



**Health and
Disability Ethics
Committees**

**Northern B Health and Disability
Ethics Committee**

**Annual Report
2024**

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About this report

This report is a summary of the activities of the Northern B Health and Disability Ethics Committee (HDEC) for the period of 01 July 2023 – 30 June 2024. 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.

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. An appointment round is planned for the remaining months of 2024 and full membership will continue. Historically, it has been difficult to recruit non-lay members with a medical background, but with the expertise shared across the four HDECs any gaps have been overcome. I am so 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 long-awaited Sector Day held in December 2023 was a highlight, and after years of Zoom-only interactions, the opportunity to be together face to face was exceptionally valuable. It was particularly rewarding to meet new members in person, and to farewell our long serving Manager Nic Aagaard.

Another highlight has been the opening of channels for communication for the HDEC Chairs on an as-needed basis with SCOTT and GTAC. It is important that peer and ethical review of proposals work in harmony. Likewise, Locality Authorisation (including Consultation) is an essential element of the country's suite of protections, and with the changes to the national health authority there may be an opportunity to consolidate Locality Authorisation processes for research to retain district interests in a streamlined or coordinated way. This may be helpful for clinical trials to open more sites across the country, reducing the administrative burden and time costs for Investigative teams who additionally carry a high clinical load.

The Advisors of the Secretariat continue to exhibit very high levels of professionalism and expertise even in the disruptive and uncertain context of a change of Government. Their workload is heavy, yet the weekly HDECs meetings invariably operate smoothly. It is critical that the resources for all the committees supported by the Secretariat do not fall to unsustainable levels, and that the focus remains squarely on matters that fall within HDECs Scope of Review. This, of course, has consequences for the IECs and their institutions who must continue to support and educate health researchers whose inquiry falls outside our scope whilst ensuring sound governance and management for studies which do have an HDEC approval. Variability between the universities and other research institutions with respect to their roles and obligations as study Sponsors is still apparent.

The members of NTB continue to hold research accountable to the National Ethical Standards, most especially with respect to voluntary and informed consent. Complex and overly long Information Sheets are invariably called out as such, and participant friendly alternatives – such as diagrams, tables or flowcharts – suggested. We insist that the research elements are distinguished from Standard of Care (in New Zealand), the risks are accurately described, and the benefits of participation are not overstated or ambiguous. This latter includes not naming an investigational or experimental product as “treatment”. A revised plain language template Information Sheet and Consent Form will be available in the latter part of 2024, and it is hoped that this will overcome some of the challenges to informed consent presented by difficult and technical language.

While anticipated, a surge in volume of applications involving AI or algorithm development has not yet eventuated for HDECs. Although much of this work is likely falling outside HDECs Scope (as a secondary use of identifiable health data with or without consent) it is important that this kind of activity complies with the required ethical and data standards. It is uncertain whether it is all being captured within existing review structures nationally.

Finally, I wish to express my gratitude to the sponsors, researchers and coordinators who continue to strive for scientific integrity and good ethical conduct, and for knowledge which can improve the health and wellbeing of all New Zealanders. Their willingness to attend NTB meetings, respectfully engage in ethical discourse and respond to the Committee's requirements reflects well on New Zealand as a great place to do research. I look forward to the coming year.

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	5
No. of applications approved subject to conditions / pending at first review	21
No. of applications deferred (provisionally approved) at first review and subsequently approved	45
No. of applications deferred as at time of report	10
No. of applications that were declined 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.)	6
<i>No. of applications which do not require ethics committee approval (across all four Committees that were deemed out of scope)</i>	<i>773</i>
No. of studies withdrawn by researcher	0
No. of studies terminated by sponsor	0
No. of studies transferred to another EC	0
Total number of applications received by full EC	88

Summary of applications received under expedited / low risk review.

(All outcomes refer to outcome of first review.)

No. of applications approved	9
No. of applications approved subject to conditions / pending at first review	39
No. of applications deferred at first review and subsequently approved	62
No. of applications deferred as at time of report	13
No. of applications declined	13
Total number of applications received under expedited / low risk review	136

Total number of applications received

224

Complaints and overdue application summary

This section outlines complaints about decisions made by the Committee during 2024.

Complaints received

Complaint one

Type of complaint: Study Conduct

Date resolved: 05 July 2023

Complaint received: 01 July 2023

Nature of complaint:

A participant attempted to contact study coordinators via multiple methods and received no response for almost a month or auto-replies directing to emails that did not work.

Actions taken:

The Secretariat investigated whether the information provided to participants was up to date and contacted the study team. Response was received by Sponsor that this was a one-off incident, and points of contact will be monitored more closely. Their responses were still not timely to the participant, and the CI and study contact were reminded again to ensure all contact information is correct and to ensure responsiveness to participants.

Outcome:

The Secretariat received no further contact indicating the participant was experiencing delays.

Complaint two

Type of complaint: Study Conduct

Date resolved: 26 January 2024

Complaint received: 01 December 2023

Nature of complaint:

A person went to a clinical trials unit and was made to feel uncomfortable. During the pre-screening, they allege misconduct by the nurse and that they were pressured into remaining, including forced back onto the bed and had their ID taken from them. They note they had participated in multiple trials at this trials unit before and that this was an exceptional circumstance.

Actions taken:

The Secretariat with permission contacted the trial unit to discuss the matter.

Outcome:

The complainant had contacted the unit before contacting us, and received an apology and acknowledgement of the incident before the complainant contacted the HDECs. The site provided details outlining the steps that were taken to address the complaint so it would not happen again. The Chair considered the actions satisfactory to address the complaint. The complainant was advised to contact the HDC if they feel they want to lodge a further complaint.

Overdue review

Average review times take into account 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 17 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). The reason for the slight deviation outside expectation was due to Secretariat delays in process the letters following review by the sub-committee.

Average review time was 29 days for full applications. Target timeframe for full applications is 35 days ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 54-59). There were no notable exceptions outside of the target timeframe for the reporting period.

Appendix 1: Details of applications reviewed¹

Applications reviewed by the committee

Review reference	Formal title	Coordinating investigator	Date received	Date of first review	Outcome of first review	Status at time of report	Date of final status decision	Locality	Local sponsor	Global sponsor	Clock days
2024 EXP 17996	A review of Canterbury Dog Bite Injury Demographics: Pre and Post Christchurch City Councils 2016 bylaw change.	Dr Nikita Quinn	10/03/2024	11/03/2024	Provisionally Approved	Approved	11/03/2024				13
2024 EXP 19469	Changes in Epidemiology and Outcomes in a National Burn Centre over 17 years (2006-2023)	Dr Anna Dargan	18/03/2024	18/03/2024	Provisionally Approved	Approved	19/03/2024		National Burn Centre, Middlemore Hospital		1
2024 EXP 19931	Child Protection assessment of children aged 0-2 years with skull fractures at Starship Child Health.	Dr Juliet Soper	20/05/2024	17/06/2024	Approved	Approved	19/06/2024		Te Whatu Ora Te Toka Tumai		1
2024 EXP 16679	Factors influencing complication rates of sentinel node biopsy melanoma patients in the Canterbury region.	Dr James Eason	15/01/2024	15/01/2024	Declined	Declined	16/01/2024				1
2023 EXP 16690	What factors influence successful breastmilk feeding in very preterm pēpi (infants) in Aotearoa (New Zealand) neonatal intensive care units?	Doctor Barbara Cormack	7/08/2023	7/08/2023	Provisionally Approved	Approved	8/08/2023	Te Whatu Ora locality	Liggins Institute		1
2024 EXP 19958	Technology enhanced kaiāwhina-based support to optimise type 2 diabetes management in primary care	Associate Professor Lynne Chepulis	30/04/2024	30/04/2024	Provisionally Approved	Approved	1/05/2024	Primary Health Care Centre	University of Waikato		2
2023 EXP 18375	Epidemiology, antimicrobial susceptibility, and mechanisms of resistance to cefiderocol and aztreonam / ceftazidime-avibactam in Carbapenemase producing Enterobacterales	Dr Sarah Sarah	6/10/2023	10/10/2023	Approved NSC	Approved	11/10/2023		Te Toka Tumai Auckland		2

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

	(CPE) from the Auckland region, 2010 to 2023.										
2023 EXP 18037	Studying cancer at the single cell level: in-depth analysis for Māori health	Dr Kirsty Danielson	18/07/2023	19/07/2023	Provisionally Approved	Approved	20/07/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Otago		10
2023 EXP 18511	The Asia Pacific League of Associations for Rheumatology (APLAR) Systemic Sclerosis Incident Cohort	Dr Kamal Solanki	16/10/2023	17/10/2023	Approved NSC	Approved	19/10/2023	Private Organisation, Te Whatu Ora locality	Te whatu Ora Health New Zealand (Waikato)	Singapore General Hospital	2
2024 EXP 19216	Adrenal vein sampling in Australia & New Zealand: the patient experience	Associate Professor Marianne Elston	14/02/2024	19/02/2024	Approved NSC	Approved	19/02/2024	Te Whatu Ora locality	Te Whatu Ora Waikato		3
2024 EXP 19060	An international survey of continuous subcutaneous infusions: is there an unmet need for extended infusions 48 hours and beyond? [SCUT148]	Mrs Emma Griffiths	13/03/2024	15/03/2024	Declined	Declined	18/03/2024			Becton Dickinson	3
2023 EXP 18272	Empowering dementia carers with an iSupport Virtual Assistant (e-DiVA) in New Zealand: a pilot randomised-controlled trial.	Associate Professor Sarah Cullum	14/09/2023	19/09/2023	Approved NSC	Approved	22/09/2023	Other	The University of Auckland		3
2024 EXP 19913	Ewing Sarcoma: A retrospective review of incidence and risk factors affecting New Zealand Māori over the last 40 years	Dr Morgan Short	13/03/2024	15/03/2024	Approved NSC	Approved	18/03/2024		Te Whatu Ora Te Toka Tumai Auckland		3
2023 EXP 18233	Peripheral nerve blocks and its impact on hip fracture patients' Days alive and out of hospital at 90 days and mortality at 1 year	Dr Tin Lun Chiu	17/11/2023	22/11/2023	Approved	Approved	23/11/2023		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		3
2023 FULL 18634	Subjective Difficulty Scale in Laparoscopic Cholecystectomy: A Prospective Observational Study	Dr Luke Paterson	28/11/2023	1/12/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality			3
2023 EXP 18400	The diagnosis of systemic lupus erythematosus in general practice	Professor Ross Lawrenson	20/12/2023	21/12/2023	Provisionally Approved	Approved	10/01/2024		Director, Research & Enterprise at University of Waikato		3

