



**Health and
Disability Ethics
Committees**

**Northern B Health and Disability
Ethics Committee**

**Annual Report
2022**

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About this report

This report is a summary of the activities of the Northern B Health and Disability Ethics Committees (HDEC) for the period of 01 July 2021 – 30 June 2022. 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. Previous HDEC annual reports included information on committee membership and attendance. These details are no longer included in the report.

About the committee

The Northern B Health and Disability Ethics Committees (HDEC) is a Ministerial committee established under section 87 of the [Pae Ora \(Healthy Futures\) Act 2022](#). Its members are appointed by the Minister of Health through the public appointments process.

The primary function of the Committee is to provide independent ethical review of health research and innovative practice in order to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy by checking that it meets or exceeds established [ethical standards](#).

Approvals and registrations

The Northern B HDEC is approved by the Health Research Council Ethics Committee for the purposes of section 25(1)(c) of the [Health Research Council Act 1990](#).

The Northern B HDEC is registered (number IRB00008715) with the United States' [Office for Human Research Protections](#). This registration enables the committee to review research conducted or supported by the US Department of Health and Human Services.

Chairperson's report

It is my privilege to present this Annual Report of the work of Northern B HDEC (NTB) over the last year. In the year ending June 2022, the committee reviewed a total of 180 new applications. 117 were reviewed at full committee meetings, while 63 new applications were reviewed through the expedited (low risk) pathway.

I am happy to confirm that NTB has functioned effectively over the reporting period, and in accordance with the HRCEC's expectations for good and timely processes, the Guidelines for the Approval of Ethics Committees, and HDECs Standard Operating Procedures. Due however to the delay in appointment processes reported previously, along with member resignations, our membership numbers were diminished to the point of being non-quorate for the first half of 2022. Grateful thanks are given to the members of the other 3 HDECs who joined the remaining NTB members at our scheduled full meetings. Fortunately, another appointments round has now been completed and Mrs Leesa Russell, Mr Barry Taylor, Ms Alice McCarthy and I have now been joined by Ms Joan Pettit, Dr Amber Parry-Strong, Mr Ewe Leong Lim and Ms Maakere Marr. Together NTB is in excellent shape to face the coming year.

My sincere thanks go to all staff of the HDEC Secretariat under the leadership of Nic Aagaard, for ensuring that their committees' function smoothly, despite the pandemic disruption. I am particularly thankful for the expertise of Mrs Russell and Dr Waaka for undertaking the reviews of expedited applications, amendments, and protocol deviations with me. Across HDECs the volume of new health research needing ethical review is reduced by about 20% under last year's hectic pace. This is the first time in a long time that HDECs have not experienced year-on-year growth. Additionally, investigators are reporting long delays in opening approved studies and slow recruitment. No doubt, the combination of winter, COVID-19 and staffing issues have pulled focus onto clinical duties, and it is hoped that the flow of research will increase to pre-pandemic volumes once the tumult is over.

The emergency operating procedure (ESOP) for a rapid review of COVID related research remained open throughout the year, and sincere thanks must go to the HDEC members from each of the 4 committees who have stepped up to this challenge. There have been only a few applications of this nature.

Our new ERM platform is performing very efficiently for both applicants and reviewers, and the reporting functions and flexibility it offers are appreciated. For example, new questions requiring researchers to consider what barriers disabled persons might have in accessing their research have been added to our application form – something that would have been difficult in the previous platform. Other improvements have been made too: the template PIS has been re-worked for gender neutral language, and guidelines for recruitment advertising have been issued.

The work needed to establish the Modernisation of Ethics project has been done, but some of the bigger issues concerning HDECs scope of review and potential committee restructuring has been prudently paused as we await the current unstable context (pandemic, restructure of the Health System) to settle. We have however identified a couple of areas for improvement that can be put into play as part of the general thrust of quality improvement. In particular, it may be possible to re-instate each HDEC having a Deputy Chair (non-lay) who could step in for the Chair for occasional absences, and who would have their assigned duties in expedited review and review of responses to Provisional Approval acknowledged as claimable hours. We understand that progress on the Therapeutics Products legislation - which will bring devices into a regulatory space and provide some legislative requirements for ethics review - is still being made.

Across all 4 HDECs, and in the context of our volumes trending downwards, it is noted that the ratio of commercially sponsored to investigator-initiated intervention research is 2:1. Nearly 70% of all intervention trials of medicines and devices are done by 10

organisations, while over 40% of commercial trials (most of which are international) are in the hands of just 2 (highly effective) organisations. Taken together, these statistics may represent the fact that funding for investigator-led and New Zealand focused studies is lagging, and research expertise is clustered within a handful of institutions.

I remain confident that Northern B HDEC can continue to do its important work of assessing whether health and disability research meets the ethical standards expected.

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	0
No. of applications approved subject to conditions (minor, non-standard conditions)	23
No. of applications deferred and subsequently approved (provisionally approved before approval)	72
No. of applications deferred as at time of report (provisionally approved)	1
No. of applications that were declined in part because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu	2
No. of applications that were declined in part 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/whanau/iwi/hapu/cultural group)	16
No. of applications which were invalidated for incompleteness	0
<i>No. of applications which do not require ethics committee approval (applications submitted to all Committees that were out of scope (total across Committees)) Note: this number is greatly increased from prior reports due to the new Ethics Review Manager automatic scope check process</i>	382
No. of studies withdrawn by researcher (none made to meetings or reviewed)	3
No. of studies terminated by sponsor	0
No. of studies transferred to another EC	0
Total number of applications received by full EC	117

Summary of applications received under expedited / low risk review

No. of applications approved	2
No. of applications approved subject to conditions	15
No. of applications deferred and subsequently approved	36
No. of applications deferred as at time of report	0
No. of applications which do not require ethics committee approval (applications submitted to Committee that were incomplete or out of scope)	0
<i>No. of applications referred for full committee review</i>	6
No. of applications declined	10
No. of studies withdrawn by researcher	0
Total number of applications received under expedited / low risk review	63

Total number of applications received:

180

Complaints and overdue application summary

This section outlines complaints about decisions made by the Committee during 2022.

