Health and
Disability Ethics
Committees**

**Central Health and Disability
Ethics Committee**

**Annual Report
2023**

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Contents

About this report	1
About the committee.....	1
Chairperson’s report.....	2
Applications reviewed	3
Complaints and overdue application summary.....	4
Complaints received.....	4
Overdue review	4
Appendix 1: Details of applications reviewed.....	5
Applications reviewed by the committee.....	5

About this report

This report is a summary of the activities of the Central 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 Central 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 Central 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 Central HDEC is registered (number IRB00008712) 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

The end of another very busy year for the Central Committee, as a consequence of the amazing research that occurs in New Zealand. Thank you to our Researchers for enabling all this groundbreaking work to occur.

The quality of application is improving immensely, following templates which mean they comply with the ethical guidelines required by New Zealand and making the approval process faster. It is always harder when they are working with an overseas company and their law is different, but we are all making progress.

I must couch this progress with a "But", as in the last 6 months the committee has been intrigued at the number of researchers who state that they don't know the templates exist. Supervisors need to be very supportive of their students.

The speed of scientific progress is huge with AI as an added impact, Ethics Committees consequently need to be supported by a good back up service and training.

A change to the review structure could also be beneficial to accommodate the volume of applications. We already have an expedited path, but a "low risk" expedited review could be added to take the pressure off the full committees.

The decision process for committees needs a slight change I feel. Decisions are "approved, provisional approval, decline". The provisional approval creates a problem if it is returned but not totally addressed. The only option for the reviewer is to decline. Another provisional option would be beneficial.

I would like to take this opportunity to thank the members of the Central Committee for their commitment to the huge ethics workload they cope with alongside their full-time jobs. Without you and your dedication and good humour all the huge advances achieved in Health would not be possible.

I would also like to extend this thanks to the other Committees that I have worked with during the year.

It is busy not only for the committee members but also for our administration team, they need a huge vote of thanks for coordinating all this for us and being there for advice when needed. To have to re listen to the whole meeting again to ensure accurate minutes is true dedication.

Helen Walker QSM

Chair – Central 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)	31
No. of applications deferred (provisionally approved) at first review and subsequently approved	46
No. of applications deferred as at time of report	9
No. of applications that were declined (in part) because of no/insufficient consultation with appropriate Māori/whānau/iwi/hāpu	1
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.)	11
<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	3
No. of studies terminated by sponsor	0
No. of studies transferred to another EC	0
Total number of applications received by full EC	103

Summary of applications received under expedited / low risk review

No. of applications approved	6
No. of applications approved subject to conditions	17
No. of applications deferred and subsequently approved	50
No. of applications deferred as at time of report	11
<i>No. of applications referred for full committee review</i>	2
No. of applications declined	9
No. of studies withdrawn by researcher	0
Total number of applications received under expedited / low risk review	93

Total number of applications received:

196

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 Central HDEC matters.

Overdue review

Average review times consider the time taken for the Secretariat to process applications and the time taken for the Committee to review applications. The clock is stopped when a decision letter is emailed to applicants. Average review times exclude time taken for researchers to respond to requests for further information. Researchers have up to 90 days to respond.

Average review time was 21 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 30 days for full applications. Target timeframe for full applications is 35 days. ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 54-59).

In the expedited review pathways, the clock days went over. The reason for this average being higher than the target was while majority were under the target 15 days, some were exceeded and outliers. This was due to either the submission receiving significant amendments following provisional approval and the Committee needed the time to review this, or in one notable case, an error with the Committee member not noticing the clock has elapsed. The Secretariat since then has instituted an Overdue prompt in the review system that will mark something as overdue for increased monitoring and email the members to review it as soon as possible.

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 13069	A brief intervention to aid smoking cessation: a randomized controlled trial in Intensive Care patients	Dr Louise Trent	25/09/2022	12/10/2022	Declined	Declined	21/10/2022	Te Whatu Ora locality		
2023 EXP 17879	A digital Acceptance and Commitment Therapy and education intervention (ACT for PÄ"pi) targeting stress for parents and caregivers with preterm babies in the neonatal intensive care unit (NICU): a randomised controlled cluster trial	Dr Jane Alsweiler	6/06/2023	27/06/2023	Provisionally Approved	Approved	16/08/2023	Te Whatu Ora locality	University of Auckland	
2022 FULL 13058	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52-weeks in patients with Idiopathic Pulmonary Fibrosis IPF	Doctor Conor O'Dochartaigh	31/10/2022	16/12/2022	Provisionally Approved	Approved	21/12/2022	Te Whatu Ora locality	IQVIA	Boehringer Ingelheim
2022 FULL 13456	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52-weeks in patients with Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)	Doctor Connor O'Dochartaigh	31/10/2022	14/11/2022	Provisionally Approved	Approved	15/11/2022	Te Whatu Ora locality	IQVIA	Boehringer Ingelheim

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

2022 FULL 1367 6	A DOUBLE-BLIND, PLACEBO-CONTROLLED, SINGLE ASCENDING DOSE STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS AND PHARMACODYNAMICS PROPERTIES OF PRX 115 IN ADULT VOLUNTEERS WITH ELEVATED URIC ACID LEVELS	Dr Alex Cole	8/11/2022	22/11/2022	Approved NSC	Approved	6/12/2022	Private Organisation	Novotech	Protalix Ltd
2023 FULL 1506 3	A Double-Blind, Randomized, Placebo-Controlled, Single Dose Study to Investigate the Safety, Tolerability, and Pharmacokinetics of AB-161 Following Oral Administration in Healthy Subjects	Professor Edward Gane	9/01/2023	24/01/2023	Approved NSC	Approved	31/01/2023	Private Organisation	Novotech (New Zealand) Limited	Arbutus Biopharma
2023 EXP 15398	A multicenter study of antimicrobial de-escalation in critically ill patients	Mr Eamon Duffy	14/04/2023	20/04/2023	Provisionally Approved	Approved	1/05/2023		Te Toka Tumai	
2023 FULL 1368 9	A Multicenter, Double-blind, Randomized Phase 3 Study to Compare the Efficacy and Safety of Belzutifan (MK-6482) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab, in the Adjuvant Treatment of Clear Cell Renal Cell Carcinoma (ccRCC) Post Nephrectomy	Dr Simon Fu	9/01/2023	24/01/2023	Approved NSC	Approved	31/01/2023	Te Whatu Ora locality	Merck Sharp & Dohme (New Zealand) Limited (MSD)	Merck, Sharp & Dohme (Australia) Pty Ltd
2023 FULL 1814 8	A multinational, multicenter, prospective, randomized controlled, open label Phase 3 study with best standard of care with and without 177Lu-DOTA-rosopitamab for patients with PSMA expressing metastatic castration-resistant prostate cancer progressing despite prior treatment with a novel androgen axis drug	Dr Remy Lim	8/06/2023	27/06/2023	Provisionally Approved	Approved	6/07/2023	Private Organisation	Telix Pharmaceuticals (NZ) Ltd	Telix International Pty Ltd

2023 FULL 1518 4	A MULTIPLE-CENTER, NON-RANDOMIZED, OPEN-LABEL STUDY TO INVESTIGATE THE EFFECT OF VARIOUS DEGREES OF RENAL IMPAIRMENT ON THE PHARMACOKINETICS OF A SINGLE INTRAVENOUS DOSE OF RO7223280.	Doctor Nick Cross	16/03/2023	28/03/2023	Approved NSC	Approved	31/03/2023	Private Organisation	Labcorp New Zealand Limited	F. Hoffmann-La Roche Ltd
2022 FULL 1298 2	A Phase 1 Randomized, First in Human, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single-Ascending Doses of EMP- 01 in Healthy Adult Volunteers	Dr. Mark Marshall	12/07/2022	26/07/2022	Approved NSC	Approved	2/08/2022	Private Organisation	Novotech (New Zealand) Limited	EmpathBio, Inc.
2022 FULL 1342 2	A Phase 1 Randomized, Placebo-Controlled Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of HZN-457 in Healthy Volunteers	Dr Alexandra Cole	13/09/2022	27/09/2022	Approved NSC	Approved	3/10/2022	Private Organisation	Novotech	Horizon Therapeutics, Inc
2022 FULL 1349 1	A Phase 1 Single Ascending and Multiple Ascending Dose Study to Evaluate the Safety and Pharmacokinetics of ZB002 in Healthy Volunteers	Principal Investigator Cory Sellwood	13/09/2022	27/09/2022	Approved NSC	Approved	3/10/2022	Private Organisation	PPD, Part of Thermo Fisher Scientific	Zenas BioPharma (USA), LLC.
2023 FULL 1557 9	A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of IMVT-1402 Following Single and Multiple Doses in Healthy Participants	Dr Rohit Katial	4/04/2023	26/04/2023	Approved NSC	Approved	15/05/2023	Private Organisation	PPD, part of Thermo Fisher Scientific Office	Immunovant Sciences
2022 FULL 1323 2	A PHASE 1/2A STUDY EVALUATING THE EFFECTS OF ARO-MMP7 INHALATION SOLUTION IN HEALTHY SUBJECTS AND PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS	Dr. Alexandra Cole	9/08/2022	23/08/2022	Approved NSC	Approved	2/09/2022	Private Organisation	Novotech (New Zealand) Limited	Arrowhead Pharmaceuticals, Inc.

