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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 14 May 2024 |
| **Zoom details:** | https://mohnz.zoom.us/j/96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10:30 - 11:00am | 2024 FULL 19837 | MK-1084-004 | Dr Daisy Wing-San Mak | Maree / Nicola |
| 11:00 - 11:30am | 2024 FULL 19260 | ALLG NHL39 Polar Bear | Doctor Henry Ngu | Dianne / Amy |
| 11:30 - 12:00pm | 2024 FULL 19816 | MK-2870-010 with or without pembrolizumab in HR+/HER2- metastatic breast cancer | Dr. Soizick Mesnage | Devonie / Neta |
| 12:00 - 12:30pm | 2024 FULL 20075 | BerriQi-kids study | Dr Starin Mckeen | Dominic / Devonie |
| 12:30 - 1:00pm |  | **BREAK (30 mins)** |  |  |
| 1:00 - 1:30pm | 2024 FULL 20086 | 222090 RSV OA=ADJ-012 An extension/crossover vaccine study against respiratory syncytial virus given to adults 60 years of age and above who participated in 006 study. | Dr Mathanki Vivekananda | Dianne / Nicola |
| 1:30 - 2:00pm | 2024 FULL 20130 | Efficacy of a diagnostic device in Respiratory infection | Dr Tori Middlemiss | Dominic / Amy |
| 2:00 - 2:30pm | 2024 FULL 19646 | BIOMAG-II | Dr Jithendra Somaratne | Maree / Devonie |
| 2:30 - 3:00pm | 2024 FULL 18383 | Versa Vascular FHU | Professor Mark Webster | Nicola / Neta |
| 3:00 - 3:20pm |  | **BREAK (20 mins)** |  |  |
| 3:20 - 3:50pm | 2024 FULL 19945 | Liraglutide effect on BSGM | Dr Charlotte Daker | Maree / Nicola |
| 3:50 - 4:20pm | 2024 FULL 20324 | Uplifting the mana of Pacific young people (2) | Ms Rupi Riley | Amy / Neta |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Devonie Waaka  | Non-lay (Intervention studies)  | 18/07/2016  | 18/07/2019  | Present  |
| Mr Dominic Fitchett  | Lay (the Law) (Chair) | 05/07/2019  | 05/07/2022  | Present  |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Dr Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Apologies |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |

## Welcome

The Chair opened the meeting at 10:30am with a karakia and welcomed Committee members, noting that apologies had been received from Associate Professor Nicola Swain.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Patries Herst confirmed her eligibility and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 09 April 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 19837** |
|   | Title:  | A Phase 3, Randomized, Double-blind, Multicentre Study of MK-1084 in combination With Pembrolizumab Compared With Pembrolizumab Plus Placebo as First-line Treatment of Participants With KRAS G12C-Mutant, Metastatic NSCLC With PD-L1 TPS ≥50% |
|   | Principal Investigator:  | Dr Daisy Wing-San Mak |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Limited (MSD) |
|   | Clock Start Date:  | 02 May 2024 |

Dr Daisy Wing-San Mak was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee noted the survey involved questionnaires that ask about anxiety and depression and expressed concern that the PIS instructs participants to contact a member of the study staff. This requires participants to initiate the conversation and any experiencing depression or anxiety may internalise and not want to reach out. The Committee queried how the Researcher would respond to this. The Researcher confirmed the questionnaires would be completed on-site and clinicians would offer support at the time, ask how they are feeling and address any concerns at the visit.
2. The Committee advised therapeutic studies may not be terminated solely for commercial reasons.
3. The Committee advised translation certificates are not reviewed.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested ethnicity data based on StatsNZ ethnicity fields is collected at a site-level for final reporting to HDEC. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**Main PIS**

1. Please include a lay title.
2. Please move the line about an interpreter to the beginning of the sheet.
3. Please explain what biomarkers and assay validation are when they are first mentioned.
4. Please undertake a general revision to simplify or define technical/medical terms and use plain language where possible.
5. Please include how much reimbursement participants are entitled to.
6. Please include information on how long each visit is expected to take.
7. Please remove the final column in the table on page 7 as this contains notes primarily for doctors and nurses.