2023 EXP 18227	Waerea: Māori whānau experiences of assisted dying in Aotearoa New Zealand	Dr Tess Moeke-Maxwell	24/07/2023	24/07/2023	Provisionally Approved	Approved	25/07/2023	Tertiary Education Institution			4
2023 EXP 18540	A pilot dose duration-response study using Diprosone® ointment (Organon, 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	19/09/2023	23/09/2023	Approved NSC	Approved	26/09/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd	4
2023 EXP 18623	A pilot dose duration-response study using Diprosone® OV ointment (Organon, 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	19/09/2023	21/09/2023	Approved NSC	Approved	26/09/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd	4
2024 EXP 18929	Afghan Health Survey	Mr Alex Martin	4/03/2024	9/03/2024	Approved NSC	Approved	11/03/2024	Other	Health Research Council of New Zealand		4
2024 EXP 19468	Changes in Epidemiology and Outcomes in a National Burn Centre over 17 years (2006-2023)	Dr Anna Dargan	7/03/2024	9/03/2024	Declined	Declined	11/03/2024		Middlemore Hospital, Department of Plastic Surgery		4
2023 EXP 19264	Enterococcus faecalis endocarditis receiving benzylpenicillin and ceftriaxone treatment from an Outpatient Parenteral Antibiotic Therapy Service within the Auckland and Christchurch regions.	Dr Simon Briggs	13/12/2023	18/12/2023	Approved	Approved	19/12/2023				4
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 Ravinder Ogra	3/07/2023	5/07/2023	Provisionally Approved	Approved	7/07/2023		Middlemore Hospital		13

2023 EXP 18006	Stroke in Paediatric Bacterial Meningitis in the Auckland Region	Dr Margot Price	2/07/2023	4/07/2023	Provisionally Approved	Approved	7/07/2023				10
2023 EXP 19223	The acute effect of a blackcurrant extract in inhibiting platelet monoamine oxidase-B enzyme activity in healthy adults.	Dr Dominic Lomiwes	11/12/2023	18/12/2023	Approved NSC	Approved	19/12/2023	Other	The New Zealand Institute for Plant and Food Research Ltd.		4
2023 FULL 18598	Product Surveillance Registry - Enlighten EV ICD Study	Dr Ian Crozier	17/10/2023	18/10/2023	Provisionally Approved	Approved	19/10/2023	Te Whatu Ora locality	Medtronic New Zealand Ltd.	Medtronic, Inc.	5
2024 EXP 19834	Invasive group A streptococcal disease in Aotearoa/New Zealand 2012-2022	Ms Taliah Su'a	18/06/2024	19/06/2024	Approved NSC	Approved	24/06/2024		University of Otago		5
2023 EXP 18745	Perinatal and Neurodevelopmental Outcomes of Management Options of Monochorionic Diamniotic Twins with Type II and III Selective Fetal Growth Restriction	Dr Monique Stein	13/09/2023	15/09/2023	Approved NSC	Approved	20/09/2023		Maternal Fetal Medicine		5
2024 FULL 20003	Understanding through engagement and analysis the barriers to and enablers of meaningful employment in Aotearoa, New Zealand's manufacturing, engineering, logistics, construction and infrastructure industries for disabled people, tāngata whaikaha Māori and tagata sa'ilimalo.	Miss Grace Stratton	26/03/2024	27/03/2024	Approved NSC	Approved	2/04/2024	Other	Hanga Aro Rau		5
2023 EXP 18824	DIFFIR: Geriatric Distal Femur Fixation versus Replacement – A Randomised Controlled Trial of Acute Open Reduction Internal Fixation (ORIF) versus Distal Femoral Replacement (DFR)	Dr Tim Chuang	26/10/2023	26/10/2023	Provisionally Approved	Approved	31/10/2023	Te Whatu Ora locality		Unity Health Toronto - St. Michael's Hospital, Mount Sinai Hospital	6
2023 EXP 15149	Colonisation efficacy of Streptococcus salivarius M18 toothpaste (2023)	Professor Emeritus John Tagg	20/07/2023	20/07/2023	Provisionally Approved	Approved	27/07/2023	Other	Blis Technologies		13
2023 EXP 18498	Comparing Immediate Weight Bearing with Delayed Weight Bearing in Patients with Ankle Fractures Treated with Open Reduction Internal Fixation – a	Dr Blair Mason	16/10/2023	24/10/2023	Approved NSC	Approved	27/10/2023	Te Whatu Ora locality			6

	Randomised Control Pilot Trial Investigating the Feasibility of a Definitive RCT.										
2024 EXP 18295	Effectiveness of Preoperative Tranexamic Acid on Visual Clarity during Shoulder Arthroscopy	Dr Jonathan Chan	22/02/2024	27/02/2024	Declined	Declined	4/03/2024	Primary Health Care Centre, Te Whatu Ora locality			6
2023 EXP 18930	Long-Term Follow-Up of Subjects Treated With NTLA-2002	Dr Hilary Longhurst	2/11/2023	5/11/2023	Approved NSC	Approved	10/11/2023	Private Organisation	Simbec-Orion	Intellia Therapeutics Inc.	6
2023 EXP 19202	Retrospective cohort study of mode of birth and indications for caesarean amongst pregnant patients with diabetes at Counties Manukau Health	Dr Charlotte Oyston	14/11/2023	16/11/2023	Approved NSC	Approved	22/11/2023		Te Whatu Ora Counties Manukau		6
2023 FULL 18079	Retrospective study on the outcomes of subtotal cholecystectomy performed in Christchurch Hospital	Dr Saxon Connor	21/08/2023	1/09/2023	Approved NSC	Approved	6/09/2023	Te Whatu Ora locality			6
2023 EXP 16763	The HARNESS study: Harnessing the immune system for predicting postoperative recovery after major surgery.	Dr Kathryn Hally	2/11/2023	4/11/2023	Approved NSC	Approved	10/11/2023	Te Whatu Ora locality, Tertiary Education Institution	Te Whatu Ora - Capital, Coast and Hutt Valley		6
2024 EXP 19377	The impact of a minimally processed seaweed meal on the appearance of amino acids in peripheral circulation in healthy adults	Dr Farha Ramzan	26/01/2024	31/01/2024	Approved NSC	Approved	5/02/2024	Tertiary Education Institution	University of Auckland		6
2024 EXP 19965	The Lotu Factor: Religiosity, COVID-19 and Tongan Wellbeing in New Zealand	Dr Nasili Vakauta	13/05/2024	17/05/2024	Provisionally Approved	Provisionally Approved		Other			6
2024 EXP 20008	Gastric motility rhythms response to heart rate variability biofeedback interventions	Professor Greg O'Grady	19/04/2024	22/04/2024	Provisionally Approved	Approved	26/04/2024	Private Organisation, Tertiary Education Institution	The University of Auckland		7
2024 EXP 19397	The acute effect of consuming hops extract in modulating plasma neurotransmitter concentrations in healthy adults.	Dr Dominic Lomiwes	15/04/2024	16/04/2024	Provisionally Approved	Approved	16/04/2024	Other	The New Zealand Institute for Plant and Food Research Ltd.		7

2023 EXP 18949	A review of attendance to the CMDHB burns MDT clinic (adults and paediatrics).	Senior Physiotherapist Stephanie Clarke	1/11/2023	5/11/2023	Approved	Approved	10/11/2023		Te Whatu Ora Health New Zealand Counties Manukau		7
2024 EXP 20222	Bowel cancer new zealand 'never too young' survey	Dr Oliver Waddell	6/05/2024	9/05/2024	Declined	Declined	15/05/2024	Private Organisation , Tertiary Education Institution			7
2023 EXP 18747	Effect of Pre, Peri and Post-Operative Factors On Re-Presentation and Readmission Following Colorectal Cancer Resection Surgery In Northland, New Zealand.	Dr. Scott McLaughlin	1/11/2023	5/11/2023	Approved	Approved	10/11/2023		Te Whatu Ora Te Tai Tokerau		7
2024 EXP 19085	Evaluating the influence of trout fishing participation on angler mental health and wellbeing	Mr Cohen Stewart	29/01/2024	31/01/2024	Approved	Approved	7/02/2024	Other, Private Organisation	New Zealand Fish & Game Council		7
2024 FULL 18217	International Network of Antibiotic Allergy Nations (iNAAN): New Zealand	Dr Tim Cutfield	13/05/2024	20/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality		Austin Health	7
2024 EXP 19234	JOURNEYS - Where are the inequities in the journey from health to gynae cancer in Aotearoa?	Dr Carrie Innes	26/02/2024	2/03/2024	Approved NSC	Approved	8/03/2024	Primary Health Care Centre, Private Organisation , Te Whatu Ora locality, Tertiary Education Institution	University of Otago, Christchurch		7
2024 EXP 20340	Multifaceted stressors experienced by Asian migrants impacted by gambling harm and mental health issues	Dr Bo Ning	30/05/2024	10/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Ministry of Health		7
2023 EXP 15595	Neuroplasticity and pain: Can a combination of brain imaging (EEG) and gene expression profiling (mRNA sequencing) predict who turns chronic?	Dr Imran Khan Niazi	11/10/2023	17/10/2023	Declined	Declined	19/10/2023	Private Organisation	New Zealand College of Chiropractic		7
2024 EXP 20073	Nutrition therapy in Paediatric patients requiring Extracorporeal Membrane Oxygenation: A	Ms Bridget Little	20/05/2024	18/06/2024	Approved NSC	Approved	24/06/2024		Starship Child Health		7