2023 FULL 15130	A PHASE 1B OPEN-LABEL/ PHASE 2 DOUBLE-BLIND PLACEBO-CONTROLLED STUDY FOR PHARMACODYNAMIC ACTIVITY, PHARMACOKINETICS, SAFETY AND TOLERABILITY OF KAN-101 IN PATIENTS WITH CELIAC DISEASE	Dr Dean Quinn	16/02/2023	28/02/2023	Approved NSC	Approved	16/03/2023	Private Organisation	Pfizer New Zealand Limited	Kanyos Bio, Inc., a wholly-owned subsidiary of Anokion SA
2023 FULL 15301	A Phase 2 Study Evaluating INCB099280 in Participants With Select Solid Tumors Who Are Immune Checkpoint Inhibitor Naive	Dr Orlaith Heron	13/06/2023	20/06/2023	Provisionally Approved	Approved	27/06/2023	Te Whatu Ora locality	Iqvia	Incyte Corporation
2022 FULL 13023	A Phase 2 Study to Evaluate Efficacy, Safety and Tolerability of VIR-2218 and VIR-3434 in Participants with Chronic Hepatitis D Virus Infection (SOLSTICE)	Prof. Edward Gane	11/07/2022	26/07/2022	Approved NSC	Approved	2/08/2022	Private Organisation	PPD Global Limited	Vir Biotechnology, Inc.
2022 FULL 13665	A phase 2, multicenter, randomized, double-blind, placebo-controlled, single dose, dose-ranging study to determine the safety and immunogenicity of bivalent GI.1 and GI.4 vaccine administered orally to healthy volunteers aged ≥ 18 years and ≤ 80 years old.	Doctor Paul Hamilton	7/11/2022	22/11/2022	Approved NSC	Approved	6/12/2022	Private Organisation	Novotech (New Zealand) Limited	Vaxart, Inc
2022 FULL 13788	A Phase 2a Proof-of-Principle Study of the Acute Antidepressant Effects of Two Intravenous Doses of VLS-01-IV in Participants with Major Depressive Disorder	Dr. Cameron Lacey	4/11/2022	22/11/2022	Approved NSC	Approved	6/12/2022	Private Organisation	Novotech (New Zealand) Limited	Viridia Life Sciences Australia Pty. Ltd.
2022 FULL 13251	A Phase 2b Randomised Controlled Trial of Sodium Selenate as a Disease Modifying Treatment for Probable Behavioural Variant Frontotemporal Dementia	Dr. Campbell Le Heron	6/09/2022	21/09/2022	Provisionally Approved	Approved	23/09/2022	Private Organisation		Alfred Health

2023 FULL 1398 5	A Phase 3 Open-label Clinical Study of Doravirine/Islatravir (DOR/ISL [100 mg/0.25 mg]) Once Daily for the Treatment of HIV-1 Infection in Participants Who Previously Received DOR/ISL (100 mg/0.75 mg) QD in a Phase 3 Clinical Study	Dr Alan Pithie	9/02/2023	23/02/2023	Provisionally Approved	Approved	24/02/2023	Te Whatu Ora locality	MSD New Zealand	Merck Sharp & Dohme (Australia) Pty Ltd, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA
2022 FULL 1275 8	A Phase 3 Open-Label, Randomized Study of Pirtobrutinib (LOXO-305) versus Ibrutinib in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BRUIN-CLL-314)	Dr Kirsty Marshall	22/08/2022	3/09/2022	Provisionally Approved	Approved	5/09/2022	Private Organisation, Te Whatu Ora locality	IQVIA RDS Pty Limited	IQVIA RDS Pty Limited
2023 FULL 1370 0	A Phase 3, 24-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm Efficacy and Safety Study with Open-label Extension of BLU-5937 in Adult Participants with Refractory Chronic Cough Including Unexplained Chronic Cough (CALM-2).	Dr Michael Epton	10/01/2023	9/02/2023	Provisionally Approved	Approved	10/02/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	IQVIA RDS Pty Limited	Bellus Health, Inc.
2022 FULL 1325 8	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 50 Years of Age or Older.	Professor Richard Stubbs	10/08/2022	23/08/2022	Approved NSC	Approved	2/09/2022	Private Organisation	Merck Sharp & Dohme (Australia) Pty Ltd, Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD)	Merck Sharp & Dohme (MSD) a subsidiary of Merck & Co., Inc., Rahway, NJ, USA
2023 FULL 1522 0	A Phase 3, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Demonstrate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, for Stroke Prevention after an Acute Ischemic Stroke or High-Risk Transient Ischemic Attack (LIBREXIA-STROKE)	Dr. Karim Mahawish	15/06/2023	2/07/2023	Provisionally Approved	Approved	3/07/2023	Te Whatu Ora locality	Janssen-Cilag (New Zealand) Limited	Janssen Research & Development, LLC

2023 FULL 15285	A Phase 3, Randomized, Double-blind, Placebo-controlled, Event-driven Study to Demonstrate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, After a Recent Acute Coronary Syndrome	Dr Jocelyne Benatar	22/05/2023	25/05/2023	Provisionally Approved	Approved	2/06/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	Janssen-Cilag (New Zealand) Limited	Janssen Research & Development
2023 FULL 13920	A Phase 3, Randomized, Multi-regional, Double-blind, Double-dummy Parallel-group, Placebo and Allopurinol-controlled Study to Assess the Efficacy and Safety of Tigulixostat in Gout patients with Hyperuricemia.	Dr Alan Doube	15/05/2023	25/05/2023	Provisionally Approved	Approved	2/06/2023	Private Organisation, Te Whatu Ora locality		LG Chem Ltd
2022 EXP 13004	A Phase 4 Randomized, Double-blind, Dose-Flexibility Study of Upadacitinib in Adult Subjects with Moderate to Severe Atopic Dermatitis (Flex-Up)	Dr Marius Rademaker	27/10/2022	10/11/2022	Provisionally Approved	Approved	15/11/2022	Private Organisation, Te Whatu Ora locality	AbbVie Ltd	AbbVie Ltd
2023 FULL 17870	A PHASE I/II STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS, AND EFFICACY OF NXT007 IN PERSONS WITH SEVERE OR MODERATE HEMOPHILIA A	Dr. Laura Young	11/05/2023	23/05/2023	Provisionally Approved	Approved	20/07/2023	Te Whatu Ora locality		Roche Products (New Zealand) Ltd.
2022 FULL 12802	A PHASE Ib, OPEN-LABEL STUDY EVALUATING THE SAFETY, PHARMACOKINETICS, AND ACTIVITY OF GDC-1971 IN COMBINATION WITH ATEZOLIZUMAB IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC SOLID TUMORS	Dr Sanjeev Deva	9/08/2022	23/08/2022	Approved NSC	Approved	2/09/2022	Private Organisation, Te Whatu Ora locality	PPD, part of Thermo Fisher Scientific	Genentech, Inc
2022 FULL 12636	A phase III randomized, double-blind, placebo-controlled parallel group trial to examine the efficacy and safety of BI 425809 once daily over 26 week treatment period in patients with schizophrenia (CONNEX-1)	Associate Professor Sylvester Wayne Miles	1/11/2022	21/11/2022	Provisionally Approved	Approved	22/11/2022	Te Whatu Ora locality		Boehringer Ingelheim Pty Ltd