**Limited Screening PIS**

1. Please explain what assay validation and biomarkers are the first time they are referenced.
2. Please revise the use of information section to remove anything not relevant to the limited screening PIS (notifiable diseases, GP notification).

**Treatment beyond progression PIS**

1. Please include a lay title.
2. Please simplify the assessment table significantly, including every blood test is not necessary, and the sheet can simply say blood/urine tests will happen on the applicable visits.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please ensure good quality ethnicity data based on New Zealand census categories is collected at a site-level for final reporting to HDEC *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*

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| **2**   | **Ethics ref:**   | **2024 FULL 19260** |
|   | Title:  | R-MINI-CHOP versus R-MINI-CHP in combination with polatuzumab-vedotin, as primary treatment for patients with diffuse large B-cell lymphoma, ≥ 80 years, or frail ≥ 75 years - an open label randomized Nordic Lymphoma Group phase III trial |
|   | Principal Investigator:  | Dr Henry Ngu |
|   | Sponsor:  | Australasian Leukaemia and Lymphoma Group |
|   | Clock Start Date:  | 02 May 2024 |

Dr Henru Ngu, Ms Sophie Goodger and Ms Raisa Mathias were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Coordinating Investigator confirmed they have experience as a principal investigator and sub-investigator on other clinical studies.
2. The Researcher confirmed Roche would supply the study drug but not have any control over the dataset or publication. The Researcher confirmed Roche would not have access to the raw data.
3. The Researcher confirmed potential participants can discuss the study with the research team separate to their clinical provider.
4. The Researcher confirmed an auditor would have access to identifiable information on-site only.
5. The Researcher confirmed a fund existed at Auckland Hospital that could provide support to participants for travel costs for the study-specific visits.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested the Researcher supply an independent external peer review. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.29)
2. The Committee requested ethnicity data based on StatsNZ ethnicity fields is collected at a site-level for final reporting to HDEC. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*
3. The Committee noted a discrepancy between the application and information sheet on reviewing questionnaires. The application states questionnaires will be reviewed while the patient is on-site and the information sheet states the information will not be monitored during the study and participants should raise any concern themselves. Please address this and update the information sheet if required.
4. The Committee requested an update to section 9.1 of the data management to state some of the test results and dosing information generated in the study will become part of the patient’s clinical record and will not be able to be deleted. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17):*

**MAIN PISCF**

1. Please include information about any travel reimbursement.
2. Please remove “AIDS virus” when mentioning HIV.
3. Please insert the statement about letting study staff know if an interpreter is needed to the beginning of all information sheets.
4. Please amend Northern B HDEC to Southern HDEC.
5. Please remove any references to teaspoons of blood and state millilitres.
6. Please remove the duplicated information on identifiable data on page 15.
7. Please simplify the first pages to remove repeated information. Please simplify the ‘how is the study designed’ section.
8. Please remove repeated information on randomisation throughout the sheet.
9. Please include a statement explaining the mandatory exploratory research, state it will be research related to the current study and state whether it may involve genomic or genetic analysis. If it will not, please include a statement advising genes won’t be researched. If they will then please include an explanation of what this means.
10. Please limit optional research to a statement advising that information and consent for this will be sought on a separate sheet.
11. Please amend the reproductive risks sections heading to reference fathering a child rather than women of child-bearing potential and amend information in the section which mixes advice to men and women, as no one of child-bearing age will be participating.
12. Please remove the radiotherapy side effects section as these risks are not part of standard care rather than the study.
13. Please bullet point the lists of people with access to identifiable and coded information so it is easier to understand.
14. Please make it clear clinical information and test results will form part of the participant’s identifiable medical records
15. Please remove ‘with your consent’ from the GP notification statement as this should be a mandatory component of study participation.
16. Please delete repeated information on financial rights and commercial benefit on page 19.
17. Please include the city and country samples will be sent to.
18. Please clarify that karakia will not be available at the time of tissue destruction.
19. Please undertake a general proof-read for typos and formatting/font issues.