	prospective observational multisite study										
2024 EXP 20035	Outcomes of costo-osteochondral graft reconstruction of the carpal bones	Mr. Wolfgang Heiss-Dunlop	25/03/2024	31/03/2024	Approved NSC	Approved	2/04/2024	Private Organisation , Te Whatu Ora locality	Te Whatu Ora Couties Manukau		7
2023 EXP 19140	Understanding Menstrual Fluid Loss in Premenopausal Females	Dr Claire Badenhorst	10/11/2023	15/11/2023	Declined	Declined	21/11/2023	Tertiary Education Institution	Massey University		7
2024 EXP 19193	Women's experience of a mixed gender psychiatric inpatient admission in Aotearoa: A Qualitative Study.	Mrs Trudy Mowat-Gainsford	12/06/2024	14/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Health New Zealand / Te Whatu ora - Canterbury		7
2023 EXP 18836	Assessing change in Anti-Mullerian Hormone (ovarian reserve) associated with surgical excision vs conservative management of endometrioma: A longitudinal cohort study.	DR Keryn Harlow	23/10/2023	24/10/2023	Provisionally Approved	Approved	27/10/2023	Private Organisation , Te Whatu Ora locality	TWO Waitaha	University of Melbourne	8
2024 EXP 19444	Current journeys through health and wellbeing services after stroke in Ōtautahi Christchurch (Journeys Ōtautahi)	Mrs Emily Timothy	15/02/2024	16/02/2024	Provisionally Approved	Approved	19/02/2024	Te Whatu Ora locality	Te Whatu Ora, Waitaha		8
2024 EXP 19331	Demographic characteristics and survival outcomes of patients with primary central nervous system lymphoma in South Auckland, New Zealand	Dr Jian Li	11/03/2024	18/03/2024	Provisionally Approved	Approved	20/03/2024		Rearch Office Middlemore Hospital		8
2024 EXP 19693	Research on Substance Addiction (Compulsory Assessment and Treatment) Act 2017 (SACAT) Pathways for Māori and Pacific peoples	Dr Rebecca Gray	22/03/2024	25/03/2024	Provisionally Approved	Approved	26/03/2024	Primary Health Care Centre, Te Whatu Ora locality	Te Whatu Ora		8
2023 EXP 18703	Thiamine and markers of oxidative stress and mitochondrial health.	Doctor Catherine Wall	4/12/2023	4/12/2023	Provisionally Approved	Approved	5/12/2023	Other, Te Whatu Ora locality	Director, Research and Enterprise		8
2023 EXP 18666	AI prediction of Lymph Node Metastasis in T1 Colorectal Cancer	Professor Tim Eglinton	4/11/2023	9/11/2023	Approved	Approved	15/11/2023		Director, Research and Enterprise, University of Otago		8

2023 EXP 18321	Anti-vinculin blood collection study	Doctor Stefan Calder	14/09/2023	22/09/2023	Approved NSC	Approved	26/09/2023	Tertiary Education Institution	UoA		8
2023 EXP 19209	Code Crimson Management at Auckland City Hospital	Dr William Law	10/11/2023	16/11/2023	Approved	Approved	22/11/2023		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		8
2023 EXP 19390	Determining the benefit of a multidisciplinary Aerodigestive Clinic for post-operative oesophageal atresia and tracheoesophageal fistula patients: a retrospective cohort study	Dr Annabel Noakes	22/12/2023	8/01/2024	Approved NSC	Approved	16/01/2024		Te Whatu Ora Te Toka Tumai Auckland - Starship Children's Hospital		8
2023 EXP 18717	Exercise musclin and cardiac performance	Dr Timothy Prickett	13/11/2023	16/11/2023	Approved NSC	Approved	22/11/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Otago Christchurch		8
2023 EXP 18180	Long-term Ileo-anal Pouch Outcome Study (LIPOS) : Protocol for a prospective single-centre observational cohort study of the patient-report long-term outcomes of Ileo-anal Pouch Procedures.	Mr Wasilwa Baraza	10/11/2023	16/11/2023	Declined	Declined	22/11/2023	Private Organisation , Te Whatu Ora locality			8
2023 EXP 13810	Predicting influenza disease burden in New Zealand and informing strategies to manage future disease burden	Professor Cameron Grant	9/08/2023	11/08/2023	Approved	Approved	18/08/2023		University of Auckland		8
2023 EXP 19459	Prevalence and reporting rates of incidental dental disease on trauma CT scans in a New Zealand Population	Dr David Becker	23/12/2023	8/01/2024	Approved NSC	Approved	16/01/2024		Research Locality Coordinator Counties Manukau		8
2024 EXP 18294	Patient satisfaction and complications of modified Kelly stitch procedure for women with stress urinary incontinence	Dr Marizanne Reyneke	3/03/2024	6/03/2024	Provisionally Approved	Approved	8/03/2024	Te Whatu Ora locality			9
2023 EXP 18263	Research to understand the influence of people with dementia mate wareware in the planning and delivery of their support	Mrs Elizabeth Smith	24/08/2023	25/08/2023	Provisionally Approved	Approved	25/08/2023	Private Organisation	Alzheimers NZ		9

	services and the impact of peer support on their lives										
2024 EXP 19554	Retrospective analysis of PSMA SPECT CT	Dr. Stefan Gabrielson	6/03/2024	11/03/2024	Provisionally Approved	Approved	11/03/2024		Radiology services		9
2023 EXP 19305	Long-term Ileo-anal Pouch Outcome Study (LIPOS) : Protocol for a prospective single-centre observational cohort study of the patient-report long-term outcomes of Ileo-anal Pouch Procedures.	Mr Wasilwa Baraza	19/12/2023	21/12/2023	Provisionally Approved	Provisionally Approved		Private Organisation , Te Whatu Ora locality			9
2023 EXP 18586	Transforming crisis communication for linguistic minority communities	Dr. Shinya Uekusa	6/12/2023	11/12/2023	Approved NSC	Approved	18/12/2023	Other	Research & Innovation, University of Canterbury		9
2023 EXP 19239	Experience of feeding disorders and dysphagia in children with neurodevelopmental disabilities	Dr Mei Peng	14/12/2023	20/12/2023	Provisionally Approved	Approved	10/01/2024	Tertiary Education Institution	University of Otago		10
2024 EXP 19402	A summary report on Human T-cell Lymphotropic Virus type 1 (HTLV-1) among blood and organ donors screened at the New Zealand Blood Service	Dr Karen Bartholomew	18/04/2024	24/04/2024	Approved NSC	Approved	29/04/2024		Te Whatu Ora		10
2024 EXP 19338	Abdominal aortic aneurysm (AAA), atrial fibrillation (AF) and co-located screening tests for Māori and Pacific in Wellington	Dr Karen Bartholomew	22/01/2024	24/01/2024	Approved NSC	Approved	2/02/2024	Primary Health Care Centre	Te Whatu Ora - Waitemata		10
2024 EXP 19599	Exploring values, perspectives and experiences of people with advanced kidney failure using cannabis to manage symptoms.	Professor Suetonia Green	25/01/2024	27/01/2024	Declined	Declined	5/02/2024	Te Whatu Ora locality	University of Otago		10
2023 EXP 19212	Investigating the effect of acute and chronic Comvita propolis supplementation on immune cell function in healthy adults	Dr Dominic Lomiwes	20/11/2023	24/11/2023	Approved NSC	Approved	1/12/2023	Other	The New Zealand Institute for Plant and Food Research Ltd.		10
2023 EXP 19096	Neuroplasticity and pain: Can a combination of brain imaging (EEG) and gene expression profiling (mRNA sequencing) predict risk of chronic pain?	Dr Imran Khan Niazi	20/11/2023	23/11/2023	Approved NSC	Approved	1/12/2023	Private Organisation	New Zealand College of Chiropractic		10