2023 EXP 13764	A pilot dose duration-response study using Advantan® fatty 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	13/04/2023	23/04/2023	Provisionally Approved	Approved	24/04/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd
2023 FULL 13765	A pivotal in vivo bioequivalence study comparing methylprednisolone aceponate fatty ointment (Nova Chem, Australia) to Advantan® fatty ointment (Leo Pharma Pty Ltd, Australia), using the ED50 for Advantan® fatty 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	14/05/2023	25/05/2023	Provisionally Approved	Approved	2/06/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd
2022 FULL 12769	A Randomised Trial of Shock Energy for Electrical Cardioversion of Persistent Atrial Fibrillation	Dr Allan Plant	2/08/2022	9/08/2022	Provisionally Approved	Approved	12/08/2022	Te Whatu Ora locality		
2023 FULL 15293	A randomized, double-blind, placebo-controlled Phase 3 study of darolutamide plus androgen deprivation therapy (ADT) compared with placebo plus ADT in patients with high-risk biochemical recurrence (BCR) of prostate cancer	Mr. Kevin Bax	9/03/2023	28/03/2023	Provisionally Approved	Declined	31/03/2023	Private Organisation, Te Whatu Ora locality	Bayer New Zealand Limited	Bayer Consumer Care AG
2022 FULL 13791	A Randomized, Double-blind, Placebo-controlled, 3 part Study of ABCI: Single-ascending Dose Phase 1a Study in Healthy Volunteers (Part A), a 14- and 28-day Multiple-ascending Dose Phase 1b Study in Healthy Volunteers (Part B), and a 28 day	Dr Cory Sellwood	9/11/2022	22/11/2022	Approved NSC	Approved	6/12/2022	Private Organisation	Novotech	cystetic Medicines

	Phase 2a Study in Subjects with Cystic Fibrosis (Part C)									
2023 FULL 15452	A SINGLE ASCENDING DOSE (SAD) STUDY TO EVALUATE THE SAFETY AND PHARMACOKINETICS (PK) OF ZB004 IN HEALTHY VOLUNTEERS	Doctor Cory Dean Sellwood	13/03/2023	28/03/2023	Approved NSC	Approved	31/03/2023	Private Organisation	PPD, Part of Thermo Fisher Scientific	Zenas BioPharma (USA), LLC.
2022 EXP 12091	A Study to Evaluate the Effects of Dual Anti-Platelet Therapy on the Platelet-Neutrophil Interaction	Dr. Kathryn Hally	15/09/2022	26/09/2022	Provisionally Approved	Approved	27/09/2022	Tertiary Education Institution		
2023 EXP 17953	Effect of novel functional connectivity neurofeedback training on pain and function in chronic low back pain- A pilot double blinded randomised placebo-controlled trial.	Professor Dirk De Ridder	10/05/2023	22/05/2023	Provisionally Approved	Approved	27/07/2023	Tertiary Education Institution	University of Otago	
2022 EXP 13957	Accuracy of Personal Wearable ECG Devices in Pacemaker Patients	Miss Priya Garg	20/12/2022	27/01/2023	Approved NSC	Approved	30/01/2023	Te Whatu Ora locality		
2023 FULL 15631	Active Support as an Antecedent Intervention for Challenging Behaviour in Adults with Intellectual or Developmental Disability	PhD Candidate, MedPsych Sophia Kennedy	12/06/2023	27/06/2023	Approved NSC	Approved	4/07/2023	Private Organisation		
2023 EXP 13859	Acute effects of a dairy protein (whey) hydrolysate on postprandial metabolism in healthy adults: glycaemia, thermogenesis, gut barrier function, immune/inflammation	Associate Professor Jennifer Miles-Chan	11/01/2023	27/01/2023	Provisionally Approved	Approved	30/01/2023	Tertiary Education Institution	Office of Research Strategy and Integrity, University of Auckland	

2023 FULL 15200	ADVANCED NanoTherapies Dual Active Pharmacological Ingredient (Dual-API) Drug-Coated Balloon to treat De-Novo lesions in patients with symptomatic stable angina, unstable angina and NSTEMI	Prof Mark Webster	28/03/2023	26/04/2023	Provisionally Approved	Approved	28/04/2023	Te Whatu Ora locality		Advanced NanoTherapies, Inc
2023 FULL 18050	An Extension Study to Monitor Long-Term Safety of LUM-201 Treatment in Children with Idiopathic Growth Hormone Deficiency	Dr. Esko Wiltshire	9/06/2023	27/06/2023	Provisionally Approved	Approved	16/08/2023	Other	Novotech (New Zealand) Limited	Lumos Pharma
2023 FULL 16702	AN OPEN-LABEL, RANDOMIZED PHASE IB/II STUDY EVALUATING SAFETY, TOLERABILITY, AND CLINICAL ACTIVITY OF FORINTAMIG-BASED TREATMENT COMBINATIONS IN PARTICIPANTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA	Prof Peter Browett	14/06/2023	27/06/2023	Approved NSC	Approved	4/07/2023	Private Organisation		Roche Products (New Zealand) Ltd
2022 EXP 12541	Analysis of PMMRC data to determine the mortality associated with Neonatal Encephalopathy in New Zealand	Dr Malcolm Battin	18/08/2022	24/08/2022	Provisionally Approved	Approved	25/08/2022	Te Whatu Ora locality		
2022 EXP 11911	Are elite rugby players'™ career and mTBI histories linked to later life changes in brain structure and decisions to retire from rugby?	Dr Mangor Pedersen	21/07/2022	26/07/2022	Provisionally Approved	Approved	28/07/2022	Tertiary Education Institution	Auckland University of Technology	
2022 FULL 13309	Argi Medtech Coherent Sine Burst (CSE) Electroporation System Pilot Study in Patients with Atrial Fibrillation	Dr Matthew Daly	9/12/2022	22/12/2022	Provisionally Approved	Approved	23/12/2022	Te Whatu Ora locality		Arga Medtech SA

2022 EXP 12628	Assessment of mitochondrial metabolism in liver biopsies from resection specimens and liver grafts	Associate Professor Louise Barbier	14/10/2022	1/11/2022	Approved NSC	Approved	2/11/2022	Te Whatu Ora locality		
2023 EXP 16650	Association between side of colon cancer and histopathological features	Dr Daniel Carson	9/05/2023	16/05/2023	Provisionally Approved	Approved	18/05/2023		Tauranga Hospital	
2022 FULL 12897	Asthma Review and Management in New Zealand Community Pharmacy - a Single Cohort, Open Label Non-Randomised Pilot Study	Dr Alex Semprini	5/08/2022	23/08/2022	Approved NSC	Approved	2/09/2022	Other, Primary Health Care Centre, Private Organisation	Medical Research Institute of New Zealand	
2022 FULL 11019	Australasian Paediatric Endocrine Group Patient Registry (APR)	Dr Craig Jefferies	3/08/2022	11/08/2022	Provisionally Approved	Approved	12/08/2022	Te Whatu Ora locality		
2022 FULL 11727	Automatic versus manual oxygen titration using a novel nasal high-flow oxygen delivery device in adults attending the Emergency Department: a randomised controlled trial	Dr Louis Kirton	22/08/2022	25/08/2022	Provisionally Approved	Approved	29/08/2022	Te Whatu Ora locality	Fisher and Paykel Healthcare Limited	
2022 EXP 11873	Autonomic nervous system responses to six weeks of chiropractic care in people with subclinical pain: A pragmatic pilot randomised controlled trial.	Miss Marie Brunsart	1/08/2022	9/08/2022	Provisionally Approved	Approved	11/08/2022	Private Organisation	Head of School of Clinical Sciences	
2022 FULL 13890	BIO MASTER.CSP: Pivotal study of the Amvia pacemaker and Solia CSP S pacing lead on conduction system pacing.	Dr Matthew O'Connor	21/12/2022	24/01/2023	Approved NSC	Approved	31/01/2023	Te Whatu Ora locality		BIOTRONIK Australia Pty Ltd, BIOTRONIK SE & Co. KG

