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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 15 August 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:30pm-1:00pm | 2023 FULL 15488 | FAST study: Feasibility ASessment of circulating Tumour DNA (ctDNA) in the diagnosis of advanced lung cancer | Dr Annie Wong | Ms Catherine Garvey & Dr Kate Parker |
| 1:00pm-1:30pm  | 2023 FULL 15434 | Lignocaine intra-abdominal implant for pain relief in colon surgery | Dr Claudia Patterson | Ms Kate O’Connor & Dr Andrea Forde |
| 1:30pm-2:00pm | 2023 FULL 11995 | COMBINE-INTERVENE Trial | Dr Scott Andrew Harding | Ms Catherine Garvey & Dr Sotera Catapang |
| 2:00pm-2:30pm | 2023 FULL 18346 | Examining an Aotearoa-specific early autism support programme. | Dr Hannah Waddington | Mr Jonathan Darby & Ms Jade Scott |
|  |  | **BREAK 30 MINUTES** |  |  |
| 3:00pm-3:30pm | 2023 FULL 18407 | RT-310 Dose Escalation Study | Professor Peter Gilling | Mr Jonathan Darby & Dr Andrea Forde |
| 3:30pm-4:00pm | 2023 FULL 15602 | Australia and New Zealand Mechanical and Circulatory Support Registry | Dr Cara Wasywich | Ms Kate O’Connor & Dr Kate Parker |
| 4:00pm-4:30pm | 2023 FULL 16720 | Selution4BTK | Dr Andrew Holden | Ms Catherine Garvey & Ms Jade Scott |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mr Derek Chang  | Non-lay (Intervention studies)  | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 19/03/2019  | 19/03/2022  | Present |
| Dr Sotera Catapang  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Ms Kate O’Connor (Co-opt) | Lay (Ethical/Moral reasoning)  | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members, noting that apologies had been received from Mr Derek Chang.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Kate O’Connor confirmed their eligibility and were 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 18th July 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 15488** |
|   | Title:  | FAST study: Feasibility ASessment of circulating Tumour DNA (ctDNA) in the diagnosis of advanced lung cancer |
|   | Principal Investigator:  | Dr Annie Wong |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 3rd August 2023 |

No one from the research team 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.

Kate Parker declared a potential conflict of interest and the Committee decided to continue with her as reviewer.

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 that Otago University is the sponsor and must be indicated as such. *Health and Disability Ethics Committees Standard Operating Procedures* para *144*
2. The Committee requested that the researcher be clear that the study is occurring in Wellington and Auckland and that all documents be amended to reflect this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7a & 7.19)*
3. The Committee requested independent scientific peer review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.25-9.32)*
4. The Committee requested provision of CI indemnity.
5. The Committee noted that the protocol had not been finalised and was a draft document. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para* *9.7)*
6. The Committee noted that there needs to be locality approval at all participating sites.
7. The Committee queried how participants will be recruited for the qualitative interviews. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.16)*
8. The Committee queried why there is no reimbursement of travel costs.
9. The Committee requested clarification that blood is sent to "local labs" then on to the University of Auckland lab, and that some of the sample from each participant is intended to be sent to the US for the Guardant360 assay. This should be made consistent across all documentation. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.16)*
10. The Committee requested rationale of the next steps after the testing as they are entirely at the discretion of the participants treating clinician and there is nothing protocolised about the way forward. This should be made very clear in the Participant Information Sheets. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.16)*
11. The Committee noted that the interview questions, and questionnaires for clinicians were not provided. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.16)*
12. The Committee requested the following changes to the Data and Tissue Management Plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*:
	1. Please review to ensure this contains information relevant to this study removal of reference to tissue unrelated to this study, removal of reference to identifiable data not being collected.
	2. Please include details of overseas laboratories.
	3. Please include relevant details of local laboratories.

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 to state the realistic benefits of the study as this is currently over-sold.
2. Please mention the oncogene occurrence in Pasifika and Māori if known.
3. Please clarify that there is a chance that an oncogene may be identified for which the possible treatment is non-funded.
4. Please remove the table on page 3 as this is repetitive and adds no value.
5. Please clarify if the tissue overseas will be able to have a karakia performed prior to destruction as stated in the application form.
6. Please clarify whether data sent overseas will be shared with international researchers.
7. Please clarify why there is no koha for participants.
8. Please provide the addresses of all labs overseas.
9. Please remove reference to the MoST study.
10. Please correct the following sentence: “In approximately 20% of patients with advanced cancer does not obtain a tissue diagnosis due to patient frailty, challenging location of the tumour or insufficient tissue for testing.”
11. Please remove references to teaspoons and use millilitres.
12. Please specify how participants will be selected to participate in the interviews and what the interview questions will be. All questionnaires must be provided for review.
13. Please clarify what is intended by "ongoing access to your relevant medical records".
14. Please amend the phone numbers for the Ministry of Health.
15. Please use the term “study” rather than “program”.
16. Please provide a PIS for clinicians if it is intended to have clinicians participating by way of completing questionnaires