2023 EXP 19354	The influence of nitrogen dioxide on cognitive and physical performance	Associate Professor Nicholas Gant	4/12/2023	9/12/2023	Declined	Declined	18/12/2023	Other	University of Auckland		10
2024 EXP 18721	Referrals for learning and behavioural difficulties in school aged children referred to Kidz First Ambulatory Paediatrics- are there referral related barriers delaying care?	Dr Latitia Patel	17/04/2024	17/04/2024	Provisionally Approved	Approved	22/04/2024		Te Whatu Ora Counties Manukau		11
2023 EXP 18964	CXCL9 as a surrogate IHC marker of POLE for the Molecular profiling of Endometrial Cancer	Dr Claire Henry	21/11/2023	23/11/2023	Approved NSC	Approved	4/12/2023	Te Whatu Ora locality, Tertiary Education Institution	Research and Enterprise, University of Otago		11
2023 EXP 19190	Neurofeedback intervention for managing neuropathic-like pain experience in musculoskeletal conditions; an open-label pilot-feasibility clinical trial.	Dr Jerin Mathew	8/11/2023	14/11/2023	Approved NSC	Approved	21/11/2023	Tertiary Education Institution	Department of Anatomy, School of Biomedical Sciences, University of Otago		11
2024 EXP 19349	Profiling the effects of oestrogens, progestogens and allopregnanolone on the brain during neurosteroid withdrawal: toward treating catamenial epilepsy (P2TCAT)	Dr Rachael Sumner	17/04/2024	23/04/2024	Approved NSC	Approved	29/04/2024	Other	The University of Auckland		11
2023 EXP 18429	Validation of tools to measure experience of whānau engagement	Dr Ainsleigh Cribb-Su'a	11/08/2023	21/08/2023	Approved NSC	Approved	25/08/2023	Other, Private Organisation			11
2024 EXP 18588	A pilot study investigating relationships between habitual diet and acute stress and relaxation response	Dr Tracey Bear	8/02/2024	9/02/2024	Provisionally Approved	Approved	12/02/2024	Other	Plant & Food Research		12
2023 EXP 18662	Associations and mechanisms linking transport and health: outcome-wide analyses	Dr Sandar Tin Tin	17/09/2023	19/09/2023	Provisionally Approved	Approved	22/09/2023	Tertiary Education Institution	University of Auckland		12
2024 EXP 19213	Investigating smart phone tracking apps for IBS	Dr. Kate MacKrell	19/04/2024	23/04/2024	Provisionally Approved	Approved	26/04/2024	Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland		12
2024 EXP 19560	Investigating the frequency of ICU admissions from	Doctor Stephen Yu	14/02/2024	16/02/2024	Provisionally Approved	Approved	19/02/2024		Te Whatu Ora Canterbury		12

	odontogenic infections over a ten-year period in a tertiary New Zealand Hospital.										
2023 EXP 18298	Te Ara Poutama: Living Well with Heart Disease & Restoring the Balance: Heart health of Wahine, Fafine, Va'ine, Fifine & Women of Aotearoa.	Mrs Erina Korohina	23/08/2023	24/08/2023	Provisionally Approved	Approved	25/08/2023	Other, Private Organisation			12
2024 FULL 19200	The Effect of Appendectomy on the Gut Microbiome	Professor Frank Frizelle	16/05/2024	17/05/2024	Provisionally Approved	Approved	24/05/2024	Te Whatu Ora locality	Te Whatu Ora Canterbury		12
2023 EXP 12699	The use of canines as a non-invasive diagnostic tool for prostate cancer detection in urine samples	Professor Sarah Young	4/10/2023	6/10/2023	Provisionally Approved	Approved	11/10/2023	Other			12
2024 EXP 19587	Functional Outcomes in Operative Management of Proximal Hamstrings Ruptures	Dr Erynne Scherf	16/04/2024	20/04/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Te Whatu Ora Waitaha Canterbury		12
2024 EXP 18708	Investigating thyroid function in pregnancy in New Zealand women	Associate Professor Louise Brough	4/06/2024	7/06/2024	Provisionally Approved	Provisionally Approved		Tertiary Education Institution	Massey University		12
2023 EXP 17852	National Health Data Platform, University of Auckland	Associate Professor Katrina Poppe	22/08/2023	31/08/2023	Declined	Declined	13/09/2023	Tertiary Education Institution	University of Auckland		12
2023 EXP 18704	The adaptation of a web-based psychosocial intervention for cancer survivors	Dr Deborah Raphael	21/11/2023	28/11/2023	Approved NSC	Approved	4/12/2023	Other	University of Auckland		12
2023 EXP 18084	Validity of patient and therapist ratings of task challenge in stroke rehabilitation.	Associate Professor Nada Signal	23/08/2023	1/09/2023	Approved NSC	Approved	13/09/2023	Tertiary Education Institution	Auckland University of Technology		12
2023 EXP 18399	A novel glycaemic digital management tool: a pilot study	Mr Lachlan Lee	15/11/2023	16/11/2023	Provisionally Approved	Approved	22/11/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Otago		13
2023 FULL 19058	An international audit and cohort study of Wound Closure and Surgical Site Infection Prevention Strategies in Abdominal Surgery (WOLVERINE)	Dr Anthony Lin	16/11/2023	17/11/2023	Provisionally Approved	Approved	21/11/2023	Te Whatu Ora locality	Te Whatu Ora Capital, Coast and Hutt Valley	The University of Birmingham	13
2023 EXP 15333	Cutaneous infections caused by a novel nontuberculous mycobacterium, Aotearoa New Zealand	Dr Andrew Fox-Lewis	27/11/2023	28/11/2023	Provisionally Approved	Approved	4/12/2023	Te Whatu Ora locality			13

2023 FULL 18147	Liver Fibrosis in Inflammatory Bowel Disease: Prevalence and Risk Factors.	Doctor Laura Hollingsworth	7/10/2023	9/10/2023	Provisionally Approved	Approved	11/10/2023	Te Whatu Ora locality	Te Whatu Ora Southern / Otago University		13
2023 EXP 17996	A review of Canterbury Dog Bite Injury Demographics: Pre and Post Christchurch City Councils 2016 bylaw change.	Dr Nikita Quinn	24/11/2023	2/12/2023	Provisionally Approved	Provisionally Approved					13
2023 EXP 19180	How does the Digestible Indispensable Amino Acid Score (DIAAS) influence Protein Turnover in Older Adults?	Professor David Rowlands	29/11/2023	2/12/2023	Declined	Declined	15/12/2023	Tertiary Education Institution	Riddet Institute		13
2023 FULL 18809	He rapunga hauora mō te matewareware: A prevalence study	Dr Makarena Dudley	17/10/2023	28/10/2023	Declined	Declined	10/11/2023	Other			14
2023 EXP 13146	Goals of Care Discussion in Patients Presenting for Hip Fracture Surgery at Te Toka Tumai.	Dr Catherine Sayer	21/12/2023	8/01/2024	Provisionally Approved	Approved	15/01/2024				14
2023 EXP 19062	Determining Days Alive and Out of Hospital at 90 Days for Emergency Department Patients with Sepsis	Associate Professor Peter Jones	20/10/2023	26/10/2023	Approved NSC	Approved	6/11/2023		Te Toka Tumai		14
2023 EXP 15443	A molecular triage test to reduce colposcopy referrals after HPV testing	Professor Marilyn Hibma	28/11/2023	29/11/2023	Provisional Approval	Approved	5/12/2023	Primary Health Care Centre, Te Whatu Ora locality, Tertiary Education Institution	University of Otago		15
2023 EXP 18701	Community Research Rōpū: establishment needs in a rural rohe.	Dr Emily Gill	14/11/2023	14/11/2023	Provisionally Approved	Approved	22/11/2023	Other			15
2023 EXP 18527	Estimating the prevalence of screening positive for and testing positive for sleep apnoea during pregnancy among a sample of people birthing in and around Auckland, New Zealand: A feasibility study	Dr Kathleen Antony	23/11/2023	28/11/2023	Provisionally Approved	Approved	4/12/2023	Other, Primary Health Care Centre, Te Whatu Ora locality	University of Auckland		15
2023 EXP 15519	The effects of consuming a heritage apple puree in patients with ulcerative colitis	Dr Noha Nasef	11/09/2023	11/09/2023	Provisionally Approved	Approved	13/09/2023	Other	Massey University Human Ethics		15

2024 EXP 19948	A Study to Determine the Effects of in vivo Dual Anti-Platelet Therapy (DAPT) on Neutrophils.	Dr Kathryn Hally	21/06/2024	28/06/2024	Provisionally Approved	Provisionally Approved		Tertiary Education Institution	Victoria University of Wellington		15
2024 EXP 19710	Defining inflammatory markers in different grades of acute cholangitis	Dr Andrei Belyaev	3/02/2024	6/02/2024	Approved NSC	Approved	21/02/2024				15
2024 EXP 19417	Better rehabilitation: An intervention promoting non-conscious motor control for people with poststroke mental fatigue.	Dr Merel Hoskens	16/05/2024	19/05/2024	Provisionally Approved	Approved	24/05/2024	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	University of Waikato		16
2023 EXP 18800	The Role of Mast Cell Activation in Gastrointestinal and other Systemic Diseases	Dr. Hannah Giles	7/12/2023	14/12/2023	Provisionally Approved	Approved	18/12/2023	Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	Auckland Hospital		16
2024 EXP 19305	Long-term Ileo-anal Pouch Outcome Study (LIPOS) : Protocol for a prospective multi-centre observational cohort study of the patient-reported long-term outcomes of Ileo-anal Pouch Procedures	Mr Wasilwa Baraza	30/05/2024	4/06/2024	Provisionally Approved	Approved	17/06/2024	Private Organisation, Te Whatu Ora locality	N/A		25
2023 EXP 15556	Experience of Patients with Sub-Threshold Abdominal Aortic Aneurysms	Dr Oliver Lyons	8/09/2023	11/09/2023	Provisionally Approved	Approved	13/09/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality			17
2023 EXP 18302	Quantitative sleep and physical activity in older adults with early cognitive changes in the Dementia Prevention Research Clinics, Aotearoa New Zealand	Dr Sarah Buchanan	3/08/2023	7/08/2023	Provisionally Approved	Approved	8/08/2023	Tertiary Education Institution	University of Otago		17
2023 EXP 18329	A pilot dose duration-response study using Diprosone® cream (Organon, Australia) to determine	Dr Noelyn Hung	11/08/2023	15/08/2023	Provisionally Approved	Approved	16/08/2023	Private Organisation	Zenith Technology	Nova Chem Australasia Pty Ltd	18