2022 FULL 1232 4	Breathing Control Training (BCT) as a Treatment for Functional Seizures (FS). A multi centre single blinded randomised befriendng controlled efficacy and acceptability trial.	Associate Professor Roderick Duncan	15/12/2022	21/12/2022	Provisionally Approved	Approved	22/12/2022	Other, Te Whatu Ora locality		
2023 FULL 1543 5	C5261001: A PHASE 1/2/3 STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF COMBINED MODIFIED RNA VACCINE CANDIDATES AGAINST COVID-19 AND INFLUENZA IN HEALTHY INDIVIDUALS	Dr Claire Thurlow	14/03/2023	28/03/2023	Approved NSC	Approved	31/03/2023	Other, Private Organisation	Pfizer New Zealand Limited	BioNTech SE
2022 EXP 12986	CAMERA STUDY	Professor Jeroen Douwes	29/12/2022	27/01/2023	Provisionally Approved	Approved	30/01/2023	Tertiary Education Institution	Research Ethics Office, Massey University	
2022 EXP 12220	Can the co-creation of an action plan support healthy smartphone habits for new mothers?	Ms Miriam McCaleb	13/07/2022	18/07/2022	Provisionally Approved	Approved	19/07/2022	Tertiary Education Institution	University of Canterbury	
2023 EXP 15284	Cause-specific mortality among children with cancer in Aotearoa, New Zealand	Dr Andrew Wood	15/03/2023	25/03/2023	Approved NSC	Approved	28/03/2023			
2023 FULL 1523 9	CEC-4/CEL: A phase IIb, double-blind, randomised, placebo-controlled trial to evaluate the efficacy and tolerability of ZED1227 in celiac disease subjects experiencing symptoms despite gluten-free diet	Dr Penelope Jane Montgomery	8/03/2023	16/05/2023	Provisionally Approved	Approved	17/05/2023	Private Organisation	Novotech (New Zealand) Limited	Dr. Falk Pharma GmbH

2022 EXP 12747	CENIC II New Zealand Supplement. Perceptions, Concerns, Needs and Intentions Related to Reducing Nicotine in Combusted Tobacco	Professor Chris Bullen	27/05/2022	18/07/2022	Provisionally Approved	Approved	21/07/2022	Other	University of Auckland (Ethics and Integrity)	Wake Forest University School of Medicine
2023 EXP 13820	CLIMATE. Assessing the Clinical utility of miR-371a-3p as a marker of residual disease in Clinical Stage 1 Testicular Germ Cell Tumour, following orchidectomy.	Doctor Orlaith Heron	21/12/2022	9/03/2023	Provisionally Approved	Approved	17/03/2023	Te Whatu Ora locality		ANZUP Cancer Trials Group Ltd
2022 EXP 12756	Cochlear Implant Outcomes in Children with Bilateral Cochlear Nerve Deficiency	Doctor Zhenggu Zang	30/12/2022	27/01/2023	Approved NSC	Approved	30/01/2023			
2022 EXP 12520	Co-design of frailty interventions and core outcome measures for community dwelling older adults living with frailty	Dr Katherine Bloomfield	22/12/2022	27/01/2023	Provisionally Approved	Approved	30/01/2023	Te Whatu Ora locality	University of Auckland	
2023 EXP 15279	Co-designing with consumersâ€™ rehabilitation services following amputation	Ms Vanessa Cameron	24/03/2023	19/04/2023	Declined	Declined	20/04/2023	Te Whatu Ora locality		
2023 EXP 17960	Co-designing with consumersâ€™ rehabilitation services following amputation	Ms Vanessa Cameron	23/05/2023	29/05/2023	Provisionally Approved	Approved	31/05/2023	Te Whatu Ora locality		
2023 FULL 15199	COG ACNS1821: A Phase 1/2 Trial of Selinexor (KPT-330) and Radiation Therapy in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG)	Dr Andrew Dodgshun	17/03/2023	26/04/2023	Approved NSC	Approved	15/05/2023	Te Whatu Ora locality		Children's Oncology Group

2022 FULL 1134 2	COG ACNS2021: A Phase 2 Trial of Chemotherapy followed by Response Based Whole Ventricular & Spinal Canal Irradiation (WVSCI) for Patients with Localized Non-Germinomatous Central Nervous System Germ Cell Tumour	Dr Stephen Laughton	8/11/2022	15/11/2022	Provisionally Approved	Approved	17/11/2022	Te Whatu Ora locality		Children's Oncology Group
2022 FULL 1248 7	COG AOST2031: A Phase 3 Randomised Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma	Dr Tristan Pettit	23/08/2022	4/09/2022	Provisionally Approved	Approved	5/09/2022	Te Whatu Ora locality		Children's Oncology Group
2022 FULL 1284 1	COG APAL2020SC: Paediatric Acute Leukaemia Screening Trial - Developing New Therapies for Relapsed Leukaemia	Dr Andrew Wood	1/07/2022	26/07/2022	Approved NSC	Approved	2/08/2022	Te Whatu Ora locality		Children's Oncology Group
2022 EXP 13043	Colonisation efficacy of Streptococcus salivarius M18 toothpaste.	Professor Emeritus John Tagg	18/07/2022	26/07/2022	Provisionally Approved	Approved	27/07/2022	Private Organisation	Blis Technologies	
2022 FULL 1400 9	Comparative evaluation of pain among the patients treated with different available external splintage devices for simple wrist fracture during the first two weeks of splintage	Dr Pranesh Kumar	3/12/2022	24/01/2023	Declined	Declined	31/01/2023	Primary Health Care Centre		
2022 EXP 14029	Comparative study of severe head injury outcomes using CRASH & IMPACT prognostic calculators in a New Zealand setting	Dr Harini Ravi	7/12/2022	21/12/2022	Approved	Approved	10/01/2023			
2023 EXP 12694	Comparing Nail versus locking plate in displaced three-part proximal humerus fractures; A multi-centre randomised controlled trial (PHINZ trial), investigating the effect on function post-operatively	Dr Zohreh Jafarian Tangrood	26/04/2023	23/05/2023	Declined	Declined	6/06/2023	Te Whatu Ora locality		

2022 FULL 12790	CSL300_3001: A Pivotal Phase 3 Trial to Evaluate the Safety and Efficacy of Clazakizumab for the Treatment of Chronic Active Antibody-Mediated Rejection in Kidney Transplant Recipients	Dr Ian Dittmer	31/08/2022	5/09/2022	Provisionally Approved	Approved	6/09/2022	Te Whatu Ora locality	Novotech (New Zealand) Limited	CSL Behring LLC
2023 FULL 17923	Cue Health International Influenza Clinical Study	Dr. Tori Middlemiss	23/06/2023	18/07/2023	Provisionally Approved	Approved	18/07/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	IQVIA RDS Pty Limited	Cue Health Inc
2022 EXP 12873	Development and Validation of a Prediction Model for Legionnaires' Disease and investigation of novel pneumonia aetiology diagnostic tests	Dr Michael Maze	4/08/2022	9/08/2022	Provisionally Approved	Approved	11/08/2022	Te Whatu Ora locality	University of Otago	
2023 EXP 15241	Development of a cohort builder tool to facilitate the inclusion of patients into clinical trials in oncology	Dr Clement Korenbaum	2/06/2023	27/06/2023	Approved	Approved	4/07/2023		University of Auckland	
2022 EXP 13380	Difference in Rates of Opioids on Discharge after Lower Limb Arthroplasty between Public and Private Hospitals (DROPP study)	Dr Zeyin Li	10/08/2022	25/08/2022	Provisionally Approved	Provisionally Approved				
2023 FULL 13039	Early Detection of Keratoconus (KC) using Artificial Intelligence (AI): Prospective Clinical Validation of the AI Model	Dr Rasha Altaie	4/02/2023	23/02/2023	Provisionally Approved	Approved	24/02/2023	Other, Te Whatu Ora locality		
2023 EXP 15418	Early Hearing Detection and Intervention; experiences of indigenous families (New Zealand Māori)	Dr Andrew Wood	22/04/2023	1/05/2023	Provisionally Approved	Approved	1/05/2023	Te Whatu Ora locality	University of Auckland	