**OPTIONAL FUR PISCF**

1. Please explain whether future unspecified research may involve genetic or genomic research.
2. Please delete the paragraph about additional mandatory samples.
3. Please remove references to teaspoon blood volume measurements and state millilitres.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please supply an independent scientific peer review (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.29*)
4. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Dianne Glenn and Ms Amy Henry.

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| **3**   | **Ethics ref:**   | **2024 FULL 19816** |
|   | Title:  | An Open-label, Randomized Phase 3 Study of MK-2870 as a Single Agent and in Combination with Pembrolizumab Versus Treatment of Physician’s Choice in Participants with HR+/HER2- Unresectable Locally Advanced or Metastatic Breast Cancer |
|   | Principal Investigator:  | Dr. Soizick Mesnage |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Limited (MSD) |
|   | Clock Start Date:  | 02 May 2024 |

Dr. Soizick Mesnage, Dr Nel Peiris, Dr Meghan Mcilwain, Ms Sophie Goodger and Mr Rafael Souza were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee advised translation certificates are not reviewed.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee queried ongoing access to the drug post-trial completion and noted the National Ethical Standards state ongoing access should be provided in therapeutic studies if participants are receiving clinical benefit. The Researcher agreed to confirm with the Sponsor that the intervention would be continued until disease progression or toxicity. If ongoing access will not be provided and compassionate access will not be offered until the drug is registered in New Zealand this must be justified against the Standards. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.9; 10.15).*
2. The Committee requested ethnicity data based on StatsNZ ethnicity fields is collected at a site-level for final reporting to HDEC. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*
3. The Committee requested the comment in section 7.3 of the data and tissue management plan (DTMP) is removed. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).
4. The Committee requested blood samples are included in section 4 of the DTMP. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

**Main PIS**

1. Please explain what assay validation and biomarkers are on page 5.
2. Please undertake a general revision for typos, grammatical errors and white space.
3. Please make it clear the quality-of-life questionnaires will not be reviewed until the end of the study and not sighted by staff.
4. Please adapt the sheet for a New Zealand context (e.g. replace acetaminophen with paracetamol).
5. Please state how many people have received the investigational product to date, including how many people with breast cancer.
6. Please include a line advising participants they can request to see a table of the schedule of assessments.
7. Please clarify that karakia will not be available at the time of tissue destruction on page 5.
8. Please include the city and country samples will be sent to.

**Screening PIS**

1. Please explain what assay validation and biomarkers are.

**Limited Screening PIS**

1. Please explain what assay validation and biomarkers are the first time they are referenced.
2. Please review the use of information section and delete statements that are not applicable to the limited screening (eg GP notification, notifiable disease notification).

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka and Ms Neta Tomokino.

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| **4**  | **Ethics ref:**   | **2024 FULL 20075** |
|   | Title:  | BerriQi for post-respiratory infection recovery in primary school age kids in Motueka, NZ |
|   | Principal Investigator:  | Dr Starin Mckeen |
|   | Sponsor:  | Anagenix Ltd |
|   | Clock Start Date:  | 02 May 2024 |