	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.								Corporation Limited		
2024 EXP 18734	Assessing the safety and efficacy of Systane Hydration PF and Systane Hydration Preserved (DEN923-I001)	Professor Jennifer Craig	27/06/2024	1/07/2024	Provisionally Approved	Approved	5/07/2024	Private Organisation, Tertiary Education Institution	Senior Ethics Advisor, Office of Research Strategy & Integrity (ORSI), The University of Auckland	Alcon Research LCC	18
2024 EXP 19014	Diagnosis and monitoring of brain tumours through liquid biopsy.- A pragmatic prospective study to find a blood test to identify brain tumours. DiMon-LB study	Professor Giles Critchley	8/01/2024	9/01/2024	Provisionally Approved	Approved	15/01/2024	Te Whatu Ora locality	Health Research South		18
2024 EXP 19133	The development of a performance-based assessment system and a VR-based rehabilitation system for people with Knee Osteoarthritis	Mr Xingye Cheng	16/05/2024	17/05/2024	Provisionally Approved	Approved	24/05/2024	Tertiary Education Institution	University of Auckland		18
2024 EXP 19583	Visual performance and patient-reported outcomes in mild glaucoma patients with non-diffractive wavefront-shaped extended depth-of-focus intraocular lens implantation	Professor Helen Danesh-Meyer	7/05/2024	16/05/2024	Provisionally Approved	Approved	23/05/2024	Private Organisation	Eye Institute Limited		18
2024 EXP 20096	Magnetic Resonance Imaging (MRI) of brain motion as an indicator for raised intracranial pressure	Dr Samantha Holdsworth	29/05/2024	3/06/2024	Provisionally Approved	Provisionally Approved		Other, Private Organisation, Te Whatu Ora locality	Mātai Medical Research Institute		18
2024 EXP 20157	Outcomes following lung transplantation for interstitial lung diseases in New Zealand	Dr Jeong Suk Oh	28/06/2024	12/07/2024	Provisionally Approved	Provisionally Approved			Te Whatu Ora, Health NZ		18
2023 FULL 18459	A Phase 1 Open-label, Multicenter, First-in-human, Ascending Single-dose Study Evaluating the Safety and Tolerability of a Lipid Nanoparticle Formulation of CRISPR-Guide RNA-Cas9	Professor Russell Scott	21/08/2023	30/08/2023	Approved NSC	Approved	13/09/2023	Private Organisation	CARSL Consulting (Clinical and Regulatory Services Limited)	CRISPR Therapeutics AG	19

	Nuclease (CTX310) for In Vivo Editing of the Angiopoietin-like 3 (ANGPTL3) Gene in Subjects With Refractory Dyslipidemias										
2023 FULL 18108	A pilot safety study of warm and humidified carbon dioxide delivery in patients undergoing laparoscopic colorectal surgery	Dr Ryan Salter	23/08/2023	28/08/2023	Approved	Approved	13/09/2023	Te Whatu Ora locality	Fisher & Paykel Healthcare		19
2023 FULL 13751	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	7/07/2023	20/07/2023	Provisionally Approved	Approved	27/07/2023	Te Whatu Ora locality		Biotest AG	39
2023 FULL 18000	MinDART: A randomised attention-control trial compared to a Memory Cafe intervention	Associate Professor Emma Febvre-Richards	19/07/2023	25/07/2023	Approved NSC	Approved	8/08/2023	Other, Tertiary Education Institution	Massey University;		19
2023 FULL 18386	Validation of an extraction free qPCR assay for the detection of Group A Streptococcus in throat swabs.	Dr Rebecca Lucas-Roxburgh	23/08/2023	28/08/2023	Approved	Approved	13/09/2023	Private Organisation			19
2023 EXP 13585	Developing a new Parkinson's disease marker using the eye's reflex tears	Professor John Dalrymple-Alford	7/11/2023	8/11/2023	Provisionally Approved	Approved	15/11/2023	Private Organisation	University of Canterbury		19
2024 EXP 20178	Digital Technologies for Stroke Prevention Trial	Prof. Rita Krishnamurthi	28/05/2024	30/05/2024	Provisionally Approved	Approved	11/06/2024	Other, Primary Health Care Centre, Te Whatu Ora locality	Auckland University of Technology		19
2023 EXP 18018	How can optimal first trimester medical abortion care be provided in the primary care setting, and what does the sector require to do this?	Ms Emma Macfarlane	28/08/2023	7/09/2023	Provisionally Approved	Approved	11/09/2023	Primary Health Care Centre	University of Otago, Research and Enterprise		19
2024 EXP 18607	Te Iti Kahurangi - Unveiling the silence for term pēpi: preventability reviews.	Dr Liza Edmonds	10/05/2024	17/05/2024	Provisionally Approved	Approved	24/05/2024		Te Herenga Waka		19
2023 FULL 18823	The GORE VBX FORWARD Clinical Study: A Comparison of	Associate Professor	19/12/2023	19/12/2023	Provisionally Approved	Approved	20/12/2023	Te Whatu Ora locality	Auckland City Hospital - Te	W. L. Gore & Associates, Inc.	20

	the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis to Bare Metal Stenting for Patients with Complex Iliac Occlusive Disease	Andrew Holden							Whatu Ora Te Toka Tumai		
2024 FULL 20347	A collaborative approach to choosing a behavioural intervention	Dr Rebecca Sharp	21/05/2024	28/05/2024	Provisionally Approved	Provisionally Approved		Other	The University of Auckland		20
2024 FULL 20129	A Multinational, Multicenter, Prospective, Randomized, Controlled, Open-Label, Phase 3 Study of Lutetium (177Lu) rosopatomab tetraxetan in Combination with Standard of Care Versus Standard of Care Alone in Patients with PSMA Positive Metastatic Castration-Resistant Prostate Cancer Previously after Androgen Receptor Pathway Inhibitor Treatment	Dr Simon Fu	16/05/2024	27/05/2024	Provisionally Approved	Provisionally Approved		Private Organisation, Te Whatu Ora locality	Telix Pharmaceuticals (NZ) Ltd	Telix (Innovations) Pharmaceuticals Pty Ltd	20
2023 FULL 18885	A Phase 1 Open-label, Multicenter, First-in-human, Ascending Single Dose Study Evaluating the Safety and Tolerability of a Lipid Nanoparticle Formulation of CRISPR-Guide RNA-Cas9 Nuclease (CTX320) for In Vivo Editing of the Apolipoprotein(a) Gene (LPA) in Subjects with Elevated Lipoprotein(a) and a History of Atherosclerotic Cardiovascular Disease or Calcific Aortic Valve Stenosis	Professor Russell Scott	25/10/2023	26/10/2023	Approved NSC	Approved	15/11/2023	Private Organisation	CARSL Consulting (Clinical and Regulatory Services Limited)	CRISPR Therapeutics AG	20
2024 FULL 20305	A Phase 1, Randomized, Double-blinded, Placebo-controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single Ascending Doses of L608 for Inhalation in Healthy Participants.	Dr Christopher Wynne	21/05/2024	27/05/2024	Approved NSC	Approved	12/06/2024	Private Organisation	Novotech (New Zealand) Limited	Pharmosa Biopharm Inc.	20
2023 FULL 18950	A Phase 2, Randomized, Double-blind, Placebo- and Active-comparator-controlled Clinical Study of Adjuvant V940 (mRNA-	Dr Nicola Lawrence	24/10/2023	28/10/2023	Approved NSC	Approved	15/11/2023	Te Whatu Ora locality	Merck, Sharp & Dohme (Australia) Pty Ltd (MSD)	Merck, Sharp & Dohme (Australia) Pty Ltd (MSD)	20

	4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With High-risk Muscle-invasive Urothelial Carcinoma Post radical Resection										
2023 FULL 1874 8	A Phase 3 Program to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Moderately to Severely Active Systemic Lupus Erythematosus	Dr Mark Sapsford	14/09/2023	28/09/2023	Approved	Approved	12/10/2023	Te Whatu Ora locality	Abbvie	Abbvie	20
2024 FULL 1966 1	A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Global Study to Evaluate the Efficacy and Safety of Intravenous AOC 1001 for the Treatment of Myotonic Dystrophy Type 1.	Dr Richard Roxburgh	21/05/2024	27/05/2024	Approved NSC	Approved	12/06/2024	Tertiary Education Institution	Clinical and Regulatory Services (CARSL) Consulting	Avidity Biosciences	20
2024 FULL 1992 4	A Randomized, Double Blind, Placebo-Controlled Pilot Study to Evaluate the Efficacy and Safety of Myrecil® in Genitourinary Syndrome of Menopause.	Dr Sylvia Rosevear	21/05/2024	28/05/2024	Provisionally Approved	Provisionally Approved		Primary Health Care Centre	Weir Science Ltd		20
2024 FULL 1809 6	Assessing the acceptability and feasibility of using the Aotearoa New Zealand Health Transition Skills list to create a health transition learning goal as part of the individualized education plan of young people with neurodevelopmental disability.	Dr Rachel Howlett	21/02/2024	28/02/2024	Approved NSC	Approved	13/03/2024	Other	Starship Childrens Hospital		20
2023 FULL 1905 0	Clinical trial investigating the efficacy and safety of insulin delivery with a prototype ultra-low-cost insulin pump in adults with type 1 diabetes	A/Prof. Martin de Bock	18/10/2023	28/10/2023	Approved NSC	Approved	15/11/2023	Private Organisation , Tertiary Education Institution	University of Otago		20
2024 FULL 1900 7	Feasibility and effectiveness of a home-based training protocol to enhance swallowing skills in children with cerebral palsy: A pilot project	Dr Ksenia Bykova	21/02/2024	24/02/2024	Declined	Declined	13/03/2024	Other	University of Canterbury, Rose Centre		20
2023 FULL 1791 6	FEBCON-ED study: A stepped-wedge cluster randomised controlled clinical trial of usual care vs regular antipyretics for children presenting with a FEBrile	Professor Stuart Dalziel	14/09/2023	28/09/2023	Approved NSC	Approved	12/10/2023	Te Whatu Ora locality	Starship Children's Hospital, Te Toka Tumai - Auckland	Monash Medical Centre Paediatric ED, Monash Health	20