Complaints received

Complaint one

Type of complaint: Breach of Ethical Standards

Review date: Resolved 07 April 2022

Complaint received: 18 March 2022

Nature of complaint:

The Secretariat received a complaint from a researcher not involved with the study regarding advertising they had received for a study approved by Northern B. They complained that the ethics reference was withheld and difficult to obtain from the researchers and found the advertisements to not be in line with the national ethical standards. Further, from the details in the advertisement it was difficult to ascertain which study the advertisement referred to due to a 'nickname' being used to label the study and the HDEC Secretariat needed to contact the clinical trials group for the ethics reference directly.

Actions taken:

This was escalated to the Chair of Northern B for discussion of whether this was still in line with the national ethical standards.

The clinical trials group running the study were advised to please ensure any 'nickname' they wish to label their study is included somewhere in their HDEC submission in future so the Secretariat may easily identify the study.

Outcome:

After investigation and further discussion with members, Northern B were comfortable this study still remained within the standards, however, they noted that for clinical trials, they wished to see final drafts of advertisements to ensure what is approved is actually what is being presented to potential participants, as in this case they did not match up with the drafts the Committee had approved. The clinical trials group of the study were advised of the complaint received and were cautioned around how difficult it was to obtain the ethics reference for this study for members of the public and the HDECs alike. They were also informed that the Committee did not find that they had breached the standards in this instance but were cautioned that using advertisements which are different from the version approved by the committee risks breaching the standards. The complainant was advised of the decision and feedback provided to the group. In addition, [guidance around advertising for clinical trials](#) were formulated and uploaded to the website after discussion of this for consistency at a Chairs day meeting. The complainant was advised of the outcome.

Complaint two

Type of complaint: Privacy issue

Review date: Resolved 30 March 2022

Complaint received: March 2022

Nature of complaint:

A complaint was received relating to a study under the COVID-19 review pathway (that sits under Northern B) of a concern of how people who were previously confirmed cases were contacted by the Ministry of Health about a COVID-19 survey and were concerned that the list could be used by the Ministry for a variety of reasons and were

not aware if the Ministry kept records of those with other diseases. It was clear as part of the ethical discussion that the researchers of the study would not be aware who was contacted regarding this survey and the Ministry likewise would be unaware of who elected to participate.

Actions taken:

This was escalated to the Chair and approving Committee, who requested the PI be advised that an objection was raised to this form of recruitment. An amendment for this study was under review at the time the complaint was received. The amendment was to extend the ethical approval for an additional round of text messaging. The amendment was Provisionally Approved, with conditions around improving the information in the recruitment text message. The Committee noted the researchers must reword the text message to include reassurance regarding privacy. They were also asked to include information in their protocol on how to handle or mitigate the risk of potential persons feeling harassed or concerned about their privacy so the Committee can be assured the researchers have appropriate responses in place.

Outcome:

The complainant was advised of the recruitment process, the ethical considerations in allowing it and of the change to the text notification in light of their concern and were advised to contact the Ministry directly with any concerns regarding their information being held as a past confirmed case.

The response from the PI regarding this under the amendment was later provided and approved to the Committee.

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 26 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 41 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 both review pathways, the clock days went over. This appears to be primarily due to the changeover of review system the HDECs were using partway through the reporting period, causing delays as a result of committee members, secretariat and researchers becoming more familiar with the system and able to respond in a timely manner.

It should be noted that Northern B were also delegated responsibility of monitoring the applications assigned under the COVID-19 review pathway as per the [emergency SOP](#). These applications have been factored into the total and review times for Northern B.

Appendix 1: Details of applications reviewed¹

Applications reviewed by full committee

Review reference	Project title	Coordinating investigator	Review date received	Review status	Coordinating investigator organisation	Sponsor organisation
21/NTB/190	(duplicate) Non-Invasive Ventilation Mask Assessment	Dr Robert Martynoga	6/07/2021 14:38	Approved	Waikato DHB	Fisher & Paykel Healthcare
21/NTB/228	(duplicate) Safety and Effectiveness of Eye90 Microspheres _® in the Treatment of HCC and mCRC	Associate Professor Andrew Holden	12/08/2021	Approved	Auckland District Health Board	ABK Medical Inc.
21/NTB/213	(duplicate) Use of a smart-phone based portable fundus camera in a rural General Practice	Dr Scott Davidson	2/08/2021	Approved	Dargaville Medical Center	oDocs Eye Care Ltd
21/NTB/218	006 Efficacy study of GSK [€] ™s investigational respiratory syncytial virus (RSV) vaccine in adults aged 60 years and above.	Dr Dean Quinn	5/08/2021	Approved	P3 Research	PPD
21/NTB/225	A Biosimilar Study to Compare BP11 with EU-Xolair [®] and US-Xolair [®] in Healthy Males	Dr Leanne Barnett	10/08/2021	Approved	NZCR	Syneos Health
2022 EXP 11909	A pathway to care for New Zealand military Veterans experiencing pain and distress.	Associate Professor David McBride	19/04/2022 12:11	Declined	University of Otago	University of Otago
2022 FULL 12364	A Phase 1 study of BGB-24714 a Second Mitochondrial-derived Activator of Caspases Mimetic (Smac) as Monotherapy & Chemotherapy combo in participants with advanced or metastatic solid tumours	Dr Sanjeev Deva	14/04/2022 15:53	Approved	Auckland District Health Board	BeGene NZ Unlimited
2021 FULL 11288	A Phase 2 Open-Label Extension Study of Belcesiran in Patients with AATLD	Professor Edward Gane	13/10/2021 11:39	Approved	New Zealand Clinical Research and Auckland City Hospital (ADHB)	Medpace Australia Pty Ltd, Dicerna Pharmaceuticals, Inc., CARSL Consulting
2022 FULL 11744	A Randomized, Double Blind, Placebo-Controlled study to Evaluate	Dr Anthony Jordan	3/06/2022 15:22	Approved	Auckland City Hospital	KalVista Pharmaceuticals Ltd, PPD