2022 FULL 1267 6	Eastern Porirua Community Gout Project	Mr Ajay Kumar	12/12/2022	30/01/2023	Provisionally Approved	Approved	31/01/2023	Primary Health Care Centre	Cannons Creek Pharmacy	
2022 EXP 13630	Effect of phenylephrine and norepinephrine on cerebral blood flow during general anaesthesia in adult patients having non-cardiac surgery: a single centre, investigator blinded randomised control trial.	Dr Chen Chen	4/11/2022	10/11/2022	Provisionally Approved	Approved	15/11/2022	Te Whatu Ora locality	Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland	
2022 EXP 12925	Effects of bovine collagen hydrolysate protein and milk protein on joint pain, osteoarthritis symptoms, collagen synthesis and degradation, inflammation, skin elasticity and hydration in postmenopausal women with knee pain.	Prof Jane Coad	11/08/2022	25/08/2022	Approved NSC	Approved	29/08/2022	Tertiary Education Institution	Massey University	
2022 EXP 13559	Efficient per-protocol estimates from the Balanced trial	Hon. Prof Timothy Short	31/10/2022	15/11/2022	Approved	Approved	15/11/2022		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland	
2022 FULL 1178 6	Elucidating the effects of nebulized sodium nitrite and argon on blood pressure and cerebrovascular haemodynamics	Dr Mickey Fan	20/07/2022	28/07/2022	Provisionally Approved	Approved	1/08/2022	Te Whatu Ora locality, Tertiary Education Institution	The Health Research Council of New Zealand	
2022 EXP 13783	Engagement with Māori and Pasifika patients around vitamin C supplementation study	A/Prof Anitra Carr	27/10/2022	20/11/2022	Declined	Declined	21/11/2022	Te Whatu Ora locality	Te Whatu Ora " Waitaha Canterbury	
2023 EXP 15448	Epidemiology and Clinical Features of Giant Cell Arteritis in Waikato Region from 2014 to 2022	Dr Philippa van Dantzig	4/04/2023	20/04/2023	Provisionally Approved	Approved	21/04/2023		Rheumatology Research Department	

2022 EXP 11941	Equity in paediatric asthma in New Zealand Emergency Departments; a multi-centred retrospective cohort study	Prof Stuart Dalziel	22/11/2022	2/12/2022	Provisionally Approved	Provisionally Approved				
2023 FULL 15364	Evaluation of an implementation intervention to enhance national translation of nurse-initiated protocols for fever, hyperglycaemia and swallowing management following stroke: a cluster randomised controlled trial.	Dr Julia Stark	4/04/2023	26/04/2023	Approved NSC	Approved	15/05/2023	Te Whatu Ora locality	University of Auckland	Australian Catholic University
2022 EXP 12550	Evidence of acute hypoxia ischaemia in infants reported to PMMRC Neonatal Encephalopathy dataset	A.Prof Malcolm Battin	18/08/2022	24/08/2022	Provisionally Approved	Approved	25/08/2022	Te Whatu Ora locality		
2022 FULL 13115	Examining Food Insecurity in a Regional New Zealand Emergency Department	Dr Stephanie Richling	13/07/2022	26/07/2022	Declined	Declined	2/08/2022	Te Whatu Ora locality		
2023 EXP 15164	Exploring functional connectivity neurofeedback training for treatment of fibromyalgia- A pilot double blinded randomised placebo-controlled study.	Professor Dirk De Ridder	27/02/2023	9/03/2023	Provisionally Approved	Approved	17/03/2023	Tertiary Education Institution	University of Otago	
2023 EXP 16710	Feasibility of using the Gait&Balance app in chiropractic clinics for measuring balance in older adults	Dr Usman Ghani	19/06/2023	23/06/2023	Provisionally Approved	Approved	28/06/2023	Other	New Zealand College of Chiropractic	
2023 FULL 13947	First in Human and Early Feasibility Clinical Study of the FloStent System	Professor Peter Gilling	23/02/2023	10/03/2023	Provisionally Approved	Approved	21/03/2023	Private Organisation , Te Whatu Ora locality		Rivermark Medical Inc, Avania Clinic

2022 EXP 12652	Fluorescent dye imaging to demonstrate reflux in the superficial microvenous network of the leg: A pilot cohort study	Dr Jolanta Krysa	15/11/2022	30/11/2022	Provisionally Approved	Approved	2/12/2022	Te Whatu Ora locality, Tertiary Education Institution	Research Office, University of Otago	
2023 EXP 13446	Genetic Sequencing of Tissue Banked Pancreatic Adenocarcinoma Specimens Northern Regional Tissue Bank.	PROFF/MR JONATHAN KOEA	21/06/2023	23/06/2023	Provisionally Approved	Approved	28/06/2023	Te Whatu Ora locality		
2022 EXP 12825	Genetics of Non-Identical Twinning	Professor Martin Kennedy	25/08/2022	6/09/2022	Approved NSC	Approved	9/09/2022	Tertiary Education Institution		Queensland Institute for Medical Research-Berghofer (Brisbane)
2022 EXP 12566	Genomic and Epigenomic markers for early detection and predicting treatment response in lung cancer	Dr Ben Brockway	30/06/2022	4/07/2022	Provisionally Approved	Approved	6/07/2022	Private Organisation, Te Whatu Ora locality	University of Otago	
2022 EXP 13892	Guillain–Barré syndrome in the time of the SARS-CoV-2 pandemic"	Dr Eileen Mc Manus	29/11/2022	3/12/2022	Approved	Approved	6/12/2022	Te Whatu Ora locality		
2022 EXP 12997	Health Related Quality of Life in Cancer Patients of Different Ethnicities	Dr Mei Sze Lee	19/07/2022	27/07/2022	Declined	Declined	28/07/2022	Te Whatu Ora locality, Tertiary Education Institution		
2023 EXP 15173	Health Related Quality of Life in Cancer Patients of Different Ethnicities	Dr Mei Sze Lee	12/01/2023	8/02/2023	Declined	Declined	22/02/2023	Te Whatu Ora locality, Tertiary Education Institution		

2023 EXP 13817	Impact of inflammation on colon cancer biology	Dr Silke Neumann	10/02/2023	23/02/2023	Provisionally Approved	Approved	17/03/2023	Te Whatu Ora locality, Tertiary Education Institution		
2022 EXP 13141	Impact of referral pathways on the time to first cancer treatment in non-screen detected breast cancer in regional New Zealand	Dr Tara Linton	12/08/2022	24/08/2022	Provisionally Approved	Approved	3/10/2022			
2023 FULL 12707	Improving health services for people with musculoskeletal chest pain - a randomised controlled feasibility trial	Dr Ewan Kennedy	9/01/2023	24/01/2023	Provisionally Approved	Declined	16/03/2023	Other, Te Whatu Ora locality, Tertiary Education Institution		
2023 FULL 15594	Improving perioperative outcomes after adrenalectomy for pheochromocytoma (Periop-Phaeo): proposal for an international multi-centre study	Dr Philippa Mercer	5/04/2023	20/04/2023	Approved	Approved	21/04/2023	Te Whatu Ora locality		Queen Elizabeth Hospital
2022 FULL 11917	In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) of drug absorption across human skin.	Dr Noelyn Hung	4/08/2022	23/08/2022	Provisionally Approved	Approved	14/12/2022	Private Organisation		
2022 EXP 13278	Incidence of rebound pain and patient-perceived quality of single shot peripheral nerve block provision and transition among patients at ADHB.	Dr Lora Pencheva	27/07/2022	11/08/2022	Provisionally Approved	Approved	9/09/2022	Te Whatu Ora locality	ADHB	
2022 FULL 13497	Infant Interfaces and Accessories Sizing Study, NZ	Miss Kelly Gradon	4/11/2022	22/11/2022	Provisionally Approved	Approved	7/12/2022	Private Organisation	Fisher & Paykel Healthcare	

