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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 May 2021 |
| **Meeting venue:** | Via Zoom <https://mohnz.zoom.us/j/96507589841> Meeting ID: 965 0758 9841 |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 06 April 2021 |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55pm  12.55-1.20pm  1.20-1.45pm  1.45-2.00pm  2.00-2.25pm  2.25-2.50pm  2.50-3.15pm | i 21/NTB/103  ii 21/NTB/104  iii 21/NTB/105  Break  iv 21/NTB/110  v 21/NTB/111  vi 21/NTB/112 |
| 3.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |  |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 20/05/2017 | 20/05/2020 | Present |  |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |  |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Present |  |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |  |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |  |
| Ms Susan Sherrard | Lay (consumer/community perspectives) | 19/03/2019 | 19/03/2022 | Present |  |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members.

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 06 April 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/NTB/103** |
|  | Title: | AIRVO3: Post-Cardiothoracic |
|  | Principal Investigator: | Mr Raulle Sol Cruz |
|  | Sponsor: | Fisher and Paykel Healthcare Limited |
|  | Clock Start Date: | 22 April 2021 |

Raulle Sol Cruz and Paul Young 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 Study

* The main aim of this study is to determine whether automatic oxygen adjustment by the AIRVO3 device keeps blood oxygen levels in the correct range for a greater amount of time compared to the usual manual adjustment by nurses for intensive care patients who require supplemental oxygen after their cardiothoracic surgery.

Summary of resolved ethical issues

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

* The Committee considered the request for a closed meeting and clarified the difference between a closed and open meeting for HDEC review. The Chair declined the request for a closed meeting on the grounds that the discussion of the ethical aspects of the study will not reveal trade secrets and will not prejudice the commercial activities of the sponsor. The Researchers were comfortable for the review of the application to proceed under normal open circumstances.
* The Committee queried how the blind element of the study will be maintained given the study is comparing automated and manually controlled devices. The Researcher advised that normal practice for Intensive Care Unit (ICU) nurses is to check devices on a regular basis and provide care to patients at the same time. The nurses will still need to check that the automated equipment is functioning correctly when providing patient care and therefore participants will not be able to tell which arm of the study they are in.
* The Committee noted the Researcher’s confirmation that participants will receive a printout or email copy of their signed consent form after signing on a tablet.
* The Committee queried the composition of the Data Safety & Management Committee as a statistician has not been identified and is typically included in discussions to ensure there is no unfavourable statistically significant outcomes for one arm of the trial or other. The Researcher confirmed that the research team’s statistician, Professor Mark Weatherall, will sit on this committee.

Summary of outstanding ethical issues

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

* The Committee noted that recruitment will take place only one day prior to the patient’s (elective) surgery and questioned if it is possible to provide more advance notice. The Researcher advised that with regards to the practice for cardiac surgery, there is no opportunity to meet with patients face-to-face before the operation. However, they could phone patients and provide the information sheet earlier.
* The Committee requested that consideration is given to the consenting timeline and introducing the participant information sheet and consent form (PIS/CF) to potential participants earlier in their patient journey. This is to ensure that patients have enough time to fully consider all elements of participation in the study prior to the face-to-face (pre-surgery assessment) discussion.
* The Committee noted that only one cardiac surgery patient per day will be enrolled in the study and queried how the selection process will work and if it means that ineligible patients will receive the PIS/CF. The Researcher advised that they plan to enrol only the first patient from the operating list that they receive from the hospital the day before, but which is not finalised until the day of surgery. He confirmed that, because of this, they will need to send the PIS/CF to all patients.
* The Committee recommended that, given not all patients will end up being eligible and selected for the study on the day, this needs to be communicated to participants in advance (i.e.in the PIS/CF) to ensure they understand that they are not being excluded for arbitrary reasons.
* The Committee advised that it is not standard practice to ask participates to keep details of the study confidential as it is contrary to the idea that they are free to discuss it with friends and family as part of their right to considering participation or withdrawal. The Committee note that asking participants to refrain from taking photos of the equipment is acceptable. Please address accordingly in the PIS/CF.
* The Committee advised that Medicines NZ guidelines do not apply to devices or MedTech (as per application question R.1.10) and requested that any references to these guidelines are removed from the PIS/CF.
* The Committee accepted that the nurse usability survey is anonymous and completing it is evidence of consent. However, more information about the study is required for this consent to be informed. The Committee suggest adding brief information to the beginning of the questionnaire (e.g. what the study is about, what is required from them, and contact details)
* The Committee noted that while the Data Management Plan is generally good, the reference to data not being sent overseas but held on an Australian server is confusing. Please review the PIS/CF to ensure that what participants are being told lines up with what is stated in the Data Management Plan and is easy for the participant to understand. For example, address the difference between sent and held overseas, state that both New Zealand and Australian privacy laws apply, include reference to data being sent overseas in main body of PIS/CF not just in the consent form.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