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

	the Efficacy and Safety of two dose levels of KVD900 for treatment of Angioedema Attacks type I or II.					
21/NTB/188	A self-compassion chatbot for adolescents with T1D	Dr Anna Serlachius	5/07/2021 11:42	Approved	The University of Auckland	The University of Auckland
2022 FULL 12800	A study into the effects of a booster dose of an mRNA COVID-19 vaccine	Dr. Richard Stubbs	8/06/2022 12:17	Approved	P3 Research Ltd	Wuhan Recogen Biotechnology Co., Ltd , Pharmaceutical Solutions
2021 FULL 11341	A study of a weekly injection compared to a once daily injection for the treatment of obesity	Doctor Michael Williams	30/11/2021 16:10	Approved	Lakeland Clinical Trials	Sciwind Biosciences APAC CO Pty. Ltd., Novotech (New Zealand) Limited
21/NTB/187	A validation of placental pathology reports in New Zealand.	Miss Esti de Graaff	2/07/2021 20:09	Approved	University of Auckland	University of Auckland
2022 FULL 12325	ABI-H3733-102: A Study of ABI-H3733 in Participants with Chronic Hepatitis B Virus Infection	Prof. Edward Gane	21/04/2022 15:15	Approved	New Zealand Clinical Research Ltd	Assembly Biosciences, Inc., PPD Global Limited
2022 FULL 11761	ADELE: Adjuvant tislelizumab plus chemotherapy in high risk endometrial cancer	Dr Michelle Wilson	20/04/2022 20:51	Approved	Auckland District Health Board, University of Sydney	Auckland District Health Board, University of Sydney
21/NTB/185	AHSCT NZMS	Dr Zoe Dyer	1/07/2021	Approved	ADHB	ADHB
2022 EXP 11933	ALEXA	Mrs Elizabeth Thatcher	16/03/2022 13:08	Declined	Waitemata District Health Board	Waitemata District Health Board
2022 FULL 11578	Alliance Glenoid Post-market study	Dr Marc Hirner	27/04/2022 17:07	Approved	Northland District Health Board	ZB
2022 FULL 12045	An Aotearoa New Zealand Diet for Metabolic Health and Whā• nau Wellbeing: He Rourou Whai Painga	Professor Jeremy Krebs	12/05/2022 18:19	Approved	University of Otago	University of Otago
2022 FULL 12272	AROPOC3-2003: An Extension Study to Investigate the Clinical Effectiveness and Safety of ARO-APOC3 in Adults with Dyslipidemia	Dr. John Baker	21/04/2022 7:57	Approved	Middlemore Clinical Trials	Arrowhead Pharmaceuticals, IQVIA RDS Pty. Limited,
2021 FULL 11459	AROC3-1001: A Study of ARO-C3 in Healthy Adults and in Adults with Paroxysmal Nocturnal Haemoglobinuria and Adults with Complement-Mediated Renal Disease	Doctor Mark Marshall	18/10/2021 14:24	Approved	New Zealand Clinical Research Ltd	Arrowhead Pharmaceuticals, Inc., Novotech (New Zealand) Limited
2022 FULL 12332	ARORAGE-1001: A Study to Evaluate ARO-RAGE Inhalation Solution in Healthy Participants and in Patients with Asthma	Dr. Mark O'Carroll	29/04/2022 13:41	Approved	New Zealand Clinical Research Ltd	Arrowhead Pharmaceuticals, Inc., Novotech (New Zealand) Limited
2022 FULL 11946	Artificial Intelligence to improve polyp detection at colonoscopy	Doctor Cameron Schauer	15/05/2022 15:24	Approved	Waitemata District Health Board, Olympus Corporation	Waitemata District Health Board, Olympus Corporation