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **2**  | **Ethics ref:**   | **2023 FULL 15434** |
|   | Title:  | Effectiveness and safety of a lignocaine eluting intraperitoneal implant for pain relief in elective laparoscopic colectomy |
|   | Principal Investigator:  | Dr Andrew Hill |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 3rd August 2023 |

Dr Andrew Hill 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 clarified the involvement of the Queens University of Belfast.
2. The Committee clarified the historic controls were all laparoscopic surgeries.
3. The Committee clarified the manufacturing would be GMP but that there would be a sterilisation process subsequent and additional to the initial manufacturing.
4. The Committee clarified the process of extraction of the device.
5. The Committee clarified that the trial exclusion criteria for cognitively impaired people would almost entirely only relate to patients with dementia. in circumstances where they are unable to respond to questionnaires.

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 that the sign-off for the local sponsor would need to go through the University of Auckland research office. (*Health and Disability Ethics Committees Standard Operating Procedures* para *144)*
2. The Committee noted that the balance of benefit was commercial and that there would need to be ACC-equivalent insurance provided for participants and the protocol must state that this is a commercial trial. *(Health and Disability Ethics Committees Standard Operating Procedures* para *144)*
3. The Committee queried the submission of the device to SCOTT. The researcher noted that SCOTT had provided some advice but were yet to formally respond to the application that had been sent to that committee. (*Health and Disability Ethics Committees Standard Operating Procedures* para *10 & 11)*
4. The Committee requested provision of the Investigator’s Brochure.
5. The Committee queried the process for laparoscopic colectomy and the researcher noted that in sheep laparotomy was done for ease rather than laparoscopic surgery. The researcher noted that the investigative procedure could also be done by means of an open colectomy.
6. The Committee queried the charter for data collection and request more details to this effect in the data management plan. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
7. The Committee noted that as this was a first in human device trial that there should typically be some inert testing prior to testing with anaesthetic first. The Researcher noted that there was no potential benefit from placing a blank device in a human in this case and therefore would not be ethical as it would not have any benefit but there would be inherent risk.
8. The Committee noted that the Data Management Plan (DMP) was not sufficient for review and will need to be rewritten. The Committee suggested using the HDEC DMP template as this will identify all relevant aspects required by HDEC. This should contain more detail about collection, access, storage and destruction of study data, both identifiable and coded throughout the study lifecycle. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
9. The Committee requested provision of CI indemnity and a commercial insurance certificate. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
10. The Committee noted that should SCOTT not provide review on all or part of the study, then the Committee will require independent scientific peer review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*

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 refer to the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) to ensure that there is no missing information that participants need to be able to make an informed decision.
2. Please detail how this process differs from standard of care.
3. Please disclose conflicts of interest especially where this may relate to commercial interest.
4. Please refer to the [HDEC PIS/CF consent form as a template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) as there is a lot of information missing as to what if required for HDEC review.
5. Please ensure that support contacts are provided for the Advocacy and Māori cultural support.
6. Please consider use of a diagram to better show the process and device.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **3**   | **Ethics ref:**   | **2023 FULL 11995** |
|   | Title:  | COMBINEd Ischemia and Vulnerable Plaque Percutaneous INTERVENtion to Reduce Cardiovascular Events |
|   | Principal Investigator:  | Dr Scott Andrew Harding |
|   | Sponsor:  | DIAgnostic Research And Management (DIAGRAM) B.V |
|   | Clock Start Date:  | 3rd August 2023 |

No one from the research team 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 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 clarification as to whether this study is investigator led or commercially sponsored as there is conflicting information in the study documentation.
2. The Committee requested clarification as to why the study excluded pregnant and lactating people.
3. The Committee requested provision of scientific peer review.
4. The Committee queried the funding by Abbot Vascular as noted in the application form.
5. The Committee requested that someone other than the site investigator who is also the treating clinician carry out the consenting to avoid the risk of coercion for participants.
6. The Committee requested the following changes to the Protocol:
	1. Please clarify “In the OCT-FFR arm OCT-guided PCI and stent optimalisation is mandatory” where it is not in the comparative group.
	2. Please provide the document describing the sham OCT, which is referred to in the protocol.