* Please explain in the in the information sheet that participants will not be assessed for the study until finalisation of the operating list on the day (as per the Committee’s point above).
* Please explain more clearly to participants what is happening with their data as per the Committee’s point above.
* Please remove the confidentiality signing panel from the consent form as per the Committee’s point above.
* Please remove references to Medicines NZ guidelines (as per Committee’s point above).
* Please amend the ethical approval statement on page 2 as HDECs do not approve studies, they only approve the ethical aspects of the study as per the New Zealand Ethical Standards for Health and Disability Research.
* Please check wording is correct on page 3-4 that states, ‘will [not] cause you to receive O2 for longer than necessary’.
* Please add the sponsor’s name and address to the front-page header.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee
* Please update the study protocol, taking into account the feedback provided by the Committee.

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| **2** | **Ethics ref:** | **21/NTB/104** |
|  | Title: | FRAIL M |
|  | Principal Investigator: | Dr Rajeev Rajagopal |
|  | Sponsor: | Australasian Leukaemia & Lymphoma Group |
|  | Clock Start Date: | 22 April 2021 |

Rajeev Rajagopal and Nicola Jackson 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 Study

* The study will test different combinations and different doses of Bortezomib (Velcade), Lenalidomide (Revlimid) and dexamethasone in transplant-ineligible multiple myeloma patients. The primary outcome is overall response rate to the drug stratified by the three groups of frailty/fitness and the occurrence of significant toxicity within the first 4 cycles of treatment. The study will take place in both Australia and New Zealand with 100 NZ participants.

Summary of resolved ethical issues

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

* The Committee queried if the drugs used in the study are funded in New Zealand. The Researcher advised that Bortezomib is funded and Lenalidomide is funded only as a third-line treatment. He added that they are using the latter as first-line treatment in the study and as such is not available to the participants outside the trial.
* The Committed requested clarity on what the exploratory secondary objectives detailed in the Protocol will entail. The Researcher advised that, currently, they will not be participating in the extra correlative studies due to inadequate lab facilities in New Zealand. The Committee advised that, should this change, it will need to be submitted for HDEC review through the post-approval amendment pathway.
* The Committee queried the purpose of the travel questionnaire. The Researcher responded that it is in relation to the health economics of the trial.
* The Committee noted that there is not a separate peer review, however there was a rigorous process for developing and reviewing the protocol and that all ALLG trials undergo peer agreement at national Haematology Society of Australia and New Zealand meetings before adoption in New Zealand. The Committee considered this adequate peer review.
* The Committee queried if travel costs will be reimbursed and who will fund this. The Researcher confirmed that travel costs will be reimbursed and funded from the study budget that is both the sponsor and the haematology research unit have contributed to.
* The Committee queried what data ALLG is receiving about participants. The Researcher confirmed that it will be de-identified data.
* The Committee noted that the study is for the benefit of a collaborative group and not primarily commercial but were pleased to see there is back up compensation insurance available.
* The Committee noted that the Researcher’s confirmation that ALLG will undertake remote monitoring for the study.