2022 FULL 11392	ASCiminib Evaluation in Newly Diagnosed CML: the ASCEND-CML13 study	Dr Alwyn D'Souza	24/03/2022 12:00	Approved	Capital and Coast District Health Board	Australasian Leukaemia and Lymphoma Group
2022 EXP 11350	Assessing Parkinson's disease using Artificial Intelligence (AI)	Prof. Tim Anderson	25/05/2022 11:46	Approved	New Zealand Brain Research Institute	New Zealand Brain Research Institute
2022 EXP 12261	Assessment of colonisation of dairy free probiotic bacterium Streptococcus salivarius from lozenges to the oral cavity.	Professor Emeritus John Tagg	5/04/2022 14:54	Approved	Blis Technologies Ltd	Blis Technologies Ltd
2021 FULL 11242	ATB1651-101: A Study to Assess ATB1651 in Adults with Mild to Moderate Onychomycosis	Doctor Chris Wynne	20/09/2021 13:00	Approved	New Zealand Clinical Research	AmtixBio Co., Ltd, Novotech (New Zealand) Limited
2021 FULL 11061	Australia and New Zealand Fragility Fracture Registry	Dr Roger Harris	20/10/2021 16:03	Declined	Osteoporosis New Zealand	Accident Compensation Corporation
2022 EXP 11692	Barriers to engagement in chronic pain services	Ms Jill Collier	4/03/2022 15:04	Approved	Waitemata District Health Board	Waitemata District Health Board
21/NTB/189	BGB-11417-105 in Combination With Dexamethasone and Carfilzomib/Dexamethasone in Patients With Relapsed/Refractory Multiple Myeloma	Dr Rajeev Rajagopal	7/07/2021 14:31	Approved	Middlemore Clinical Trials	BeiGene NZ, Ltd.
2021 EXP 11357	Blackcurrant and immune response study	Dr Kerry Bentley-Hewitt	18/11/2021 14:44	Approved	The New Zealand Institute for Plant and Food Research	The New Zealand Institute for Plant and Food Research
21/NTB/183	Cerebral Palsy Respiratory Project	Professor Susan N Stott	5/07/2021 9:02	Declined	Auckland District Health Board	
21/NTB/230	Cognitive difficulties in OST service users	Miss Tara Hayward	13/08/2021	Approved	University of Otago	University of Otago
2022 FULL 12856	Comparison of two melatonin formulations under fasting conditions	Dr Noelyn Hung	23/06/2022 14:59	Approved	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd
2022 FULL 12859	Comparison of two melatonin formulations under fed conditions	Dr Noelyn Hung	23/06/2022 15:27	Approved	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd
2022 FULL 12860	Comparison of two melatonin tablets taken for 5 consecutive days each.	Dr Noelyn Hung	23/06/2022 15:28	Approved	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd
2022 FULL 11779	Comparison of two melatonin tablets under fasting conditions and at steady state.	Dr Noelyn Hung	9/02/2022 16:01	Approved	Zenith Technology Corporation Limited	Neo Health (OTC) Pty Ltd
2022 FULL 11445	Comparison of two melatonin tablets under fasting conditions.	Dr Noelyn Hung	9/02/2022 15:58	Approved	Zenith Technology Corporation Limited	Neo Health (OTC) Pty Ltd
2022 FULL 11772	Comparison of two melatonin tablets under fed conditions	Dr Noelyn Hung	9/02/2022 16:00	Approved	Zenith Technology Corporation Limited	Neo Health (OTC) Pty Ltd.

2021 FULL 11796	Continuous glucose monitoring in patients with type 1 and 2 diabetes	A/Prof Benjamin Wheeler	5/12/2021 19:35	Approved	University of Otago	i-SENS Inc.
2022 FULL 12434	Disability, home and family in a multicultural context	Associate Professor Brigit Mirfin-Veitch	18/05/2022 13:41	Approved	Donald Beasley Institute	Jubilee Trust
2021 FULL 11177	DPX-Survivac in R/R DLBCL	Dr Sophie Leitch	30/11/2021 10:41	Approved	North Shore Hospital	IMV Inc., Precision for Medicine (Aust) Pty Ltd (Clinical Research Organisation), Calyx Bioconsulting Ltd
2022 FULL 11830	DR10624-101: A Study to Evaluate Single and Multiple Ascending Doses of DR10624	Principal Investigator Alexandra Cole	14/03/2022 10:58	Approved	New Zealand Clinical Research,	Zhejiang Doer Biologics Co., Ltd, PPD Global Limited, Grant Thornton New Zealand Limited
2022 FULL 11506	Dulaglutide and a low calorie diet in T2DM	Dr Carl Peters	25/03/2022 14:56	Approved	Waitemata DHB	Waitemata DHB
2022 FULL 11797	Duplicate Submission ANZFFR	Dr Roger Harris	14/01/2022 14:01	Approved	Osteoporosis New Zealand	Accident Compensation Corporation
2022 FULL 12798	DYNE101-DM1-201: A study looking at multiple doses of DYNE-101 in patients with Myotonic Dystrophy Type 1	Associate Professor Richard Roxburgh	25/05/2022 9:47	Approved	University of Auckland	Dyne Therapeutics, Inc, PPD, Part of Thermo Fisher Scientific
2022 FULL 12454	Dyspnoea and exercise intolerance in pulmonary arterial hypertension	Dr Michael Plunkett	9/05/2022 14:20	Approved	University of Auckland	University of Auckland
21/NTB/227	ECMT-154 for the Topical Treatment of Eczema	Dr Gabby Shortt	11/08/2021	Declined	MRINZ	Manuka Bioscience
2021 FULL 11027	EDP 938-201: A Study to Evaluate EDP 938 Regimens in Infants With RSV (RSVPEDs)	Dr. Thorsten Stanley	16/09/2021 13:47	Approved	Capital and Coast District Health Board	Enanta Pharmaceuticals, Inc., Pharmaceutical Research Associates New Zealand Limited
21/NTB/222	Evaluating method for determining lymphatic composition via central venous sampling.	Professor John Windsor	9/08/2021	Approved	University of Auckland	University of Auckland
2022 EXP 11253	Evaluating musculoskeletal response to local muscle vibration	Associate Professor Justin Fernandez	1/03/2022 19:47	Approved	University of Auckland	University of Auckland
2022 FULL 11788	Evolut, EXPAND TAVR II Pivotal Trial	Dr Sanjeevan Pasupati	13/04/2022 8:38	Approved	Waikato Hospital	Medtronic Inc., Medtronic New Zealand Limited
2022 EXP 12304	Examining how good artificial intelligence is in looking for fractures on an X-ray	Dr Jason Woon	28/04/2022 15:04	Declined	ADHB	ADHB
2021 EXP 11313	Exhaled Breath Analysis of Healthy People	Dr Jean Marshall	8/10/2021 12:50	Approved	Fisher & Paykel Healthcare	Fisher & Paykel Healthcare
2022 FULL 12519	Exploring Novel Non-Invasive Neuromodulation for Improving Cognitive Functioning.	Professor Dirk De Ridder	3/05/2022 6:56	Approved	University of Otago	University of Otago