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

1. Please explain the need for blinding of the participants and how the sham optical coherence topography is performed.
2. Please amend the Ministry of Health contact number as the Ethics number is no longer active.
3. Please remove the data linking sections as there is no data linkage.
4. Please ensure that all risks are noted, including risks involved during ECG and blood drawing etc.

**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 supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Dr Sotera Catapang.

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| **4**   | **Ethics ref:**   | **2023 FULL 18346** |
|   | Title:  | Pilot and randomised controlled trail of an Aotearoa-specific early autism support programme. |
|   | Principal Investigator:  | Dr Hannah Waddington |
|   | Sponsor:  | Victoria University of Wellington |
|   | Clock Start Date:  | 3rd August 2023 |

Dr Hannah Waddington and Carla Wallace-Watkin 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 clarified that the aim was for the coaches to be the same for all sessions per 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 that the adverts state the approving HDEC is Northern B and should be amended to Northern A.
2. The Committee noted that the RCT section of the study should be submitted as an amendment to the study once the pilot has been completed.
3. The Committee queried if the information that the coaches will offer about the strategy will be freely available outside of the study; if not and part of the participant-facing study materials this will need to be provided for review.
4. The Committee queried if it was possible for the koha to be increased given the extensive time requirements on participants.
5. The Committee requested clarification of the safety plan and how coaches will be accompanied and if they will require a police check and any reason as to why the coaches may only be accompanied by a buddy on the first check.
6. The Committee suggested that the researcher should advise General Practitioners of participation for the safety of participants given that some of the questions are potentially likely for distress to be incurred. This should not be an optional part of participation.
7. The Committee suggested calculating age in months for clarity in inclusion and exclusion of participants and, additionally, aid replication of data and publishing of data.

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

1. Please add that a second coach will attend 2 sessions to observe the coach.
2. Please clarify the exclusion criteria to note that the study would exclude participants with any “known” genetic variations that may affect their condition.

**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 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).*

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| **5**   | **Ethics ref:**   | **2023 FULL 18407** |
|   | Title:  | Safety and Feasibility Dose Escalation Study for Evaluation of RT-310 for Treatment of Lower Urinary Tract Symptoms (LUTS)Secondary to Benign Prostatic Hyperplasia (BPH) |
|   | Principal Investigator:  | Professor Peter Gilling |
|   | Sponsor:  | Resurge Therapeutics Inc |
|   | Clock Start Date:  | 3rd August 2023 |

Ms Marg Ross, Maggie LeDang, John Stankus, Dr Shahram Gholami, Mikael Trollsas, and Thijs Wervelman 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 clarified that this is a first in human study.
2. The Committee clarified that the investigational product is not protein-bound and that the risk of systemic toxicity is very low, particularly in comparison to IV equivalent treatment.
3. The Committee clarified that this would require locality approval prior to starting the trial.
4. The Committee clarified that treatments as part of the study would be paid for by the sponsor.

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 how the recruitment would be managed given they were already receiving treatment with Professor Gilling. Their participation would be based on their dissatisfaction with their current treatment. The Committee noted that the recruitment needed to be done by a member of the team who was not already their treating physician. This should be a clear process in the protocol and participant information sheet/consent form (PIS/CF).
2. The Committee requested provision of independent scientific peer review or the response from SCOTT should they review this application.
3. The Committee noted that the reimbursement for travel only is not sufficient given this is a FIH study and that participants would be inconvenienced given the time required for participation.
4. The Committee noted that recruitment would be primarily of people in the public system not private.
5. The Committee queried the inclusion of “in-utero children” in the indemnity, please amend this as applicable.
6. The Committee requested clarification in the protocol around the process for managing lesions discovered as part of the MRIs undertaken in this study
7. The Committee requested the Researcher remove any reference to 16-year-olds in the data management plan and others as this is not relevant to the study.

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

1. Please make it clear that there would be an additional MRI for the participants.
2. Please clarify if karakia is available for participants.
3. Please clarify the safety plan for the quality-of-life questionnaires. The timeline for review of surveys and the management of any potential distress must be outlined in the PIS for participants.
4. Please amend the amount of blood to be in millilitres not in teaspoons.
5. Please note that notification of the General Practitioner should not be optional.
6. Please clarify the physician follow up.
7. Please change the reference to ‘child bearing’ and refer to conception of children.