	CONvulsion to the Emergency Department.										
2024 FULL 18606	Hapū Whānau: Implementing iwi-owned service hubs to improve health outcomes	Professor Bev Lawton	20/05/2024	28/05/2024	Provisionally Approved	Provisionally Approved		Primary Health Care Centre	Victoria University of Wellington		20
2024 FULL 20251	ReNew: A Phase 3, Randomized, Double-Masked, Placebo-Controlled Clinical Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Subcutaneous Injections of Elamipretide in Subjects who have Dry Age-Related Macular Degeneration (Dry AMD)	Dr James Borthwick	17/05/2024	27/05/2024	Provisionally Approved	Provisionally Approved		Private Organisation	Research Associates Ltd	Stealth BioTherapeutics Inc	20
2023 FULL 17972	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	27/07/2023	28/07/2023	Provisionally Approved	Approved	16/08/2023	Te Whatu Ora locality		Professor of Respiratory Medicine, University of Western Australia	45
2024 EXP 19601	A feasibility, acceptability, and sustainability study of Movement to Music: A community support after stroke	Dr Kalie Evans	11/06/2024	17/06/2024	Provisionally Approved	Provisionally Approved		Other, Primary Health Care Centre, Private Organisation, Te Whatu Ora locality			20
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	6/07/2023	7/07/2023	Provisionally Approved	Approved	28/07/2023	Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	Auckland University of Technology		41
2024 FULL 20002	A Phase IIa/IIb, randomised, double blind, placebo-controlled, parallel-group dose-finding study to examine the efficacy and safety of BI 1839100 administered orally over a 12 week treatment period in patients with idiopathic pulmonary fibrosis	Dr. Catherina Chang	11/04/2024	28/04/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Boehringer Ingelheim NZ Limited	Boehringer Ingelheim Singapore Pte. Ltd.	21

	or progressive pulmonary fibrosis with clinically meaningful cough										
2024 FULL 19766	A quantitative study comparing ankle x-ray imaging and low-dose computed tomography (CT) scans for post-operative evaluation of total ankle replacements (TARs).	Dr Sibusiso Mdletshe	15/04/2024	29/04/2024	Provisionally Approved	Provisionally Approved		Private Organisation, Te Whatu Ora locality	RHCNZ		21
2024 FULL 20097	A randomised, double-blind, placebo-controlled, dose-finding study evaluating efficacy, safety and tolerability of different oral doses of BI 1819479 over at least 24 weeks in patients with idiopathic pulmonary fibrosis (IPF)	Dr. Catherina Chang	17/04/2024	30/04/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Boehringer Ingelheim NZ Limited	Boehringer Ingelheim Pty Ltd	21
2024 FULL 19941	A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Study Evaluating the Safety and Efficacy of Pirfenidone Solution for Inhalation (AP01) in Subjects with Progressive Pulmonary Fibrosis (PPF)	Dr Michael Epton	11/04/2024	29/04/2024	Approved NSC	Approved	17/05/2024	Te Whatu Ora locality	Syneos Health New Zealand Limited	Avalyn Pharma Inc.	21
2023 FULL 18604	Defining the Genetics of Developmental Disorders	Professor Stephen Robertson	25/08/2023	1/09/2023	Approved NSC	Approved	12/10/2023	Te Whatu Ora locality	University of Otago		21
2023 EXP 19008	What are the research priorities for youth mental health and substance use in Aotearoa New Zealand	Dr Kaaren Mathias	20/11/2023	22/11/2023	Provisionally Approved	Approved	27/11/2023	Other, Primary Health Care Centre	University of Canterbury		22
2023 FULL 13624	Fibrinogen Concentrate vs. Cryoprecipitate in Traumatic Haemorrhage: A Multi-centre Randomised Controlled Trial	Dr James Moore	25/07/2023	27/07/2023	Provisionally Approved	Approved	28/07/2023	Te Whatu Ora locality		Monash University	23
2023 FULL 18372	A NON-RANDOMIZED, OPEN-LABEL, NON-CONTROLLED, ADAPTIVE, MULTIPLE-DOSE STUDY TO INVESTIGATE THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF ZOSURABALPIN FOLLOWING INTRAVENOUS ADMINISTRATION IN HEALTHY PARTICIPANTS	Dr Nick Cross	22/11/2023	24/11/2023	Provisionally Approved	Approved	27/11/2023	Private Organisation	Pharmaceutical Research Associates New Zealand Limited	F. Hoffmann-La Roche Ltd	23

2024 EXP 20272	Investigating Barriers and Enablers to Preventive HIV Access for Māori (PrEP Pilot Project)	Dr Tanya Allport	30/05/2024	5/06/2024	Provisionally Approved	Approved	11/06/2024	Other			24
2023 EXP 18340	Recurrence rates of scalp Squamous Cell Carcinoma (SCC)	Dr Hannah Kim	18/07/2023	8/08/2023	Approved NSC	Approved	14/08/2023				24
2023 FULL 16757	Improving health services for people with musculoskeletal chest pain - a randomised controlled feasibility trial	Dr Ewan Kennedy	5/09/2023	7/09/2023	Provisionally Approved	Approved	11/09/2023	Other, Te Whatu Ora locality, Tertiary Education Institution			25
2024 FULL 19550	A Phase 3, Two-Stage, Randomized, Multicenter, Open-label Study Comparing Mezigdomide (CC-92480), Bortezomib, and Dexamethasone (MeziVd) Versus Pomalidomide, Bortezomib and Dexamethasone (PVd) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM): Successor-1	Dr Marie Hughes	4/04/2024	5/04/2024	Provisionally Approved	Approved	10/04/2024	Primary Health Care Centre	Bristol Myers Squibb	Bristol Myers Squibb	25
2023 FULL 13714	A sector analysis of the needs of transgender adults, youth and parents of transgender children within primary healthcare services	Dr. Katie McMenamin	31/08/2023	10/09/2023	Provisionally Approved	Approved	27/09/2023	Other, Primary Health Care Centre			44
2023 EXP 15436	A prospective database for neuroendocrine cancer (NET) patients recommended for peptide radionuclide receptor therapy (PRRT) in New Zealand.	Dr Laird Cameron	27/09/2023	6/10/2023	Provisionally Approved	Approved	11/10/2023	Te Whatu Ora locality	The University of Auckland		25
2024 EXP 19831	Retrospective Analysis of Sarcoma Cases	Dr Cameron Tuckey	24/05/2024	30/05/2024	Provisionally Approved	Approved	11/06/2024		Te Whatu Ora		25
2023 EXP 15090	Barriers to Testing Access	Principal Advisor Neelam Bhikha	17/07/2023	24/07/2023	Declined	Declined	15/08/2023	Private Organisation	Te Whatu Ora		25
2023 FULL 15134	Paediatric Eye Health Services in New Zealand - An investigation into the prevalence of visual conditions in New Zealand 7 year olds	Dr Rebecca Findlay	20/07/2023	20/07/2023	Provisionally Approved	Approved	27/07/2023	Other	University of Auckland		26

2023 FULL 18958	Improving the dietary intake of residential care facility residents through the fortification of everyday foods.	Dr Karen Munday	13/12/2023	14/12/2023	Provisionally Approved	Approved	20/12/2023	Other	Fonterra Research and Development Centre		26
2024 FULL 20112	PRECISION-TBI - A multi-centre observational cohort study of patients with traumatic brain injury	Dr Jonathon Taylor	10/06/2024	11/06/2024	Provisionally Approved	Approved	17/06/2024	Te Whatu Ora locality	Te Whatu Ora Health New Zealand	Australia and New Zealand Intensive Care Research Centre, Department of Epidemiology and Preventive Medicine School of Public University Health and Preventive Medicine Monash University	26
2023 FULL 18627	03.18 I-MAT: Immunotherapy Merkel Adjuvant Trial: A randomised, placebo-controlled, phase II trial of adjuvant Avelumab in patients with stage I-III Merkel cell carcinoma.	Dr Gareth Rivalland	20/11/2023	27/11/2023	Approved NSC	Approved	19/12/2023	Te Whatu Ora locality		Melanoma and Skin Cancer Trials Ltd	26
2023 FULL 19192	A PHASE 1, OPEN-LABEL, RANDOMIZED, SINGLE-DOSE, CROSSOVER STUDY TO EVALUATE THE RELATIVE BIOAVAILABILITY OF BCX10013 TABLET VS. CAPSULE FORMULATIONS	Dr Alexandra Cole	23/11/2023	27/11/2023	Approved	Approved	19/12/2023	Private Organisation	Novotech (New Zealand) Limited	BioCryst Pharmaceuticals, Inc.	26
2023 FULL 19250	A Phase 2b, randomized, controlled, open-label study to evaluate the immune response and safety of the RSVPreF3 OA investigational vaccine in adults (≥18 years of age) when administered to lung and renal transplant recipients comparing 1 versus 2 doses and compared to healthy controls (≥50 years of age) receiving 1 dose.	Dr Nine Smuts	22/11/2023	27/11/2023	Approved NSC	Approved	19/12/2023	Private Organisation	GSK New Zealand	GSK Australia	26