2021 EXP 11075	Functional outcomes after transanal total mesorectal excision (TaTME).	Associate Professor Tim Eglinton	28/11/2021 20:47	Approved	University of Otago	University of Otago
2022 FULL 11603	GB5121-2101 Study for relapsed/refractory primary or secondary central nervous system lymphoma	Dr Samar Issa	10/03/2022 15:48	Approved	Middlemore Hospital	Gossamer Bio Services, Inc. on behalf of GB005, Inc., a wholly owned subsidiary of Gossamer Bio, Inc.
21/NTB/221	GBP510_003:(COVID-19) SK SARS-CoV-2 Vaccine	Dr Richard Stubbs	13/08/2021 11:38	Declined	P3 Research	Novotech (New Zealand) Limited
2021 EXP 11331	GLOW STUDY	Dr Amanda Lyver	19/10/2021 8:47	Declined	CDHB	Stanford University
2021 EXP 11497	Head and Neck cancer in Northern New Zealand	Professor Richard Douglas	17/11/2021 11:14	Approved	The University of Auckland	The University of Auckland
2022 EXP 11904	Hormone profiles and biomarkers in concussion in female athletes; A case series study	Miss Natalie Hardaker	26/03/2022 7:15	Approved	Auckland University of Technology	Auckland University of Technology
2022 EXP 11655	Hormones and concussion in females	Miss Natalie Hardaker	25/03/2022 16:56	Approved	Auckland University of Technology, AUT	Auckland University of Technology, AUT
2022 FULL 11696	HOVON 150 AML/ AMLSG 29-18	Dr Claire Hemmaway	18/05/2022 11:09	Approved	Auckland City Hospital	Australasian Leukaemia & Lymphoma Group
2021 EXP 11620	How does Opioid Substitution Treatment work?	Mr Oliver Birch	5/11/2021 17:47	Declined	The University of Auckland	The University of Auckland
2022 EXP 12194	How Does Opioid Substitution Treatment Work?	Mr Oliver Birch	21/03/2022 10:56	Approved	The University of Auckland	The University of Auckland
2021 FULL 11028	Hyperbaric Oxygen Therapy South Pacific Utilisation Registry (HOTSPUR)	Dr Greg van der Hulst	16/12/2021 12:02	Approved	Canterbury District Health Board	Canterbury District Health Board
2022 EXP 11360	Identification of the effects of methamphetamine using MRI scans	Associate Professor Miriam Scadeng	21/02/2022 14:08	Approved	University of Auckland	Mātai Medical Research Institute
2022 EXP 11704	Immune and bacterial interactions in Inflammatory Bowel Diseases	Prof Michael Schultz	13/05/2022 15:20	Approved	University of Otago	University of Otago
21/NTB/224	Immunity and Molecular signatures of COVID-19	Dr Anna Brooks	16/08/2021 16:26	Declined	University of Auckland	
2021 EXP 11167	Impacts of COVID-19 in Aotearoa Ngā Kawekawe o Mate Korona	Dr Mona Jeffreys	1/11/2021 14:01	Declined	Te Herenga Waka Victoria University of Wellington	Te Herenga Waka Victoria University of Wellington
2022 EXP 11794	Investigating visual hallucinations in Parkinson's disease	Dr Kyla-Louise Horne	26/04/2022 17:00	Approved	New Zealand Brain Research Institute	New Zealand Brain Research Institute
2022 EXP 11182	Is invasive bladder examination required before surgery for bowel-bladder fistulas?	Dr. Aakaash Patel	20/01/2022 19:18	Approved	Waikato DHB	Waikato DHB

2022 FULL 11717	Ketamine assisted group mindfulness for alcohol use disorder	Dr Charlotte Mentzel	15/03/2022 21:41	Approved	Otago University	Otago University
2022 EXP 12505	Ketone monoester supplementation in individuals with fatty liver	Professor Max Petrov	23/05/2022 14:48	Approved	University of Auckland	University of Auckland
2022 EXP 12938	Ketone monoester supplementation in individuals with fatty pancreas	Professor Max Petrov	3/06/2022 8:26	Approved	University of Auckland	University of Auckland
2022 EXP 11632	Lactose as an Alternative Carbohydrate in Sports Food in Male Athletes	Professor David Rowlands	4/02/2022 14:32	Approved	Massey University	Massey University
2022 FULL 11230	LONG-TERM SAFETY AND TOLERABILITY OF REN001 IN SUBJECTS WITH PRIMARY MITOCHONDRIAL MYOPATHY (PMM)	A/Prof Richard Roxburgh	15/02/2022 11:46	Approved	University of Auckland	Reneo Pharma Ltd., Adjutor Healthcare (NZ) Limited
2022 EXP 12155	Managing constipation in Parkinson€™s using self-care techniques.	Miss Bronwyn Alexander	9/04/2022 21:21	Approved	WDHB	Te Herenga Waka – Victoria University of Wellington
2021 FULL 11413	Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study	Dr Hannah Jones	20/10/2021 16:33	Declined	Starship Child Health	Starship Child Health
2022 FULL 11776	Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) study	Dr Hannah Jones	21/01/2022 16:44	Approved	Starship Child Health	Starship Child Health
2021 FULL 11520	MB05-A-01-21: A Study to Compare MB05, EU-Sourced Synagis®, and US-Sourced Synagis® in Healthy Participants	Doctor Leanne Barnett	15/11/2021 8:20	Approved	New Zealand Clinical Research	mAbxience Research S.L., Infinity Consulting Ltd.
2021 FULL 10979	MK-1654-007: RSV Palivizumab-Controlled Evaluation of Safety, Efficacy, and Pharmacokinetics of MK-1654 in Infants and Children at Increased Risk for Severe RSV Disease	Dr Michael Meyer	17/09/2021 15:29	Declined	Middlemore Hospital, Middlemore Clinical Trials	Merck Sharp & Dohme (Australia) Pty Limited, Merck Sharp & Dohme (Australia) Pty Limited Authorising on behalf of NZ Sponsor Merck Sharp & Dohme (New Zealand) Ltd, 123 Carlton Gore Rd, Auckland
2022 FULL 11721	MK-1654-007: The Evaluation of Safety and Efficacy of MK-1654 in Infants and Children at Increased Risk for Severe RSV Disease	Dr Michael Meyer	29/01/2022 19:20	Approved	Middlemore Hospital, Middlemore Clinical Trials	Merck Sharp & Dohme (Australia) Pty Limited, Merck Sharp & Dohme (Australia) Pty Limited Authorising on behalf of NZ Sponsor Merck Sharp & Dohme (New Zealand) Ltd
2022 FULL 12611	MK-3475-C93: Phase 3 study of pembrolizumab versus chemotherapy in dMMR advanced or recurrent endometrial cancer	Dr Michelle Wilson	19/05/2022 12:07	Approved	Auckland City Hospital	Merck Sharpe & Dohme (MSD)