Dr Starin Mckeen and Dr Aahana Shrestha were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researcher confirmed anthocyanidin levels have been independently measured and verified and showed 30% higher levels in New Zealand berries. The Researcher confirmed the tablets are standardised. The Committee suggested adding this information to the information sheet would be useful.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted the Sponsor had chosen not to submit an application to the Standing Committee on Therapeutic Trials (SCOTT) as suggested. The Committee noted the reasoning behind this decision was BerriQi is intended to be a food product and not a therapeutic agent. The Committee noted this is inconsistent with material on the BerriQi website which makes various therapeutic claims including preventing and repairing damage to lung tissue, taking deeper breaths, reducing collagen scarring in the lung and reducing wheeze, cough and phlegm. The Researcher stated the product was marketed to distributors and not consumers and distributors changed the marketing message. The Committee noted health claims cannot be based on preclinical studies and labwork alone and it is inappropriate to place the onus on distributors to correct. The Committee advised these claims can only be made once clinical trials in humans have been performed and the claims are proven. The Committee advised if the intention is to make therapeutic claims such as on the website then SCOTT review should be obtained [per therapeutic guidelines.](https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/overview-of-therapeutic-product-regulation.pdf)(*Guideline on the Regulation of Therapeutic Products in New Zealand*, *Section 2.1; 4.1.*2).
2. The Committee noted an insurance quote was supplied and advised a full certificate was required for approval. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1*).
3. The Committee noted some health information is required to be kept for 10 years once the youngest participant turns 16 and advised the researchers to check if this applies to any of the data that will be collected in the study. If this is the case please update the data management plan (DMP) and participant information sheet to state it will be kept for 10 years once the youngest participant turns 16.
4. The Committee noted a discrepancy between the data management plan and information sheet where the consent form allows data to be withdrawn but the DMP states data will continue to be analysed. Either way is acceptable, please address this for consistency.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

**MAIN FORM**

1. Please undertake a general revision to moderate language regarding benefit.
2. Please include the full compensation statement available from the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
3. Please address who will have access to identifiable information (school staff, research team, GP, auditors from HDEC etc); use of data for future research; the risk of privacy breach; and financial benefit rights. Wording for this may be found on the [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)

**ASSENT FORM**

1. Please replace 'we would like you to help us with our research....' with 'would you like to help us with our research...' to make it more friendly and child-centric.
2. Please delete the statement that no-one will be angry if the child decides not to take part as this cannot be guaranteed.
3. Please include a space for the child to select whether they want to take part, and to write their name if able. Space should also be provided for the researcher to write the child's full name, the name of the researcher conducting the assent discussion, and the date on which assent was obtained.

**VIDEO**

1. Please review this for language that could be simplified (e.g. replace 'participate' with 'take part' or 'be in the study' and replace 'anonymous' with 'private', 'hidden' or 'secret’).
2. Please review the line stating there is nothing like this on the market as there are other natural health products for similar purposes that make similar claims.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please supply evidence of ACC-equivalent insurance for the duration of the trial (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Devonie Waaka.

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| **5**   | **Ethics ref:**   | **2024 FULL 20086** |
|   | Title:  | A phase 3b, randomized, open label, multi-country, multi-center, extension and crossover vaccination study to evaluate the immunogenicity and safety of different revaccination schedules and persistence of a single dose of the RSVPreF3 OA vaccine in adults aged 60 years and above who participated in the RSV OA=ADJ-006 study |
|   | Principal Investigator:  | Dr Mathanki Vivekananda |
|   | Sponsor:  | GSK plc |
|   | Clock Start Date:  | 02 May 2024 |

Dr Mathanki Vivekananda, Ms Katie Kennett and Ms Karen Leskie were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried if parking and transport expenses would be reimbursed. The Researcher confirmed it would.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested ethnicity data based on StatsNZ ethnicity fields is collected at a site-level for final reporting to HDEC. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*
2. The Committee requested the Researcher update the data and tissue management plan (DTMP) to remove any references to a contract research organisation (CRO). Please also review section 8.5 of the DTMP and select one of the options. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*
3. The Committee requested copies of the industry guidelines be made available to participants who request them after reading the compensation paragraphs in the PISCF.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

**Main PIS**

1. The Committee suggested a briefer lay title.
2. The Committee advised providing payment for ‘time’ may make this taxable income and suggested rephrasing it so it is koha for participants’ participation
3. Please include more information on payments (how much and in what form) participants are entitled to.
4. Please define the LRTD acronym the first time it is used.
5. Please remove the paragraph regarding the Northern Hemisphere as this is not relevant to New Zealand.
6. Please include an acknowledgement of the risk of privacy breach.
7. Please review the statement about study staff or trusted third parties collecting further information about participants after withdrawal and include an option on the consent form for participants to decline this.
8. Please move the line about an interpreter to the beginning of the sheet.
9. Please review the response to C5 in the HDEC application form and include relevant information in the PIS if these services will be available.