2023 EXP 13538	Investigating the role of mainstream pharmacological agents in the regulation of the optical properties of the in vivo human ocular lens	Dr Alyssa Lie	10/10/2022	25/10/2022	Provisionally Approved	Approved	31/01/2023	Tertiary Education Institution	The University of Auckland	
2023 EXP 16746	In-Vitro Compatibility of Human Blood to Pig Cells	Dr. Ian Dittmer	13/06/2023	23/06/2023	Provisionally Approved	Approved	18/08/2023	Other, Te Whatu Ora locality	NZeno Limited	
2023 FULL 13154	ITCC-101/APAL2020D : A randomized phase 3 trial of fludarabine/cytarabine/gemtuzumab ozogamicin with or without venetoclax in children with relapsed AML	Dr Andrew Cameron Wood	4/04/2023	26/04/2023	Approved NSC	Approved	15/05/2023	Te Whatu Ora locality	Pharmaceutical Research Associates New Zealand Limited	Leukemia & Lymphoma Society PedAL Initiative, Limited Liability Company, LLS PedAL Initiative, LLC, Princess Maxima Center for Pediatric Oncology
2023 FULL 13747	Kaitoh Atherectomy System: Peripheral Artery Revascularization of Stenotic/Restenotic disease using the Atherectomy System in the peripheral arteries	Associate Professor Andrew Holden	4/04/2023	26/04/2023	Provisionally Approved	Approved	15/06/2023	Te Whatu Ora locality		Terumo Medical Corporation
2022 FULL 13799	KEYVIBE-010 - Phase 3, Randomized, Double-blind, Active-Comparator-Controlled Clinical Study of Adjuvant MK-7684A (Vibostolimab with Pembrolizumab) Versus Adjuvant Pembrolizumab in Participants with High-risk Stage II-IV Melanoma	Dr Richard North	9/11/2022	22/11/2022	Provisionally Approved	Approved	31/01/2023	Private Organisation, Te Whatu Ora locality	Merck Sharp & Dohme (Australia) Pty Limited Authorising on behalf of NZ Sponsor Merck Sharp & Dohme (New Zealand) Ltd	Merck Sharp & Dohme (Australia) Pty Limited
2023 EXP 13846	Liver function tests as predictors of choledocholithiasis: A Retrospective Study	Mr Parry Singh	4/04/2023	19/04/2023	Provisionally Approved	Approved	1/05/2023			

2022 EXP 13955	Long Term Health Impact of COVID-19: Waikato Hospital Cohort - LOGIC	Dr Cat Chang	28/11/2022	3/12/2022	Provisionally Approved	Approved	23/12/2022	Te Whatu Ora locality		
2022 EXP 13776	Long-Term Follow-Up of Subjects Treated With NTLA-2001	Prof. Edward Gane	1/12/2022	3/12/2022	Approved NSC	Approved	6/12/2022	Private Organisation	CARSL Consulting	Intellia Therapeutics Inc
2023 FULL 12714	Marine oxygen carrier (M101) for organ preservation in liver transplantation: a randomised exploratory study	Associate Professor Louise Barbier	14/06/2023	27/06/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	University of Auckland	
2023 FULL 15380	Multicentre, adaptive, double-blind, three-arm, placebo-controlled, noninferiority trial examining antimicrobial prophylaxis duration in cardiac surgery	Dr Kelly Byrne	31/03/2023	18/04/2023	Provisionally Approved	Approved	2/06/2023	Te Whatu Ora locality	Waikato hospital	Monash University
2022 EXP 13290	Noise levels in the operating theatre during anaesthesia and surgery - a cross-sectional study (NOISE-1)	Dr Joseph Follows	15/09/2022	26/09/2022	Declined	Declined	29/09/2022		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland	
2023 EXP 15159	Noise levels in the operating theatre during anaesthesia and surgery - a cross-sectional study (NOISE-1)	Dr Joseph Follows	3/02/2023	23/02/2023	Approved	Approved	24/02/2023			
2022 EXP 13225	Non-Invasive Auricular Nerve Stimulation for Improving Swallowing Function in Parkinson's Disease	Associate Professor Yusuf Cakmak	21/11/2022	2/12/2022	Provisionally Approved	Provisionally Approved		Tertiary Education Institution		

2023 FULL 1258 7	Normal Swallowing Measures in Children	Ms Louise Bax	30/01/2023	25/10/2022	Provisionally Approved	Approved	24/02/2023	Te Whatu Ora locality	University of Auckland	
2023 FULL 1345 3	Nurturing our Whakapapa - The NOW Project	Miss Taria Tane	4/04/2023	20/04/2023	Provisionally Approved	Approved	28/04/2023	Other		
2022 FULL 1297 3	Observational study of pediatric thrombotic disease: the Throm-PED registry	Dr Peter Bradbeer	8/11/2022	23/08/2022	Provisionally Approved	Approved	16/11/2022	Te Whatu Ora locality		Scientific Subcommittee Pediatric and Neonatal Hemostasis and Thrombosis of the International Society of Thrombosis and Hemostasis (ISTH)
2023 EXP 13889	Observing ReCovery After Stroke	Professor Cathy Stinear	23/02/2023	9/03/2023	Approved	Approved	17/03/2023	Te Whatu Ora locality	The University of Auckland	
2023 EXP 13347	Online survey to investigate relationships between diet, stress, anxiety and depression in NZ adults	Dr Tracey Bear	27/05/2023	22/05/2023	Provisionally Approved	Approved	2/06/2023	Other	Plant & Food Research	
2022 EXP 12907	Optimising abdominal aortic aneurysm (AAA), atrial fibrillation (AF) and co-located screening tests for Māori and Pacific in Te Tai Tokerau	Dr Karen Bartholomew	7/07/2022	12/07/2022	Declined	Declined	15/07/2022	Primary Health Care Centre	Waitemata DHB and Auckland DHB	
2022 EXP 13484	Optimising abdominal aortic aneurysm (AAA), atrial fibrillation (AF) and co-located screening tests for Māori and Pacific in Te Tai Tokerau	Dr Karen Bartholomew	10/10/2022	16/09/2022	Provisionally Approved	Approved	21/10/2022	Primary Health Care Centre	Waitemata DHB and Auckland DHB	

2023 FULL 1556 6	Outcomes following cytoreductive surgery and hyperthermic intraperitoneal chemotherapy in the Waikato region 2008 to 2023	Mr Jasen Ly	10/05/2023	23/05/2023	Approved NSC	Approved	23/05/2023	Te Whatu Ora locality		
2023 EXP 15228	Overall health and healthcare utilisation in patients with keratoconus	Dr Isabella Cheung	8/05/2023	20/04/2023	Provisionally Approved	Approved	17/05/2023	Tertiary Education Institution	University of Auckland	
2022 FULL 1343 4	Partnering Early to Provide for Infants At Risk of Cerebral palsy (PĀPI ARC)-Evaluating the feasibility of implementing the New Zealand Best Practice Recommendations for Early diagnosis of Cerebral Palsy through a regional early diagnosis Hub.	Dr Angelica Allermo Fletcher	19/12/2022	24/01/2023	Approved NSC	Approved	31/01/2023	Te Whatu Ora locality		
2022 EXP 13475	patients with SCFE - Obese with micronutrient deficiencies?	Dr Janet Tong	27/08/2022	16/09/2022	Declined	Declined	21/09/2022			
2023 EXP 13646	patients with SCFE - Obese with micronutrient deficiencies?	Dr Janet Tong	10/01/2023	12/10/2022	Provisionally Approved	Declined	2/02/2023			
2023 EXP 13198	PC-PEP Phase 4: Predictors of Mental Health for Men with Prostate Cancer undergoing a Patient Empowerment Program	Mr. Peter Dickens	20/04/2023	16/05/2023	Provisionally Approved	Provisionally Approved		Private Organisation	Prostate Cancer Foundation of New Zealand	Nova Scotia Health / Dalhousie University
2022 EXP 12481	Personalisation of anti-obesity medication selection based on Eating Behaviour Traits: using the novel Auckland Eating Behaviour Questionnaire in patients with	Dr Ole Schmiedel	5/05/2022	17/05/2022	Provisionally Approved	Approved	27/07/2022	Te Whatu Ora locality		