2022 EXP 12268	'Monty's Surprise' apple Bioavailability study	Miss Linda Nezbedova	30/06/2022 11:21	Approved	Massey University	TE OHU RANGAHAU KAI- AgResearch and the Riddet Institute
2022 FULL 11930	My Experiences, My Rights: Supports and Services	Associate Professor Brigit Mirfin-Veitch	25/03/2022 17:13	Approved	Donald Beasley Institute	Disabled People's Organisation Coalition
2021 EXP 11017	Natural history of young onset dementia	Dr Etuini Ma'u	3/11/2021 12:14	Approved	University of Auckland	University of Auckland
2021 EXP 11454	Navigating Assisted Dying	Dr Jessica Young	15/11/2021 14:30	Approved	Victoria University of Wellington	Victoria University of Wellington
2021 FULL 11035	Needle-free blood sampling enhanced by suction for blood glucose measurement	Professor Andrew Taberner	30/11/2021 11:59	Approved	The University of Auckland	The University of Auckland
21/NTB/235	New Zealand Pregnancy Cohort and Baby Cohort annual updates	Dr Sarah Donald	9/08/2021	Approved	University of Otago	University of Otago
2021 FULL 11508	NIV Algorithm study	Dr Louis Kirton	2/12/2021 15:36	Approved	Medical Research Institute of New Zealand	Fisher & Paykel Healthcare
2021 EXP 11724	Non-hospice experiences of people with cancer	Dr Jessica Young	11/11/2021 9:08	Approved	Victoria University of Wellington	Victoria University of Wellington
2022 EXP 12080	NZ resident Samoan health and illness beliefs about cough and access to healthcare	Dr Sarah Mooney	13/02/2022 13:07	Approved	Counties Manukau Health	Thoracic Society of Australia and New Zealand
2022 EXP 12344	Odontogenic Deep Neck Space Infection - Retrospective analysis of microbial cultures and sensitivities	Dr Ruby Richardson	20/05/2022 9:11	Approved	Auckland DHB	Auckland DHB
21/NTB/214	Optimising the oral cavity and intra-nasal delivery of probiotic bacteria	Professor John R. Tagg	3/08/2021	Declined	Blis Technologies Ltd	Blis Technologies Ltd
2022 FULL 11205	Optimize Pro	Doctor Mark Webster	11/02/2022 14:15	Declined	Auckland District Health Board	Medtronic NZ Limited
21/NTB/212	Orbis QIC Test Sensitivity and Specificity Study	Dr Api Talemaitoga	28/07/2021	Approved	Southern Clinical Trials Manukau	Orbis Diagnostics Limited
21/NTB/265	Outcome of childhood head trauma	Dr Patrick Kelly	20/08/2021	Approved	Auckland District Health Board	Auckland District Health Board
2022 FULL 11876	Participate-CP: Helping kids with cerebral palsy to be more physically active through doing sports and leisure	Dr Sian Williams	4/04/2022 17:33	Approved	University of Auckland	Child Health Research Centre, University of Queensland
2022 EXP 12181	Patient adherence to Hymenoptera venom immunotherapy	Dr. Lydia (Hoi Kei) Chan	17/02/2022 16:32	Approved	Auckland District Health Board	Auckland District Health Board