**Caregiver PIS**

1. Please shorten the information regarding the trial, stating that in New Zealand only people who received placebo in study 006 will take part and will receive a single dose of the study vaccine.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

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| **6**   | **Ethics ref:**   | **2024 FULL 20130** |
|   | Title:  | Clinical Study of the Cue® Flu A + Flu B + COVID-19 + RSV Molecular Test |
|   | Principal Investigator:  | Dr Tori Middlemiss |
|   | Sponsor:  | IQVIA RDS Pty. Limited |
|   | Clock Start Date:  | 02 May 2024 |

This application was withdrawn.

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| **7**   | **Ethics ref:**   | **2024 FULL 19646** |
|   | Title:  | BIOTRONIK – Safety and Clinical Performance of the Drug Eluting Resorbable Coronary MAGnesium Scaffold System (Freesolve®) in the Treatment of Subjects with de Novo Lesions in Native Coronary Arteries:BIOMAG-II: A randomized controlled trial |
|   | Principal Investigator:  | Dr Jithendra Somaratne |
|   | Sponsor:  | BIOTRONIK Australia Pty Ltd |
|   | Clock Start Date:  | 02 May 2024 |

Ms Mandy Fish was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researcher confirmed all blood tests performed are done as standard of care.
2. The Committee advised for future submissions the risk sections should include an understanding of a summary of the risks in lay terms as would be explained to a participant.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Researcher agreed to confirm whether the composition of the data safety monitoring board (DSMB) was external or internal. The Committee advised external representation is expected in multinational drug trials and this would be its preference. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.27*).
2. The Committee requested the insurance certificate is amended to specify New Zealand as a covered territory (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1*).

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please include a lay title.
2. Please remove the line regarding articifical intelligence (AI) in the consent form or provide information in the body of the PIS if AI is intended to be used.
3. Please undertake a general revision to replace medical and scientific terms with lay language (eg efficacy, de novo, lesions).
4. Please replace the ethics approval statement on page 2 with the one available in the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)as HDEC only approves the ethical aspects of the study**.** Please amend Northern B to Southern.
5. Please revise the line describing randomisation as a toss of the coin as the chances to receive IMP vs standard of care is not 50/50.
6. Please include an indication of how long study-specific assessments are expected to take and how much longer it would take than standard care.
7. Please remove repeated descriptions of assessments.
8. Please bullet-point the risks and undertake a thorough review for lay language.
9. Please include the information from the protocol detailing the previous scaffolds and a warning on the potential risk of thrombosis.
10. Please include any recent data or risks from the study overseas.
11. Please include the risk of privacy breach.
12. Please amend the statement that data will be presented in an anonymous form; it can only be deidentified due to not being collected anonymously.
13. Please use consistency when referring to pseudonymised, deidentified and coded data.
14. Please remove repeated statements regarding data management.
15. Please clarify angiogram images will be included in the study dataset.
16. Please remove the table or revise it so it uses lay language, and does not contain repetition or inconsistent statements with the rest of the sheet.
17. Please review the sheet for any information regarding GP notification being optional or with consent as this should be mandatory in a study of this nature. Please amend it so it is mandatory and remove the ‘yes / no’ tick box on the consent form for this.
18. Please remove the ‘yes / no’ tick box regarding continued use of health data following withdrawal as this is not optional.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please confirm whether the DSMB has external representation (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.27*).
4. Please supply evidence of ACC-equivalent insurance specifying New Zealand as a covered territory. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Maree Kirk and Dr Devonie Waaka.