	obesity and type 2 diabetes to improve weight loss outcomes									
2023 FULL 13887	Phase II clinical trial of chemoradioimmunotherapy for the alleviation of oesophageal cancer complications	Dr Angela Mweempwa	13/03/2023	28/03/2023	Provisionally Approved	Approved	2/06/2023	Te Whatu Ora locality		Australasian Gastro-Intestinal Trials Group
2023 FULL 13929	Platelet Rich Plasma injections for vocal fold atrophy and scarring	Dr Jacqueline Allen	19/12/2022	24/01/2023	Provisionally Approved	Approved	8/03/2023	Private Organisation		
2023 FULL 12307	PNOC022: A Combination Therapy Trial using an Adaptive Platform Design for Children and Young Adults with Diffuse Midline Gliomas (DMGs) including Diffuse Intrinsic Pontine Gliomas (DIPGs) at Initial Diagnosis, Post-Radiation Therapy and at Time of Progression	Dr Karen Tsui	9/11/2022	22/11/2022	Provisionally Approved	Approved	13/02/2023	Te Whatu Ora locality		Australia and New Zealand Children's Haematology/Oncology Group (ANZCHOG)
2023 FULL 15129	POLysaccharide haemostat for Wound haematoma Reduction in Cardiac Implantable Electronic Devices procedures – a Randomised Controlled Trial	Dr Martin Stiles	10/02/2023	28/02/2023	Provisionally Approved	Approved	3/05/2023	Te Whatu Ora locality		Centre for Heart Rhythm Disorders
2023 EXP 15105	Pona Kaka: A kaupapa Māori approach to arthritis intervention	Dr Lily George	17/01/2023	8/02/2023	Provisionally Approved	Provisionally Approved		Other		
2023 EXP 12951	Preparing to meet the challenge of fitness to drive assessments	Dr Susan Gee	5/01/2023	27/01/2023	Approved NSC	Approved	30/01/2023	Other, Te Whatu Ora locality	New Zealand Dementia Foundation	

2022 FULL 1370 3	Preventing adverse events during paediatric cancer treatment: A multi-site hybrid randomised controlled trial of catheter lock solutions (The CLOCK trial)	Dr Andrew Wood	23/11/2022	24/01/2023	Approved NSC	Approved	31/01/2023	Te Whatu Ora locality		The University of Queensland
2022 EXP 12685	Prospective brain tumour histological and molecular prediction from MRI	Dr Hugh McHugh	11/10/2022	23/10/2022	Provisionally Approved	Approved	22/12/2022			
2023 FULL 1369 4	Prospective observational study of sequential changes to faecal microbiota of children of different ethnicities undergoing exclusion enteral nutrition therapy for Crohn's disease in New Zealand.	Dr Jonathan Bishop	16/03/2023	28/03/2023	Provisionally Approved	Approved	1/05/2023	Te Whatu Ora locality		
2022 FULL 1315 5	Prospective, multicenter, observational study to evaluate the Merit WRAPSODY [®] Endoprosthesis for treatment of stenosis or occlusion within the dialysis outflow circuit of an arteriovenous (AV) fistula or AV graft (The WRAP Registry)	Dr Rahul Bera	14/07/2022	26/07/2022	Provisionally Approved	Approved	29/08/2022	Te Whatu Ora locality		Merit Medical Systems, Inc.
2022 EXP 13550	Prostate Cancer Mortality for Māori in Southland	Associate Professor Konrad Richter	16/09/2022	30/09/2022	Provisionally Approved	Approved	18/01/2023	Te Whatu Ora locality	Health Research South	
2022 EXP 12719	Psychedelic Microdosing in Reality - An exploration of what microdosers consume and experience	Dr Rhys Ponton	21/07/2022	27/07/2022	Provisionally Approved	Approved	25/08/2022	Tertiary Education Institution		
2022 FULL 1314 4	RADAR – A randomised phase III trial with a PET response-adapted design comparing ABVD +/- ISRT with A2VD +/- ISRT in participants with previously untreated stage IA/IIA Hodgkin lymphoma	Dr Leanne Berkahn	12/10/2022	25/10/2022	Provisionally Approved	Approved	21/12/2022	Te Whatu Ora locality		Australasian Leukaemia and Lymphoma Group (ALLG)

2023 FULL 12763	Randomised controlled trial of online cognitive behavioural therapy as an initial treatment for patients waiting for in-person therapy	Professor Richie Poulton	9/12/2022	24/01/2023	Provisionally Approved	Approved	28/04/2023	Primary Health Care Centre	University of Otago	
2023 FULL 15469	Rapua te mea ngaro ka tau: Facilitating Strep A vaccine development for Aotearoa New Zealand	Ass Prof Nikki Moreland	8/03/2023	28/03/2023	Provisionally Approved	Approved	3/05/2023	Primary Health Care Centre	University of Auckland	
2022 FULL 14050	RAVEN: A PHASE I/II TRIAL TREATING RELAPSED ACUTE LYMPHOBLASTIC LEUKEMIA WITH VENETOCLAX AND NAVITOCCLAX	Dr Siobhan Cross	22/12/2022	24/01/2023	Approved NSC	Approved	31/01/2023	Te Whatu Ora locality		ANZCHOG
2022 EXP 13501	Recurrence after Conventional Excision of the Right Colon (RACER)	Professor Tim Eglinton	1/11/2022	6/12/2022	Approved NSC	Approved	7/12/2022	Te Whatu Ora locality		
2022 EXP 12912	Reducing paracetamol dosing errors for children	Dr Rawiri Jansen	11/08/2022	25/08/2022	Approved NSC	Approved	29/08/2022	Primary Health Care Centre		
2023 EXP 13968	Retrospective brain tumour histological and molecular prediction from MRI	Dr Willem Ikink	1/02/2023	23/02/2023	Approved NSC	Approved	24/02/2023			
2022 FULL 12590	Sensitivity and specificity of FAPI-PET in type 1 and 2 chemotherapy induced cardiotoxicity	Dr Andrew Henderson	13/06/2022	1/07/2022	Provisionally Approved	Approved	21/10/2022	Private Organisation		

2023 FULL 15463	Setting the research agenda for tertiary paediatric rehabilitation in Aotearoa New Zealand using a Priority Setting Partnership process	Dr Jimmy Chong	9/06/2023	27/06/2023	Declined	Declined	4/07/2023	Te Whatu Ora locality	Auckland University of Technology	
2022 FULL 12970	Sodium glucose co-transporter2 inhibitor's effect on glucose and sodium clearances in individuals with stage 4 chronic kidney disease	Professor Robert Walker	4/08/2022	23/08/2022	Provisionally Approved	Approved	21/10/2022	Te Whatu Ora locality, Tertiary Education Institution	Health Research South	
2022 FULL 12530	Studying the utility of [68Ga] FAPI PET CT in Cardiac Sarcoidosis – a pilot study (DETECT study)	Dr Andrew Henderson	28/09/2022	13/10/2022	Provisionally Approved	Approved	17/10/2022	Private Organisation		
2023 FULL 13849	SWIFT study of whole blood in frontline trauma	Dr Richard Charlewood	13/06/2023	27/06/2023	Declined	Declined	4/07/2023	Private Organisation	New Zealand Blood Service	NHS Blood and Transplant
2023 EXP 14019	Te Ngākau Aronui Observational Pilot: MRI study of victims of family harm and sexual violence	Associate Professor Miriam Scadeng	9/02/2023	28/02/2023	Declined	Declined	16/03/2023	Private Organisation	Research Operations Centre - University of Auckland	
2023 EXP 17909	The Association between Frailty Index and Severe/Critical Aortic Stenosis in New Zealand	Cardiology Research Fellow Timothy Oh	17/05/2023	1/06/2023	Provisionally Approved	Declined	18/07/2023			
2022 EXP 11366	The Australia and New Zealand Vasculitis Quality and Disease Registry	Dr Tze Liang Goh	13/09/2022	16/09/2022	Approved NSC	Approved	20/09/2022	Te Whatu Ora locality	Te Whatu Ora Health New Zealand Te Toka Tumai Auckland	The Australia and New Zealand Vasculitis Society