21/NTB/217	Patients with Type 1 Diabetes Using Hybrid Closed Loop System and Control at Home	Dr Martin de Bock	4/08/2021	Approved	University of Otago	Medtronic New Zealand Limited
21/NTB/196	PBI-0451-0001 (COVID-19): A Study to Evaluate PBI-0451 in Healthy Adults	Dr. Mark Marshall	20/07/2021 10:45	Approved	Auckland Clinical Studies	Novotech (New Zealand) Limited
2022 EXP 11425	Pelvic floor muscle contraction during routine pregnancy ultrasound	Dr Siyan Ma	16/03/2022 18:19	Approved	Counties Manukau District Health Board	Counties Manukau District Health Board
2021 FULL 11770	Phase 1 study of safety and efficacy of INS018_055 with placebo in healthy volunteers	Principal Investigator Dr Chris Wynne	18/11/2021 14:07	Approved	New Zealand Clinical Research	Insilico Medicine Hong Kong Limited, PPD
2021 FULL 11371	Phase 1 Trial of MK-1084 Alone or as Combination with Pembrolizumab for Advance Solid Tumors	Dr. Rajiv Kumar	19/10/2021 16:08	Approved	New Zealand Clinical Research	Merck Sharp & Dohme (Australia) Pty Limited, Merck Sharp & Dohme (Australia) Pty Limited Authorising on behalf of NZ Sponsor Merck Sharp & Dohme (New Zealand) Ltd
21/NTB/232	Physical activity to decrease fatigue after GBS	Dr Suzie Mudge	18/08/2021	Approved	AUT	AUT
21/NTB/194	PILOT STUDY OF KETAMINE IN PSYCHOGENIC NON-EPILEPTIC SEIZURES	Dr Charlotte Mentzel	9/07/2021 15:00	Approved	University of Otago	University of Otago
2022 EXP 12353	Pilot study: health outcomes of targeted career interventions in unemployed or underemployed Māori patients	Dr Michael Oehley	19/05/2022 12:20	Approved	Raukura Hauora o Tainui	Raukura Hauora o Tainui
2022 EXP 11891	Pituitary tumour study	Dr Marianne Elston	9/03/2022 15:00	Declined	Waikato District Health Board	Waikato District Health Board
2021 FULL 11785	Placebo-controlled study to evaluate the efficacy of mRNA-1345 vaccine.	Dr Michael Williams	13/12/2021 9:06	Declined	Lakeland Clinical Trials	ModernaTX, Inc., PPD Global Limited
2021 FULL 11469	Plant diversity, microbiota and childhood allergies	Professor Jeroen Douwes	3/12/2021 15:50	Approved	Massey University	Massey University
2022 EXP 12221	Prevalence of Biochemical Severe Vitamin D Deficiency in Auckland: linkage study	Dr Mark Bolland	10/02/2022 13:13	Approved	University of Auckland	University of Auckland
2021 EXP 11870	PRIME	Prof. Valery Feigin	6/12/2021 10:38	Declined	AUT University	AUT University
2022 EXP 11927	Probiotic colonisation study	Professor Emeritus John Tagg	5/04/2022 14:47	Approved	Blis Technologies Ltd	Blis Technologies Ltd
2022 EXP 12235	Probiotic colonisation study using Fast melts powder	Professor Emeritus John Tagg	5/04/2022 14:51	Approved	Blis Technologies Ltd	Blis Technologies Ltd
2021 FULL 11130	PRP versus corticosteroid RCT	Dr Jordan Davis	16/09/2021 14:56	Declined	Orthosports	Orthosports

2021 FULL 11531	Psychological Trauma in the Community	Dr Jeremy Baker	14/12/2021 18:24	Declined	University of Aberdeen	University of Aberdeen
2022 EXP 11845	Quantitative sleep and physical activity in older adults with early cognitive changes: a pilot study	Dr Sarah Buchanan	8/03/2022 14:55	Approved	University of Otago	University of Otago
2022 EXP 11989	Retrospective cohort study investigating the influence of anaesthetic technique on breast cancer recurrence.	Dr Marta Seretny	16/02/2022 15:51	Approved	Auckland District Health Board	Auckland District Health Board
2021 EXP 11522	ROPAC	Dr Chethan Kasargod	16/11/2021 11:12	Declined	Auckland District Health Board	EURObservational Research Programme, European Society of Cardiology
2022 FULL 11076	Sensitized Points Acupuncture for Chronic Low Back Pain: A Feasibility Study	Ms. Huijuan Tan	2/02/2022 19:19	Approved	University of Otago	University of Otago
21/NTB/226	Shapematch 10 year follow up study	Mr Simon Young	6/08/2021 13:41	Approved	Waitemata DHB, University of Auckland	Waitemata DHB
2022 EXP 12168	Shared decision making in cancer care	Dr Karol Czuba	5/04/2022 19:22	Approved	WeCare Health	Precision Driven Health
2022 EXP 12121	Skin to deltoid muscle distance at three recommended injection sites	Professor Richard Beasley	14/02/2022 16:49	Approved	Medical Research Institute of New Zealand	Medical Research Institute of New Zealand
2022 FULL 11124	SPICE IV: Early Sedation with Dexmedetomidine vs. Placebo in Older Ventilated Critically Ill Patients	Dr Colin McArthur	12/06/2022 11:44	Approved	Auckland District Health Board	Medical Research Institute of New Zealand, Monash University
21/NTB/191	Stand Strong, Walk Tall - Pilot	Dr Sarah Christofferson	2/07/2021 15:34	Declined	University of Canterbury	
2022 EXP 11998	Stand Strong, Walk Tall - Pilot	Senior Lecturer Sarah Christofferson	7/04/2022 17:12	Approved	University of Canterbury	University of Canterbury
2021 FULL 11163	Standalone Stents as Second-Stage Surgery Study	Dr Jesse Gale	13/12/2021 13:02	Approved	University of Otago	University of Otago
2022 FULL 11764	STERoid versus PRP Injection For Frozen shoulder - STIFF Trial	Dr Jordan Davis	17/05/2022 13:35	Approved	Orthosports	Orthosports
21/NTB/193	Study of efficacy and safety of MIJ821 in addition to comprehensive standard of care on the rapid reduction of symptoms of Major Depressive Disorder in subjects who have suicidal ideation with intent	Assoc Prof SW Miles	14/07/2021 9:00	Approved	Awhina Research WDHB	Novartis Pharmaceuticals Australia Pty Limited