Summary of outstanding ethical issues

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

* The Committee queried if some participants will have extra bone marrow samples taken in addition to the standard of care samples. The Researcher advised that should the standard of care marrow samples not be sufficient to enrol the participant in the study; a second sample may be required.
* The Committee requested clarify around any study specific marrow samples and recommended that these, non-standard of care, samples are appropriately managed and detailed in the in the Data and Tissue Management Plan and communicated to participants.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

* Please remove the duplicated statement on page 2, "You will be given a copy... to keep".
* Please check with Medsafe if Lenalidomide needs to be listed with them. If it does not, please remove reference to it on page 3.
* Please remove the reference to Medicare on page 4 as it is not relevant to New Zealand.
* Please correct the sentence in the inclusion criteria that states, “Overall blood health is adequate (e.g.: you have [sufficient] red blood cells and white blood cells)”.
* The Committee state that there is some ambiguity around the sponsor with the 50+ companies working with or for them. Please review the use of the term “sponsor” and be more specific about who you are referring to in the information sheet. For example, in the data management section, it says that people and companies working with or for the sponsor will receive data. Please be specific that the company supplying the drug in New Zealand will be getting the data and name the other companies working for the sponsor that will also receive the data.
* Please state that in the event that ACC does not pay out for a treatment injury, there is some back up compensation insurance available.
* Please remove the yes/no tick boxes for informing participants GP on the consent form as this is not optional.
* Please include a Māori health and support person contact details.
* Please include relevant information should any extra tissue samples be taken for research as per the Committee’s point above. E.g. tissue cultural statement, consent item.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* 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 Jane Wylie and Kate O’Connor.

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| **3** | **Ethics ref:** | **21/NTB/105** |
|  | Title: | The EMMAC Study |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 22 April 2021 |

Paul Glue, Will Evans, and Lisa Reynolds 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 Study

* This is a dual site double-blinded randomised controlled trial to assess the effects of MDMA-assisted therapy versus a psychoactive control treatment (methylphenidate) on depression and anxiety symptoms in patients with advanced-stage cancer. This is a double-blind/placebo trial with up to 24 participants who will receive MDMA or methylphenidate in clinic. Participants will have the option to receive an open label single hit of MDMA at 28 days if still depressed as part of an extension study.

Summary of resolved ethical issues

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

* The Committee noted that this application was previously declined by Northern B HDEC based on the early development of the study and the requested documentation has been provided.
* The Committee queried if there had been any further development or findings on the dose safety. The Researcher advised that the latest investigators brochure (IB) has been provided which summarises the safety matters from Multidisciplinary Association for Psychedelic Studies (MAPS) which is also being provided for FDA approval of US studies. In summary, he advised that the dose (120 mg and supplementary 60mg) appears to be well tolerated and the safety is considered acceptable.
* The Committee stated that the documentation provided did not make it clear what phase the study was and asked for clarity. The Researcher confirmed it is a phase 2 study.
* The Committee noted that there are 5 prior studies and the phase 1 of this study that have used this treatment for the conditions of anxiety and depression. The Researcher added that the most relevant study of which the results have just been published, is US study using MDMA-assisted therapy for treatment of anxiety in the setting life-threating illness of 18 participants. The Researcher advised that the study had a similar protocol and no adverse effects were reported and generally positive outcomes around anxiety.
* The Committee were pleased to see the inclusion of the Reference Manual focusing on the operational elements of the study and the Treatment Manual focusing on consistent treatment by the therapists.
* The Committee noted that the Treatment Manual was co-authored with a Māori psychologist who consulted with Kaumatua and that it, therefore, includes Tikanga.
* The Committee noted that when providing peer reviews, information on who the reviewer is, beyond their name, and why they are a good choice should be provided. Please bear this in mind for future applications.
* The Committee noted that in the application form it is unclear which principal investigator works where and what their formal positions are. Please bear that in mind for future applications.
* The Committee noted that the statement in the application that no other treatments are available for anxiety and depression refers to fast acting treatments and the unavailability of pharmaceutical treatments for fear of death.
* The Committee noted that the optional open label extension study requires a protocol and separate consent form and this documentation has not been provided. Given the extension study will not commence until the main trial finishes, the Committee recommended this documentation is submitted for HDEC review via the post-approval amendment pathway once the main study has been approved.
* The Committee queried if videoing is necessary or if this could be optional. The Researcher advised that footage will be used, not only for qualitative analysis of participant, but also to assess the therapist’s adherence to the Treatment Manual, and that filming also proves a degree of security. He advised that for these reasons his preference is to video the treatment sessions but that they would consider not videoing if a participant was strongly averse to it.