2023 EXP 15083	The changing epidemiology of paediatric acute mastoiditis in New Zealand	Dr Jonathan Stevenson	21/02/2023	23/02/2023	Provisionally Approved	Approved	17/05/2023			
2022 EXP 12070	The effect of an omega-3 rich food on markers of inflammation and severity of Achilles tendinopathy	Dr David Musson	30/06/2022	12/07/2022	Provisionally Approved	Approved	28/07/2022	Tertiary Education Institution		
2022 FULL 13022	The effectiveness of manual therapy with pragmatic multi-modal physiotherapy for rotator cuff related shoulder pain: a pilot randomized, non-inferiority controlled trial	Associate Professor Gisela Sole	7/10/2022	23/10/2022	Provisionally Approved	Approved	30/01/2023	Private Organisation , Tertiary Education Institution	School of Physiotherapy, University of Otago	
2023 EXP 16717	The Effects of a Challenge State Intervention on Patient Recovery when Undergoing Elective Orthopaedic Surgery	Dr Cindy Xin Yi Ou	26/04/2023	16/05/2023	Provisionally Approved	Approved	31/05/2023	Private Organisation , Te Whatu Ora locality		
2022 EXP 13363	The effects of acute vs chronic blackcurrant extract supplementation on exercise performance, cognition and respiratory function	Ms Lillian Morton	12/08/2022	25/08/2022	Provisionally Approved	Approved	20/09/2022	Tertiary Education Institution	University of Auckland	
2023 EXP 12204	The effects of chiropractic adjustment on autonomic nervous system function: A pilot study	Dr Nitika Kumari	22/03/2023	26/04/2023	Provisionally Approved	Approved	28/06/2023	Private Organisation	New Zealand College of Chiropractic	
2023 EXP 15344	The Epidemiology of Invasive Infant Group B Streptococcus Infection In New Zealand	Dr Jane Millar	8/05/2023	22/05/2023	Provisionally Approved	Approved	16/06/2023			

2023 EXP 15148	The evaluation of treatment outcomes for methamphetamine dependence in Aotearoa New Zealand	Associate Professor David Newcombe	5/04/2023	26/04/2023	Provisionally Approved	Approved	28/07/2023	Other, Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	University of Auckland	
2023 EXP 13406	The immune response to consuming probiotic strains in healthy adults: a randomised double-blind, placebo-controlled, parallel clinical study	Dr Christine Butts	16/01/2023	31/01/2023	Provisionally Approved	Declined	20/04/2023	Other	Fonterra Research and Development Centre	
2023 EXP 17848	The immune response to consuming probiotic strains in healthy adults: a randomised double-blind, placebo-controlled, parallel clinical study	Dr Christine Butts	22/05/2023	1/06/2023	Provisionally Approved	Approved	15/06/2023	Other	Fonterra Research and Development Centre	
2023 EXP 15412	The LipoCre Study	Professor David Rowlands	22/02/2023	28/03/2023	Provisionally Approved	Declined	3/05/2023	Tertiary Education Institution	Massey University	Pharmako Biotechnologies
2023 EXP 18021	The LipoCre Study	Professor David Rowlands	24/05/2023	22/06/2023	Provisionally Approved	Approved	17/07/2023	Tertiary Education Institution	Massey University	Pharmako Biotechnologies
2023 FULL 17893	The Role of Surgical Timing on Functional Outcomes of Traumatic Full-Thickness Rotator Cuff Tear Repair	Dr Michael van der Merwe	5/06/2023	22/07/2023	Declined	Declined	24/07/2023	Private Organisation		
2022 EXP 12005	The Use of Expiratory Muscle Strength Training (EMST) for patients with Head and Neck Cancer (HNC) Treated with Primary Chemoradiation Therapy (CRT)	Mrs Kristyn Anderson	7/04/2022	5/05/2022	Provisionally Approved	Approved	4/08/2022	Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	Auckland District Health Board	

2022 EXP 13618	The use of inflammatory markers in the diagnosis and monitoring treatment response of patients with acute cholangitis	Dr Andrei Belyaev	25/09/2022	12/10/2022	Declined	Declined	21/10/2022			
2022 EXP 13914	The use of inflammatory markers in the diagnosis and monitoring treatment response of patients with acute cholangitis	Dr Andrei Belyaev	17/11/2022	2/12/2022	Provisionally Approved	Provisionally Approved				
2022 EXP 11639	Thrombus structure and characteristics as seen with elastography pre and post abdominal aortic endovascular repair.	Ms Brigid Hill	1/12/2022	15/12/2022	Approved NSC	Approved	19/12/2022	Tertiary Education Institution		
2023 EXP 11183	To understand how heart rate variability and physical activity can be used effectively in the management of fatigue.	Dr Lynette Hodges	18/01/2023	31/01/2023	Provisionally Approved	Approved	17/03/2023	Private Organisation	Specialised Health	Specialised Health
2022 EXP 12588	Towards a targeted perioperative management intervention for total knee arthroplasty surgery- external validation of an artificial intelligence predictor model.	Dr Michal Kluger	30/09/2022	12/10/2022	Approved NSC	Approved	21/10/2022	Te Whatu Ora locality		
2022 EXP 12139	Towards personal medicine – Analysis of Receptor abundances in Multiple Sclerosis to determine treatment regime	Dr Katharina Robichon	28/06/2022	18/07/2022	Provisionally Approved	Approved	4/08/2022	Te Whatu Ora locality		
2022 EXP 13152	Transcutaneous oxygen and Nasal High Flow: a prospective, interventional, randomised, crossover, feasibility study investigating the effect of nasal high flow oxygen delivery on transcutaneous oxygen partial pressure in healthy adults.	Prof Alan Merry	4/10/2022	12/10/2022	Provisionally Approved	Approved	15/11/2022	Private Organisation	Fisher & Paykel Healthcare	

2023 EXP 13366	Understanding Anterior Cruciate Ligament Reconstruction Outcomes in New Zealand	Dr Sarah Ward	20/04/2023	16/05/2023	Provisionally Approved	Approved	27/07/2023	Tertiary Education Institution		
2022 FULL 13543	Understanding the impact of vaccination of Covid-19 infection and long-term health outcomes	Dr Julie Bennett	13/09/2022	27/09/2022	Declined	Declined	3/10/2022	Private Organisation		
2022 FULL 13732	Understanding the impact of vaccination of Covid-19 infection and long-term health outcomes	Dr Julie Bennett	13/10/2022	25/10/2022	Approved NSC	Approved	2/11/2022	Private Organisation		
2022 FULL 13824	Use of home blood pressure monitors for remote optimisation of cardiac medications (Home MED Study)	Dr Tze Vun Liew	28/10/2022	22/11/2022	Provisionally Approved	Approved	4/09/2023	Te Whatu Ora locality	Waikato Medical Research Foundation	
2022 EXP 13191	Using a multi-omics approach to predict severity of pelvic organ prolapse	Dr Emma Wade	23/09/2022	11/12/2022	Approved NSC	Approved	13/12/2022	Primary Health Care Centre, Te Whatu Ora locality	University of Otago	
2022 EXP 13723	Validity of a brief triage tool for risk management of healthy women with a family history of breast & ovarian cancer in New Zealand	Miss Ekta Bagga	17/10/2022	15/11/2022	Approved NSC	Approved	17/11/2022	Te Whatu Ora locality		
2022 FULL 13482	Variability of toe pressures during haemodialysis: Comparison of persons with and without diabetes.	Mrs Rachel Carle	14/09/2022	27/09/2022	Approved	Approved	3/10/2022	Te Whatu Ora locality	Auckland University of Technology	

2022 FULL 1290 6	VIR-MHB1-200- A Platform Study Evaluating the Efficacy and Safety of Investigational Therapies in Participants with Chronic Hepatitis B Infection (PREVAIL)	Prof Edward Gane	4/08/2022	23/08/2022	Approved NSC	Approved	2/09/2022	Private Organisation , Te Whatu Ora locality	Novotech (New Zealand) Limited	Vir Biotechnology, Inc
2022 EXP 13386	Whitu For Schools: Randomised controlled trial of an app for improving the well-being of high school students in Aotearoa	Dr Hiran Thabrew	12/10/2022	25/10/2022	Declined	Declined	2/11/2022	Other	University of Auckland	