2022 EXP 11640	Supportive care needs in prostate cancer (SUPPRO)	Professor David Baxter	3/02/2022 20:24	Approved	University of Otago	University of Otago
2021 EXP 11208	Surveillance post-intra-vessel surgery, following blunt force trauma damage to the thoracic aorta (large artery in chest)	Miss Hannah Kim	23/10/2021 14:59	Declined	University of Auckland / Auckland City Hospital	Auckland DHB
2021 FULL 11097	TARGET Protein	Dr Paul Young	23/11/2021 13:42	Approved	Capital Coast District Health Board	MRINZ, Central Adelaide Local Health Network (CALHN)
21/NTB/223	Telehealth-delivered health-promoting interventions for autistic children	A/Prof. Laurie McLay	10/08/2021	Approved	University of Canterbury	University of Canterbury
21/NTB/220	The C-CAT Study	Professor Cindy Farquhar	4/08/2021	Approved	University of Auckland	University of Auckland
2021 FULL 11036	The Cost of MND in Aotearoa New Zealand	Dr Alan Stanley	1/12/2021 10:02	Approved	HBDHB	MND New Zealand
2021 EXP 11304	The determinants of wound healing following minor amputation in patients with established diabetes.	Ms Islay Dickie	13/12/2021 22:51	Approved	Auckland City Hospital	Auckland City Hospital
2021 FULL 10950	The Early & Intensive SCI-MT Trial	Dr Joanne Nunnerley	17/11/2021 12:36	Approved	Canterbury District Health Board Board	University of Sydney
2022 EXP 10995	The effect of appetite suppressant treatment on hunger and rebound eating in fasting women	Dr Edward Walker	5/01/2022 17:53	Approved	The New Zealand Institute for Plant and Food Research	The New Zealand Institute for Plant and Food Research
2021 EXP 11576	The effect of supplementation with a blackcurrant drink containing L-theanine and pine bark extract in supporting cognitive performance.	Dr Dominic Lomiwes	23/11/2021 21:33	Approved	The New Zealand Institute of Plant and Food Research Ltd	The New Zealand Institute of Plant and Food Research Ltd
2021 EXP 11086	The effects of cognition on airway protection in neurological disease	Dr. Sarah Perry	17/12/2021 15:54	Approved	New Zealand Brain Research Institute/University of Otago	
2022 EXP 12054	The experience of LongCOVID in Waitemata DHB	Dr Rosie Dobson	12/01/2022 10:24	Approved	University of Auckland	University of Auckland
2022 FULL 12669	The First Responder Shock Trial (FIRST)	Associate Professor Bridget Dicker	19/04/2022 16:58	Declined	St John	St John
2021 EXP 11496	The Herekorenga - Freedom study	Dr Natasha Gordon	21/10/2021 10:02	Declined	Pictor Ltd	Pictor Ltd
21/NTB/234	The Relationship Between Calcium Pyrophosphate Crystal Arthritis and the Requirement for Joint Replacement Surgery	Dr David Harris	18/08/2021	Approved	Waikato DHB	Anaesthetic Research, Waikato District Health Board.

2021 EXP 11693	The role of nutrition status on survival in children diagnosed with cancer in NZ	Dr Amy Lovell	8/11/2021 21:53	Approved	The University of Auckland	The University of Auckland
2021 EXP 11031	The role of the right atrium	Dr Jichao Zhao	18/10/2021 11:11	Declined	The University of Auckland	The University of Auckland
2022 EXP 11422	The use of Artificial Intelligence to Augment Primary Care in Oral and Maxillofacial Trauma. Part I: Detection of Mandibular Fractures using Plain Film Imaging.	Dr Michael Rutledge	13/01/2022 9:02	Approved	Waikato DHB	Curtin University, Waikato District Health Board
2022 EXP 12363	Three-dimensional models of breast cancer	Dr Emma Nolan	6/05/2022 16:25	Approved	University of Auckland	University of Auckland
21/NTB/233	Tinnitus SoundSupport feature trial	Dr Grant Searchfield	18/08/2021	Approved	The University of Auckland	Oticon
2022 FULL 12858	TLC 2716-CL-101: A Study to Evaluate Single and Multiple doses of TLC-2716 in Healthy Participants	Prof. Ed Gane	21/06/2022 17:23	Approved	New Zealand Clinical Research	The Liver Company, Ltd, Infinity Consulting Ltd (on behalf of Avance Clinical)
2022 FULL 12642	Triumeq in Amyotrophic Lateral Sclerosis (LIGHTHOUSE II)	Dr Alan Stanley	26/05/2022 8:52	Approved	Hawke's Bay District Health Board	Kings College London, Stichting TRICALS Foundation, Macquarie University
21/STH/232	Vericiguat Outcomes Study in HFREF	Professor Richard William Troughton	20/08/2021	Approved	Christchurch Heart Institute	MSD Australia
21/NTB/181	VLA2001-304: A study comparing two versions of an experimental vaccine against COVID-19	Dr Simon Carson	2/07/2021	Approved	Southern Clinical Trials Ltd	PharmaSols
2022 FULL 12215	Walk a mile in their shoes - Lived experience of FASD	Dr Joanna Chu	14/02/2022 11:50	Declined	University of Auckland	University of Auckland
2022 EXP 11739	What is it like living with early-onset Parkinson's disease?	Dr Christina Buchanan	17/03/2022 14:37	Approved	Auckland District Health Board	Auckland District Health Board
21/NTB/211	Whitia Kia Ora: Bridging the gaps	Dr Anneka Anderson	22/07/2021 15:26	Approved	University of Auckland	University of Auckland
2021 FULL 11468	WP43295: A study to assess RO7276389 alone or in combination with cobimetinib for advanced solid tumours or melanoma with brain involvement	Dr Catherine Han	23/11/2021 11:17	Approved	New Zealand Clinical Research	Roche Products (New Zealand) Limited
21/NTB/192	YS-009 (COVID-19): A Study of PIKA COVID-19 Vaccine in Healthy Adults	Dr. Chris Wynne	13/07/2021 15:50	Approved	Christchurch Clinical Studies Trust Ltd (CCST)	Novotech (New Zealand) Limited