Summary of outstanding ethical issues

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

* The Committee advised that the protocol states that participants will be followed for 3 months post-randomisation or until death (whichever occurs first), however it is not clear in the participant information sheet and consent form (PIS/CF) about follow up and how it will work given there are no more study visits after the initial dose. The Researcher responded that there may be phone calls, but no formal procedure had been established.
* The Committee requested that the Researchers develop a plan for the follow-up and communicate this to participants; updating the protocol and PIS/CF accordingly.
* The Committee recommended, when making the plan, the Researchers consider how they might obtain relevant and useful data that already exists such as the participants’ hospital notes on their general health and mental state post-study (3 months).
* The Committee require a data management plan appropriate to the study to ensure the safety and integrity of participant data that complies with *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).* The plan should include follow up data (e.g. hospital records), therapist phone calls, and how the video footage will be used, how long you’re going to store it, who will have access to it, and how you’re going to keep it confidential for both the participant and the support person. This is especially important as videos of people on MDMA are extra sensitive, are identifiable and may be used after death. For guidance, please see the Data Management Plan template available on HDEC website - <https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx>
* There was discussion around the different levels of opiate use and what would be the acceptable tolerance for the study. The Committee recommended the Researchers be decisive and descriptive in their exclusion and inclusion criteria – taking into consideration if those on palliative care can remain on opiate treatment provided there are no interactions.
* The Committee advised that there were some broad terms used in the Treatment Manual that require explanation in the protocol and PIS/CF. For example, the term “therapeutic touch” and “body work” need to be defined for the lay person. In addition to this, the Committee recommended carefully considering and detailing some criteria around what appropriate forms of touch/bodywork are and the restrains around use. This will ensure clear boundaries are set for both the therapists and participants in advance of treatment.
* The Researcher confirmed that the therapists will be using non-intrusive touch techniques such as a hand on the shoulder, or gentle hand rubbing and will discuss this with participants prior to treatment as well as clarify this in the PIS/CF and Treatment Manual.
* The Committee asked that the following statement about daily contact in the Treatment Manual is checked for accuracy, "The therapists and participant commit to daily telephone contact for up to a week after each MDMA-assisted session. The therapists will be available by telephone twenty-four hours a day during this period and the entire period of study enrolment." Please find a balance that is achievable and amend as appropriate. Please also include this information in the protocol and PIS/CF so that participants know what support is available.
* The Committee requested a pamphlet for the support person is developed with information about what is expected of them and who to call for advice if something goes wrong.
* The Committee recommended the restraint protocol in the Reference Manual is updated to state that the research team will follow the restraint policy of the institution where the treatment is taking place (i.e. name the DHB/institution) and ensure the specific roles are identified and who is filling them in the flow chart to reduce confusion in the event that restraint is required.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

* Please include a ‘What will happen with my information’ section that will be informed by the Data Management Plan once developed.
* Please make it clear in the study procedure section why the inclusion and exclusion criteria are there. E.g. “You can take part in this if you meet the all of the following criteria” and “You cannot take part if you meet one or more of the following exclusion criteria”.
* Please add a ‘What will my participation involve’ section (under the exclusion/inclusion criteria) that clearly explains what participation involves (i.e. the procedures) and what is expected from participants that is outside their norm (e.g. “your participation will mean that after consent you will also need to be free from…”). Please include clear information about;
  + The washout of caffeine, nicotine and opiates (i.e. that they must be able to come off these and there may be some side effects and/or that those in palliative care can remain on the pain treatment while in the study).
  + The 12-hour fast and liquid requirements prior to intervention.
* Please review the document and correct the formatting and spelling errors.
* Please consider incorporating the comments made by Lisa Reynolds in the document as these appear to be useful.
* In the Purpose section and general outline of the study, please be clearer on what “therapy” means as this word can be applied to a variety of medical interventions and may not mean much to a lay person.
* Please explain the terms “therapeutic touch” and “bodywork” as per the Committees point above. E.g. “there may be times during the therapy when your therapist may give you a reassuring pat on the shoulder or hold your hand if you seem distressed. You and your therapist will discuss what how this might happen, what you’re comfortable with and if this is acceptable to you.”
* Please also explain any other medical terminology such as “screening” e.g. pre-trial screening is " to see if you are eligible to be in the study".
* Please make it very clear to participants how many visits there will be and what they are for, including the follow-up process. E.g. the PIS/CF describes 5 study visits, also mentions 8, but does not include 5 follow up sessions.
* Please also include the timetable of events on page 29 of the protocol in the PIS/CF as this will make it very clear to participants exactly what they are committing to.
* Please represent study days as treatment days as per the comment in the ‘Duration of Study’ section on page 5.
* Please be clear that you are consenting participants prior to screening as the first paragraph on page 7 does not make this process clear.
* Please remove the yes/no tick boxes in the consent form for items that are not truly optional.
* Please remove optional second dose from the consent form as consent will need to be sought again at time of administration. Please explain in the ‘outline of procedures’ section earlier in the document how this will work, e.g. “during the course of this study you will be offered a second dose. We will seek your consent at the time it is offered, and you can choose if you want it or not.”
* The Committee requested that the videoing element is made evident to the participant and support person, so they understand that they are consenting to in this space in advance.
* Please include information about the support that is available to participants.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* 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 Leesa Russell and John Hancock.