2023 FULL 19150	A Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ELVN-001 Following Single Doses of Capsule and Tablet Administration in the Presence or Absence of High-Fat Food and/or Proton Pump Inhibitors in Normal Healthy Participants	Dr Laura Elliott	23/11/2023	27/11/2023	Approved NSC	Approved	19/12/2023	Private Organisation	Novotech (New Zealand) Pty Ltd	Enliven Therapeutics, Inc	26
2024 EXP 20626	Establishing a translational cognitive disorders research clinic	Dr Campbell Le Heron	17/06/2024	20/06/2024	Approved NSC	Approved	17/07/2024	Other			26
2024 FULL 18155	Feasibility study of the effect of psilocybin in response to brief psychological input with psychological flexibility as a mediating factor	Dr Valerie Tan	17/06/2024	25/06/2024	Declined	Declined	17/07/2024	Tertiary Education Institution	University of Otago		26
2024 FULL 20155	M22-128: A Phase 3, Multicenter, Randomized, Open-Label Study of Epcoritamab Plus Lenalidomide Compared to Rituximab Plus Gemcitabine and Oxaliplatin in Participants with Relapsed or Refractory Diffuse Large B-Cell Lymphoma	Dr Sophie Leitch	18/06/2024	25/06/2024	Approved NSC	Approved	17/07/2024	Te Whatu Ora locality	AbbVie Ltd	AbbVie Pty Ltd	26
2024 FULL 20554	Multi-centre, Prospective, Randomized, Controlled Trial Comparing Genicular Artery Embolization Using Embosphere Microspheres to Corticosteroid injections for the Treatment of Symptomatic Knee Osteoarthritis: MOTION Study	Dr Rahul Bera	17/06/2024	24/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Research and Knowledge Centre Waitematā	Merit Medical Systems, Inc.	26
2024 FULL 20591	The PIKI study: A randomised controlled trial of paracetamol versus ibuprofen for fever and pain in children under 2 years of age.	Dr Eunicia Tan	18/06/2024	24/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Health New Zealand Te Whatu Ora - Counties Manukau		26
2023 EXP 18452	In cases of abusive head trauma in Aotearoa New Zealand, which caregivers usually injure the child?	Dr Patrick Kelly	20/12/2023	21/12/2023	Provisionally Approved	Approved	10/01/2024		Director of Starship Services, Starship Child Health, Te Whatu Ora Te		27

									Toka Tumai Auckland		
2023 FULL 1830 1	Encapsulated fecal microbiome transfer versus oral vancomycin treatment for recurrent or refractory C. difficile infection	Professor Wayne Cutfield	15/11/2023	15/11/2023	Provisionally Approved	Approved	22/11/2023	Tertiary Education Institution	University of Auckland		27
2024 FULL 1900 4	Manaaki Māmao - to care from a distance	Mrs Tiffany Neary	16/05/2024	20/05/2024	Provisionally Approved	Approved	24/05/2024	Other	St John		27
2024 FULL 1987 3	A Phase 1a/1b, Blinded, Placebo-Controlled Study of the Safety, Tolerability and Pharmacokinetics of Single- and Multiple-Ascending Doses of ABI-5366 in Healthy Subjects and in Subjects who are Seropositive for Herpes Simplex Virus Type 2 with Recurrent Genital Herpes	Prof. Edward Gane	20/03/2024	24/03/2024	Approved NSC	Approved	18/04/2024	Private Organisation	PPD, part of Thermo Fisher Scientific; TMF Group	Assembly Bioscience, Inc.	27
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 Advanced or Metastatic Solid Tumors.	Dr Peter Fong	19/07/2023	9/08/2023	Provisionally Approved	Approved	16/08/2023	Te Whātu Ora locality	PPD Part of Thermo Fisher	gRED Clinical Operations, Genentech, Inc.	48
2024 EXP 19491	Early onset colorectal cancer network Aotearoa	Dr Tamara Glyn	15/03/2024	25/03/2024	Declined	Declined	18/04/2024	Te Whātu Ora locality	University of Otago		27
2023 FULL 1780 6	Parent Perceptions of Augmented Input Using A Speech-Generating Device for Autistic Children	Ms Siobhan Gardiner	9/08/2023	11/08/2023	Provisionally Approved	Approved	6/09/2023	Tertiary Education Institution	Human Ethics Committee, Victoria University of Wellington		52
2024 FULL 1991 6	Warfarin self testing and use of a patient portal for individuals living with rheumatic heart disease and mechanical valve replacement	Dr Miriam Wheeler	14/03/2024	28/03/2024	Declined	Declined	18/04/2024	Te Whātu Ora locality	Te Toka Tumai, Te Whātu Ora		27
2024 FULL 1968 1	A SINGLE- AND MULTIPLE DOSE, OPEN LABEL, PHASE I STUDY TO INVESTIGATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS, AND IMMUNOGENICITY OF	Dr. Leanne Barnett	19/03/2024	26/03/2024	Approved NSC	Approved	18/04/2024	Private Organisation		Roche Products (New Zealand) Ltd	28

	SUBCUTANEOUSLY ADMINISTERED RO7204239 IN ADULT PARTICIPANTS WITH HIGH BODY WEIGHT										
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	26/07/2023	27/07/2023	Provisionally Approved	Approved	24/08/2023	Tertiary Education Institution	The University of Auckland		60
2024 FULL 1987 8	Utility of an Intervention Decision-Making Tool for Challenging behaviour Maintained by the Access to Tangibles	Dr Rebecca Sharp	19/03/2024	26/03/2024	Declined	Declined	18/04/2024	Private Organisation	The University of Auckland		28
2024 FULL 1956 1	A Phase 1b Multiple Ascending Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of SZN-043, in Participants with Severe Alcohol-Associated Hepatitis	Principal Investigator Edward Gane	19/01/2024	26/01/2024	Approved NSC	Approved	23/02/2024	Te Whatu Ora locality	Novotech (New Zealand) Limited c/o Novotech Australia Pty Ltd	Surrozen Operating, Inc	29
2024 FULL 1947 1	A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of ANB032 in the Treatment of Subjects with Moderate to Severe Atopic Dermatitis	Dr Penelope Montgomery	11/01/2024	31/01/2024	Approved NSC	Approved	23/02/2024	Private Organisation	Novotech (New Zealand) Pty Ltd	AnaptysBio, Inc.	29
2024 FULL 1951 5	Clinical Biomarkers and Applications in Eye Tracking	Professor Helen Danesh-Meyer	18/01/2024	30/01/2024	Declined	Declined	23/02/2024	Other, Primary Health Care Centre, Private Organisation, Te Whatu Ora locality, Tertiary Education Institution			29
2024 FULL 1943 4	Novel Medtronic Experimental Automated Insulin Delivery System (NMX-AID) in children with type 1 diabetes - Single arm study	Professor Benjamin Wheeler	12/01/2024	15/01/2024	Approved NSC	Approved	23/02/2024	Te Whatu Ora locality, Tertiary Education Institution	University of Otago		29
2024 FULL 1988 5	COMPASSIONATE INQUIRY IN WHĀNAU EARLY INTERVENTION SERVICES	Dr Lillian Ng	20/05/2024	21/05/2024	Provisionally Approved	Approved	11/06/2024	Other	University of Auckland		30

2024 FULL 20084	A single-centre, double-blind, randomized, placebo-controlled, 2-arm study to evaluate safety and efficacy of intermittent Rapamycin on muscle strength and endurance in older adults following a 13-week exercise program	Dr Joanna Wojciechowska	6/06/2024	10/06/2024	Provisionally Approved	Approved	17/06/2024	Te Whatu Ora locality	Dr Brad Stanfield Ltd		30
2024 FULL 18925	Clinical Safety and Efficacy of the VDYne	Dr Sanjeevan Pasupati	16/02/2024	19/02/2024	Provisionally Approved	Approved	22/02/2024	Te Whatu Ora locality		Mobius Medical Pty Ltd	30
2023 FULL 17872	Glucagon-like peptide-1 receptor agonists in dialysis patients	Dr Tze Liang Goh	14/09/2023	15/09/2023	Provisionally Approved	Approved	26/09/2023	Te Whatu Ora locality	Te Whatu Ora Health New Zealand Te Toka Tumai Auckland		30
2024 FULL 20102	Feasibility and effectiveness of a home-based training protocol to enhance swallowing skills in children with cerebral palsy: A pilot project	Dr Ksenia Bykova	5/06/2024	10/06/2024	Provisionally Approved	Approved	17/06/2024	Other			31
2024 FULL 19478	A Randomized, Double-Blind, Placebo-Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a Transdermal Gel to Children, Adolescents, and Young Adults with Fragile X Syndrome - RECONNECT	Dr Andrew Marshall	4/06/2024	10/06/2024	Provisionally Approved	Approved	17/06/2024	Te Whatu Ora locality	Health New Zealand - Te Whatu Ora	Avance Clinical Pty Ltd	32
2024 FULL 19541	Multi-center, double-blind, randomized, placebo-controlled, parallel-group study to evaluate the efficacy and safety of self-administered subcutaneous selatogrel for prevention of all-cause death and treatment of acute myocardial infarction in subjects with a recent history of acute myocardial infarction.	Dr Madhav Menon	18/06/2024	27/06/2024	Provisionally Approved	Approved	3/07/2024	Te Whatu Ora locality	Novotech (New Zealand) Limited	Idorsia Pharmaceuticals Ltd	33
2023 FULL 18146	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	Dr Sanjeev Deva	1/08/2023	8/08/2023	Approved	Approved	6/09/2023	Te Whatu Ora locality	BeiGene		34