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| **8**  | **Ethics ref:**   | **2024 FULL 18383** |
|   | Title:  | Transcatheter Tricuspid Repair Utilizing the Versa Vascular Repair System in New Zealand |
|   | Principal Investigator:  | Professor Mark Webster |
|   | Sponsor:  | Versa Vascular, Inc.; Occam Labs Ltd |
|   | Clock Start Date:  | 02 May 2024 |

Professor Mark Webster, Ms Mandy Fish, Mr Dan Wallace, Mr Peter Gregg and Mr Aaron Grogan were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee advised that if the entire procedure is part of the study a procedural consent form is not required, as all study activities can be described and consented to on the participant information sheet.
2. The Committee queried if the peer reviewer’s suggestions had been incorporated or rebutted. The Researcher confirmed the suggestions would be incorporated.
3. The Researcher confirmed taxis would be available to help with travel.
4. The Committee queried if the initial three-month gap before the first follow-up was appropriate. The Researcher stated the first follow-up would be done at one month over the phone and if any concerns were raised the participant would be called in for imaging.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee advised if participants are expected to visit their GP to follow up a study procedure, then the associated costs should be reimbursed. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.8; 11.20a)*
2. The Committee raised concern that once the device was implanted it cannot be removed and this was not emphasised enough in the information sheet. The Committee expressed concern that follow-up was planned for only one year in a lifelong device. The Committee queried the likelihood of device degradation or failure over the long term. The Researcher acknowledged the peer review suggested extending the follow up may be advantageous and agreed clinical follow-up could be extended to 5 years with annual phone call follow-up. The Committee requested information regarding participant follow-up is detailed in the protocol. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
3. The Committee noted a discrepancy between question G6 on the application form and page 7 of the participant information sheet. The application states the Sponsor will not store or analyse deidentified data and page 7 of the PIS says if participants choose to withdraw the researchers will continue to use data collected up to that point. Please amend the sheet if required.
4. The Committee requested the Sponsor review the insurance amount and whether this would be sufficient in the event of device failure.
5. The Committee queried how implantation of the device would affect an unborn child. The Researcher stated this was not known but the study population is likely to be older and on medications contraindicated for pregnancy. The Committee requested removal of pregnancy information if the study is unlikely to recruit anyone of childbearing potential.
6. The Committee noted the protocol stated the immediate results of the procedure would be evaluated before subsequent participants are treated and requested this be amended to ensure a specified minimum time interval between initial procedures. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
7. The Committee requested the following changes to the Data Management Plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*:
	1. Please reference applicable Auckland Hospital / Te Whatu Ora data governance policies in Section 3.
	2. Please amend Section 7.3 as no data will be collected anonymously.
	3. Please delete section 11.2.2 as it is not applicable to the current study.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please specify ultrasounds are sent to an imaging lab.
2. Please add more information regarding the permanency of the device.
3. Please highlight the statement that the device cannot be removed under the ‘What happens if I change my mind?’ section.
4. Please specify which medication participants will be told to take on page 5 and emphasise the importance of taking the anticoagulants.
5. Please make GP notification mandatory on page 9 and remove the optional ‘yes / no’ tick box in the consent form.
6. Please include an indication of how long the appointment may take so any supporting whānau can accommodate for expected time.
7. Please include a statement advising participants to report any concerns at the one-month phone call and include information that an in-person follow-up will be arranged if required.
8. Please include information detailing what will happen at the end of the study, if the participant will enter regular follow-up with the study specialist, how often they will be seen, how long the follow-up will be and what it will consist of.
9. Please remove the information stating the study may be terminated if the device is being shown to work and not require further testing.
10. Please make it clear that the procedure, imaging and blood test results will be recorded in the participant's clinical record and cannot be deleted.
11. Please delete repeated information about viewing medical records from the 'de-identified information' section; the statement deals with identifiable data.
12. Please delete repeated information under 'can I find out the results of the study'; the third paragraph is not required.
13. Please update HDEC contact details to hdecs@health.govt.nz and replace the 0800 number with the Ministry of Health general enquiries number (0800 400 569).
14. Please simplify the assessment schedule table in Appendix 1, using lay language.
15. Please elaborate the risk of the device moving mentioned in the information sheet to include adverse events from the protocol so participants understand what this would mean for them (ie what symptoms or complications it may cause).
16. Please explain what ‘TOE’ is again in the risks section as it is defined much earlier in the sheet.
17. Please clarify if implantation of the device may affect the ability of participants to undergo other procedures or scans (e.g. MRI).
18. Please include more information about the Sponsor and if it has produced other successful devices before.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please update the data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Ms Neta Tomokino.