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| **4** | **Ethics ref:** | **21/NTB/110** |  |
|  | Title: | BFTA-AU-001: A Phase 1 Bioequivalence Study of BFI-751 compared with EU-STELARA and US-STELARA |  |
|  | Principal Investigator: | Dr. Christian Schwabe |  |
|  | Sponsor: | avancecro |  |
|  | Clock Start Date: | 22 April 2021 |  |

Christian Schwabe and Courtney Rowse 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 Study

1. This is a phase one bioequivalence study. Design is randomised double blind in three groups. Comparison is of investigational product BFI-751 compared with EU-STELARA® and US-STELARA. Administration is by sub-cut injection (under the skin). Healthy volunteers aged 18-50, 282 recruited in total, across the three arms. Intervention is a single dose, and study duration for participants is 136 days.

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 insurance certificate only states Australia as the territory. Please ensure an appropriate insurance certificate is obtained with New Zealand named as a territory.
2. The Committee requested that the researchers have certainty around notifiable diseases as active acute Hepatitis B and C are both notifiable as per the Schedule of Notifiable Diseases in the Health Act (1956). Please update documentation accordingly.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Page 7, reimbursement wording seems to be aimed more at patient group than healthy volunteer (i.e. study drug given free) please amend
2. Please clarify vaping or other nicotine product in the participant information sheet for the limits of this study.
3. Please indicate clearly that data is going to the United States rather than just “overseas”

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 suggestions made by the Committee.

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| **5** | **Ethics ref:** | **21/NTB/111** |  |
|  | Title: | RESHAPING Study |  |
|  | Principal Investigator: | Dr Yuxuan Zhou |  |
|  | Sponsor: | Northland District Health Board |  |
|  | Clock Start Date: | 22 April 2021 |  |

Yuxuan Zou 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 Study

1. The primary objective of this study is to evaluate whether use of metallic augments in RSA is an effective and reliable technique to restore glenohumeral joint line anatomy in patients who have glenoid bone loss.

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 how far in advance do patients know that metal implant is likely to be used. The researcher responded that in the public setting, this is 4-6 months prior or several weeks in the private setting. They noted that they will know which potential participants will have had this implant prior to approaching for recruitment and will already have received surgery.
2. The Committee asked for clarification around TRG as this is not mentioned as a site. The researcher clarified that all CT scans will be paid for through TRG rather than the DHB.

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 asked for clarification around the role of Zimmer Biomet for this study as they are not listed as a sponsor but it is noted they are receiving some study data. The researcher clarified that this implant is used almost-exclusively by the District Health Board (DHB) and private surgeons part of the study and is one that most are familiar with. Zimmer Biomet will only receive published data and will receive no participant data. The Committee requested that this clarification that they are not a commercial supplier is documented in the protocol and participant information sheet.
2. The Committee requested a copy of correspondence from a radiologist that indicates the extra CT is safe and an appropriate amount of radiation.
3. The Committee noted that the data management information in the protocol is currently inadequate to meet the standards outlined in Chapter 12 of the National Ethical Standards and to refer to the HDEC template (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>). They stated the following:
   1. Retention of data for 2 years is too short
   2. Information about storage, security and access is required
   3. Excel spreadsheets are inadequate for security of data. The Committee stated the researcher should consult with their locality (DHB) on appropriate measures and software that can be used instead.
   4. It is unclear what data is being shared and in what form, if any. If any is being shared besides published results, please document this in a data management section and in the participant information sheet.
4. The Committee requested that the inclusion and exclusion criteria in the protocol and participant sheet is clear that only the Zimmer Biomet implant is being looked at.
5. The Committee queried if any Māori consultation and engagement had been undertaken. The researcher confirmed a process is underway, and that the HDEC approved protocol will be reviewed in due time. The Committee noted that if any major changes happen as a result of the consultation, the protocol will need to be submitted as an amendment to the Committee.