**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 Mr Jonathan Darby and Dr Andrea Forde.

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| **6**   | **Ethics ref:**   | **2023 FULL 15602** |
|   | Title:  | ANZMACS. Australia and New Zealand Mechanical and Circulatory Support Registry |
|   | Principal Investigator:  | Dr Cara Wasywich |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 3rd August 2023 |

Dr Jesus Gonzales 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 clarified how many heart transplants occur per year.
2. The Committee clarified that the registry would only capture patients from the Greenlane Hospital site as it is the only centre in New Zealand which does this procedure.
3. The Committee clarified that the registry would track long-term mechanical support that essentially would be capturing participants who were waiting for transplant.

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 independent scientific peer review as per the HDEC template. This could be done in partnership with the Te Whatu Ora data custodian as the data and privacy concerns are not adequately addressed. (*Health and Disability Ethics Committees Standard Operating Procedures* para *10 & 11)*
2. The Committee queried the request for waiver of consent for all of these patients given that there is a large window of access and follow-up for these people and therefore bountiful opportunity for consent to be included in the registry. The Committee recommend that these participants be consented as there is not sufficient justification for waiver presented in this application. Otherwise, the researcher is required to provide justification for waiver, or for op-out consent, in accordance with the NEAC Standards. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.20 & 7.21)*
3. The Committee noted that there should be a sponsor for the study, and that St Vincent’s Hospital in Australia would be the appropriate group to do this. The Committee requested that the Sponsor provide some framework for the governance of data.
4. The Committee requested a clear protocol as to how people will be recruited and approached for recruitment. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 & 9.8)*
5. The Committee noted that the consenting process could potentially be opt-out but that some participant information sheets and consent forms in that instance are still required and must be provided for review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para*  7.20, 7.21, *9.7 & 9.8)*
6. The Committee suggested that there be some Māori consultation specifically around data sovereignty given how much data may be collected about participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.3)*
7. The Committee requested further clarification and or justification as to the exclusion of patients that have received ECMO, especially with participants who may have needed ECMO for temporary support of lung function in response to acute respiratory infections.
8. The Committee requested the following changes to the Data Management Plan (DMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*:
	1. Please use the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) to rewrite the DMP as it is not sufficiently detailed in the form that has been provided.
	2. Please note that health data must be kept for at least 10 years.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *National Ethical Standards* para *7.15 & 7.16*:

1. Please provide a PIS if seeking consent or opt out consent. The PIS may be relatively brief given the nature of the registry but must ensure that participants are aware of the data governance and a clear pathway for data withdrawal.
2. Please note that any quality-of-life questionnaires need to be reviewed as they are completed, and a safety plan provided if these are outside of standard of care.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **7**   | **Ethics ref:**   | **2023 FULL 16720** |
|   | Title:  | A Prospective Randomized Multicenter Single Blinded Study to Assess the Safety and Effectiveness of the SELUTION SLR™ 014Drug Eluting Balloon in the Treatment of Below-the-Knee (BTK) Atherosclerotic Disease in Patients with Chronic Limb ThreateningIschemia (CLTI) |
|   | Principal Investigator:  | Dr Andrew Holden |
|   | Sponsor:  | MedAlliance LLC |
|   | Clock Start Date:  | 3rd August 2023 |

Dr Andrew Holden and another member of the research team 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 clarified what the standard treatment for these participants is in New Zealand and that availability of balloons in this treatment is limited in New Zealand.
2. The researcher clarified that flow treatment would be excluded in the New Zealand based study.
3. The Committee clarified that the exclusion of pregnant and lactating women was due to the age range of participants which made it unlikely that these potential participants would have vascular disease of this severity.

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 provision of the Investigator’s Brochure for review.
2. The Committee queried the single blinding process and why it is necessary. This process should also be clarified for participants so that they understand why and how this will occur.
3. The Committee noted that 16-year-olds were mentioned in the data management plan, please remove this as it does not appear to be relevant to this study.

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

1. Please amend reference to the approving HDEC to state Northern A rather than Central.
2. Please remove the 0800 Ethics number as this has been deactivated. The Ministry of Health’s general number can be provided to participants for concerns or complaints.
3. Please clarify that the angiogram at 6 months is not Standard of Care, and as such please include more information on this as it is an additional procedure only for study participants.

**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 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).*

## General business

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

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| **Meeting date:** | 19th September 2023 |
| **Zoom details:** | To be determined |

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 4.20pm.