	Tislelizumab in Patients with Advanced Solid Tumors.										
2023 EXP 18067	EVALUATION OF THE EFFECTS OF INTERVAL BETWEEN LUMBAR PUNCTURES ON CSF AND PLASMA ANALYTES IN HEALTHY VOLUNTEERS	Dr Nick Cross	25/08/2023	25/08/2023	Provisionally Approved	Approved	4/09/2023	Private Organisation	PPD, Part of Thermo Fisher Scientific	Genentech, Inc.	35
2024 FULL 19443	Implementing psychotherapy for depression in primary care: feasibility study phase 2	Professor Marie Crowe	29/04/2024	1/05/2024	Provisionally Approved	Approved	6/05/2024	Primary Health Care Centre	Pegasus Health		35
2024 EXP 13998	Photonic probe for intraoperative real-time prostate cancer diagnosis	Dr Claude Aguegaray	14/06/2024	19/06/2024	Provisionally Approved	Approved	24/06/2024	Te Whatu Ora locality	The University of Auckland		35
2024 EXP 18357	Breast Cancer Screening Images and Artificial Intelligence in New Zealand	Professor Colin Simpson	22/04/2024	23/04/2024	Provisionally Approved	Approved	1/05/2024		Victoria University of Wellington		36
2023 FULL 18663	Edwards 12F Sheath Feasibility Study	Dr James Blake	28/11/2023	29/11/2023	Provisionally Approved	Approved	15/12/2023	Te Whatu Ora locality	Edwards Lifesciences (New Zealand) Ltd	Edwards Lifesciences LLC	36
2023 EXP 18218	Bariatric real-life perspectives: Understanding pre-surgery information needs and desire for past patient stories	Miss Amy Hemmington	11/08/2023	15/08/2023	Provisionally Approved	Approved	6/09/2023	Te Whatu Ora locality	Te Whatu Ora (Counties Manukau)		37
2023 FULL 18313	An Open-label Extension Study for Participants who Completed Study IMVT-1401-3201 or Study IMVT-1401-3202 to Assess the Efficacy and Safety of Batoclimab for the Treatment of Thyroid Eye Disease (TED)	Dr Rebecca Stack	23/11/2023	28/11/2023	Provisionally Approved	Approved	12/12/2023	Primary Health Care Centre, Private Organisation	Syneos Health New Zealand Limited	Immunovant Sciences, GmbH	37
2024 FULL 19534	Automated insulin delivery to improve current care for Māori and Pacific peoples living with type 1 diabetes	Professor Benjamin Wheeler	7/05/2024	15/05/2024	Provisionally Approved	Approved	17/05/2024	Te Whatu Ora locality, Tertiary Education Institution	University of Otago		37
2023 FULL 18311	A Phase 3, Multi-center, Randomized, Quadruple-masked, Placebo-controlled Study of Batoclimab for the Treatment of Participants with Active Thyroid Eye Disease (TED)	Dr Rebecca Stack	23/11/2023	27/11/2023	Provisionally Approved	Approved	13/12/2023	Primary Health Care Centre, Private Organisation	Syneos Health New Zealand Limited	Immunovant Sciences, GmbH	38

2024 FULL 1914 9	Does posture for occiput posterior position in labour reduce operative births? A feasibility study.	Dr Jenner Barrowclough	31/01/2024	1/02/2024	Provisionally Approved	Approved	13/02/2024	Te Whatu Ora locality	Auckland University of Technology		38
2024 FULL 1971 5	REFRaME-O1: A Phase 2/3 Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) versus Investigator's Choice (IC) Chemotherapy in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (Including Fallopian Tube or Primary Peritoneal Cancers) Expressing Folate Receptor Alpha (FOLR1)	Dr Jonathan Graham	24/05/2024	28/05/2024	Provisionally Approved	Approved	6/06/2024	Te Whatu Ora locality	Premier Research	Sutro Biopharma, Inc	38
2023 FULL 1886 4	A Phase 3, Randomized, Open-label, Active-Comparator-Controlled Clinical Study to Evaluate the Safety and Efficacy of Bomedemstat (MK-3543/IMG-7289) versus Best Available Therapy (BAT) in Participants With Essential Thrombocythemia who have an Inadequate Response to or are Intolerant of Hydroxyurea.	Dr James Liang	30/11/2023	4/12/2023	Provisionally Approved	Approved	21/12/2023	Te Whatu Ora locality	Merck Sharp & Dohme (New Zealand) Limited (MSD)	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.,	39
2023 EXP 16673	Association of abdominal ultrasound features and clinical outcomes in necrotising enterocolitis: a 5-year experience in Waikato Hospital, New Zealand.	Dr Ryan Cha	13/08/2023	16/08/2023	Provisionally Approved	Approved	6/09/2023				41
2024 EXP 19970	AI in Diabetic Retinopathy Screening	Dr Cheng Kai Jin	20/05/2024	30/05/2024	Provisionally Approved	Approved	11/06/2024		Te Whatu Ora		41
2024 FULL 1841 8	Do perioperative synbiotics reduce postoperative infectious complications in patients undergoing elective colorectal resection?	Dr Claudia Paterson	6/03/2024	8/03/2024	Provisionally Approved	Approved	22/03/2024	Te Whatu Ora locality	The University of Auckland		43
2023 FULL 1832 3	Enhancing automated chyme reinfusion therapy with The Insides System	Professor Ian Bissett	13/12/2023	15/12/2023	Provisionally Approved	Approved	25/01/2024	Private Organisation , Te Whatu Ora locality	The Insides Company		44

2023 FULL 18589	A single dose, double-blind, balanced, randomised, two-treatment, two period, two sequence, two-way crossover bioavailability study comparing 1 x 370 mg Iron Polymaltose tablet (equivalent to 100 mg of elemental iron) with 1 x 370 mg Maltofer® tablet (equivalent to 100 mg of elemental iron) in iron deficient participants under fed conditions with diet control.	Dr Noelyn Hung	19/10/2023	20/10/2023	Provisionally Approved	Approved	16/11/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd	46
2024 FULL 19695	A Phase 2/3, adaptive, randomized, open-label, clinical study to evaluate neoadjuvant and adjuvant V940 (mRNA-4157) in combination with pembrolizumab (MK-3475) versus standard of care, and pembrolizumab monotherapy in participants with resectable locally advanced cutaneous squamous cell carcinoma (LA cSCC) (INTerpath-007)	Dr. Gareth Rivalland	4/04/2024	8/04/2024	Provisionally Approved	Approved	6/05/2024	Private Organisation	Merck Sharp & Dohme (Australia) Pty Ltd (MSD), Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD)	Merck Sharp & Dohme (Australia) Pty Ltd (MSD)	50
2023 FULL 14008	An open-label Randomised Controlled Trial of budesonide-formoterol as single maintenance and reliever therapy vs prescribed maintenance asthma therapy and salbutamol as reliever therapy in moderate to severe childhood asthma	Professor Stuart Dalziel	2/10/2023	3/11/2023	Provisionally Approved	Approved	9/11/2023	Te Whatu Ora locality	University of Auckland		54
2024 FULL 19298	Effect of MDMA (3,4-methylenedioxymethamphetamine) and tinnitus matched sound therapy on the perception of tinnitus and related distress: A proof-of-principle study.	Professor Dirk De Ridder	1/03/2024	1/03/2024	Provisionally Approved	Approved	5/04/2024	Tertiary Education Institution	University of Otago		61
2024 FULL 19714	Improving Access to Gender-Affirming Care – Community Drive Models of Care	Dr Tim Antric	7/04/2024	8/04/2024	Provisionally Approved	Approved	23/05/2024	Other, Primary Health Care Centre	Te Whatu Ora		65
2024 FULL 19634	A Phase 2, Multicenter, Double-Blind, Randomized, Placebo-controlled Trial, evaluating Safety, Tolerability, and Efficacy	Prof Paul Hofman	4/04/2024	8/04/2024	Provisionally Approved	Approved	23/05/2024	Private Organisation, Tertiary	Pharmaceutical Solutions Ltd	Ascendis Pharma	67

	of Subcutaneous Doses of TransCon CNP Administered Once Weekly for 52 Weeks in Infants (0 to <2 years of age) with Achondroplasia followed by an Open Label Extension (OLE) period.							Education Institution			
2024 FULL 18792	Examining the impact of Maternal PKU, a comparison to normative matched controls	Professor Suzanne Barker-Collo	24/04/2024	30/04/2024	Provisionally Approved	Approved	11/06/2024	Primary Health Care Centre	School of Psychology, The University of Auckland		72
2023 FULL 15170	Gold Study: Genomics of COVID-19 vaccine-related GBS, VITT/TTS and myocarditis/pericarditis – New Zealand's contribution to a global study	Associate Professor Helen Petousis Harris	25/08/2023	4/09/2023	Provisionally Approved	Approved	19/10/2023	Other, Primary Health Care Centre, Private Organisation, Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland	Uniservices	72
2024 FULL 19303	A Phase 3, Multicenter, Randomized, Open-Label Trial to Evaluate the Safety and Efficacy of Epcoritamab + Rituximab and Lenalidomide (R2) compared to Chemoimmunotherapy in Previously Untreated Follicular Lymphoma (EPCORE™FL-2)	Dr Leanne Berkahn	3/04/2024	8/04/2024	Provisionally Approved	Approved	16/05/2024	Te Whatu Ora locality		Abbvie Ltd	75
2024 FULL 18979	The International AML Platform Consortium (IAPC) trial	Dr Kern Chai	26/03/2024	26/03/2024	Provisionally Approved	Approved	23/05/2024	Te Whatu Ora locality			87