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

1. Please clarify what is meant by screening and safety tests for the extra CT.
2. Please amend risks of CT scan and quantify it compared to background radiation and not risk of a car accident.
3. Please amend the benefit of getting a CT scan ‘fast-tracked’ as this could result in undue influence.
4. Reimbursement of travel costs should be offered automatically to all participants. Please amend.
5. The Inclusion criteria as outlined in the protocol needs to be stated in the information sheet. Further, please state why the potential participant is being asked to participate.
6. The Committee noted that information and consent options for any other information being accessed from participants should be included (i.e. CT scans taken prior to surgery)
7. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
8. Please identify the sponsor and their address (institution) on the front-page header of the PIS
9. Please amend to state that Northern B has approved the ethical component of this study, not Central.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please supply a data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
* 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 Kate O’Connor and Leesa Russell.

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| **6** | **Ethics ref:** | **21/NTB/112** |  |
|  | Title: | CareSens Air in patients with type 1 diabetes |  |
|  | Principal Investigator: | A/Prof. Ben Wheeler |  |
|  | Sponsor: | i-SENS, Inc. |  |
|  | Clock Start Date: | 22 April 2021 |  |

Ben Wheeler and Alisa Boucsein 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 Study

1. A prospective, monocenter, single arm, open-label study to collect data for algorithm optimization of the Continuous Glucose Monitoring System ‘CareSens Air’ in children, adolescents and adult patients with type I diabetes

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 that the number of blood finger-pricks required seems onerous on the participants and queried if the researchers could reduce the intensity of testing and data collection if required. After discussion, the researcher clarified that a degree of pragmatism would be applied to receive as much data from participants without causing distress. The Committee was satisfied that participants will not undertake the required number of finger-pricks (or venous draws) if there is a burden and their data will still be included.
2. The Committee noted that if a participant turns 16 after consenting, they will need to sign an adult consent form. The researcher stated that as the participation timeframe is short, they intend to delay the consent if this would become a problem in order to avoid it. The Committee was satisfied with this response.
3. The Committee queried if a testing laboratory will receive identifiable participant samples. The researcher responded that all samples will be identified by code and glucose results will be given in printed form rather than going into the system. Any other tests will use a special form that identifies participants by code.
4. The Committee queried the amount covered by the insurance policy. After discussion and the reasoning that main issue for use of this device is skin irritation (but those with allergies are excluded), the Committee was satisfied the amount was proportionate to the risk of the study.

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 if all venous draws are optional for all participants. The researcher stated that as per the protocol, it is optional for children but not for the adult/older children. The Committee requested this is made clearer in the participant information sheet and is consistent with the written protocols. If it is optional, a yes/no tick box should be added to the consent form.
2. Given the above discussion, the Committee recommended a Data and Tissue Management Plan specific to New Zealand should be created as the current protocol does not reflect the New Zealand specific protocols described by the researcher. Please refer to the template on the HDEC website (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>)

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please amend the compensation wording for the HDEC template compensation statement. This can be found on the HDEC website (<https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>)
2. In the youngest assent form, it states there are 3 clinic visits but no mention of 5 finger-pricks while there.
3. Please ensure the option for venous blood-draw is included in the consent form for the appropriate age groups.
4. Please clarify in the main body of the information sheet before it first appears in the consent form that employees of the sponsor company may be present.
5. In addition to the University and District Health Board logo, please identify the sponsor on the front page header and provide their address.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please supply a data and tissue management plan to ensure there are New Zealand-specific protocols documented *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 & 14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by John Hancock and Jane Wylie.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee gave a farewell to Jane Wylie and Tangihaere Macfarlane with this being their last meeting.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 01 June 2021, 12:00 PM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

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.

The meeting closed at 3.20pm