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| **9**   | **Ethics ref:**   | **2024 FULL 19945** |
|   | Title:  | Effects of Liraglutide on Body Surface Gastric Mapping |
|   | Principal Investigator:  | Dr Charlotte Daker |
|   | Sponsor:  | Alimetry Ltd |
|   | Clock Start Date:  | 02 May 2024 |

Professor Chris Andrews and Ms Schynell Coutinnho were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee advised for future submissions it is preferable to refer to people joining the study as ‘participants’ rather than ‘subjects’.
2. The Committee queried if there would be an observation period following administration of liraglutide. The Researcher stated excluding an immediate allergic reaction the effects of the drug would not be evident until a later time. The Researcher confirmed participants would be on-site for 30 – 60 minutes following initial administration and provided a meal.
3. The Committee noted the response to E9 in the application form stated the study would not involve treatment provided by a registered health professional and queried how participants would be prescribed the liraglutide. The Researcher clarified this was an error.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee queried who Māori and Pacific consultation was discussed with as their names were not included in the application. The Researcher agreed to clarify.
2. The Committee queried why participants experiencing significant GI distress would not have their dose terminated as per page 19 of the protocol. The Researcher stated it was planned so the dose would be held as most people stabilise but if someone was very unwell they would be withdrawn. The Researcher stated some gastrointestinal distress was expected with these medications. The Committee noted as the dosing is not done for therapeutic purposes it would be inappropriate to maintain people on a drug if they experience significant adverse effects. The Committee requested the protocol be revised so any participants who experience significant GI distress are withdrawn from the study. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
3. The Committee queried page 38 of the protocol which states participants will be informed that clinical concerns should be directed to their healthcare provider. The Committee advised it would be inappropriate to expect participants to contact their GP if they have health they believe may be related to the study. The Researcher clarified the intention was any concerns could be addressed by the study team and agreed to update the protocol to reflect this.
4. The Committee queried the response to B19 in the application form which states no investigators have any commercial interest in the intervention or relationship to the funder, when almost all investigators are employees of the Sponsor. The Committee queried how this conflict would be managed, how participants would be informed of this and how study conduct and analysis of results would be undertaken. The Committee suggested inviting an independent researcher to assist with data analysis as this may aid publication given the conflict of interest of the investigative team. The Researcher stated there is a financial disclosure form investigators will sign before the study commences and participants will be informed. The Committee requested information regarding this is included in the information sheet. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
5. The Committee noted the study involved administration of prescription medicine and requested GP notification be made mandatory. Please amend the information sheet and consent form to address this.
6. The Committee requested section 8.5 and 11.2.1 of the Data Management Plan are amended for consistency. Section 8.5 describes future unspecified research, while Section 11.2.1 states none will be undertaken. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please include the study site and ethics approval number in the header.
2. Please refer to 'participants' rather than 'subjects' throughout.
3. Please use the second person consistently so the sheet is addressing the participant (“you” not “the participant”).
4. Please review the entire document for lay language and unexplained acronyms; the language used is not lay-friendly (comorbidity, BMI, gastric motility, lactation, 'as per ICH-GCP', IP administration, AGBW survey, concomitant medication, AE management etc).
5. Please significantly simplify the exclusion criteria; these appear to have been lifted directly from the protocol.
6. Please disclose the conflict of interest; the investigators appear to all have a financial interest in Alimetry.
7. Please explain what the GEBT consists of the first time it is mentioned; a diagram or photo of someone undergoing the test would be useful.
8. Please remove the statement about 'anonymous photos' on page 4 as it lacks context.
9. Please amend the risks section to move information explaining the BGSM and GEBT procedure and discussion of data collection elsewhere.
10. Please revise the statement that it is a ‘safe’ medication as this may downplay the potential risks and side effects.
11. Please provide frequencies for liraglutide’s adverse events and include serious risks (e.g. pancreatitis). If nausea is expected please add that this is very commonly reported. The full Medsafe Datasheet should be attached to the PISCF as an appendix.
12. Please include the commercial compensation in event of injury statement from the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
13. Please state that GP notification is a mandatory component of study participation and remove optional tick boxes regarding GP notification from the consent form.
14. Please address future use of data; access to identifiable data; and risk of privacy breach.
15. Please insert the correct HDEC contact details.hdecs@health.govt.nz and replace the 0800 number with the Ministry of Health general enquiries number (0800 400 569).
16. Please replace the ethics approval statement with the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) statement.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Maree Kirk and Dr Devonia Waaka.

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| **10**   | **Ethics ref:**   | **2024 FULL 20324** |
|   | Title:  | Uplifting the mana of Pacific young people |
|   | Principal Investigator:  | Ms Rupi Riley |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 02 May 2024 |

Ms Rupi Riley was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researcher confirmed supported decision-making will be available to participants who need it.
2. The Researcher confirmed a follow-up phone call or meeting would be provided to any participants who request it.
3. The Researcher confirmed this was in independent study and not associated with anything external such as a PhD.
4. The Committee queried the risk of identifiability at the time of publication if a particular participant came from a small community or used an identifying pseudonym. The Researcher stated schools would not be named and if a pseudonym could be identifiable, it would be discussed. The Committee suggested assigning a numerical study ID to each participant in addition to their chosen pseudonym could be useful.
5. The Committee queried the process if a student discloses something concerning. The Researcher stated two mental health professionals would be present and the person would be asked if they wished to discuss it privately and a recommendation to the participant would be provided.
6. The Committee noted recordings would be held for 10 years and advised good security measures would need to be in place to minimise the risk of privacy breach.
7. The Committee queried the peer reviewer’s comments and if they had been actioned. The Researcher confirmed some had been and others (such as the word exploration rather than investigation) were under consideration. The Researcher confirmed the peer reviewer raised no concerns about the scientific design of the study.
8. The Committee noted the intention to allow participants to withdraw their data and advised in focus group or talanoa settings one person withdrawing can change the context of contributions made by others. The Committee advised it is acceptable to tell participants that while they are free to withdraw at any time they may not be able to remove their contributions due to this.
9. The Committee advised locality authorisation be obtained through a Locality Authorisation Form on EthicsRM. This can either be done electronically on the form from the locality or a written/email authorisation may uploaded by the researcher.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted a parental consent form and queried how this would be used as participants aged 16-18 are legal adults and can provide their own consent. The Researcher stated it is culturally appropriate to involve the family and as the study takes place at school parental consent is required for school activities. The Committee advised an information sheet is appropriate but consent from parents should not be sought as consent to participate in research can only be sought from the individual themselves if they are above 16. The Committee suggested adding a line to the young person’s PIS to tell them they are welcome to discuss the study with their family.
2. The Committee requested the Researcher update the data management plan to amend Section 11 to remove safety and screening results as these are not applicable. The Committee suggested referencing the talanoa transcript here instead. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please amend ‘You have been chosen’ to ‘You have been invited’ on page 1.
2. Please state how many young people will be taking part (eg 16 voices).
3. Please include information advising that if there are serious concerns the researcher has a duty of care to follow up.
4. Please remove the ‘yes / no’ tick boxes on the consent form unless they are truly optional (i.e. the participant can answer ‘NO’ and still participate).
5. Please remove the clause for parental consent as all participants will be 16 and above.

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data management plan. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Amy Henry and Ms Neta Tomokino.

General business

1. The Chair reminded the Committee of the date and time of its next scheduled meeting:

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| **Meeting date:** | 11 June 2024 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Ms Dianne Glenn
* Dr Maree Kirk
* Mr Dominic Fitchett
1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 4:15pm with a karakia.

Unuhia te pō, te pō whiri mārama

Tomokia te aō, te aō whatu tāngata

Tātai ki runga, tātai ki raro, tātai aho rau

Haumi e, hui e, tāiki e!

(From confusion comes understanding

From understanding comes unity

We are interwoven, we are interconnected

Together as one!)