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| **Committee:** | South Health and Disability Ethics Committee |
| **Meeting date:** | 08 August 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10:30am - 11:00am | 2023 FULL 15182 | Testing whether sensors in shoe insoles can help detect and track recovery after concussion | Dr Nusratnaaz Shaikh | Devonie Waaka & Dominic Fitchett |
| 11:00am - 11:30am | 2023 FULL 17880 | Noninvasive ventilation in acute hypercapnic respiratory failure | Dr William Good | Catherine Garvey & Barry Taylor |
| 11:30am – 12:00pm | 2023 FULL 18246 | Laboratory validation of the BJIP | Dr Shivani Fox-Lewis | Helen Walker & Amy Henry |
|  |  | **BREAK 30 MINUTES** |  |  |
| 12:30pm – 1:00pm | 2023 FULL 18325 | A Clinical Trial on Safety and Efficacy of CBT-001 in Patients With Pterygium | Dr John Rawstron | Devonie Waaka & Dominic Fitchett |
| 1:00pm – 1:30pm | 2023 FULL 17975 | MK-0616-015: A Phase 3 Study of MK-0616 in Participants at High Cardiovascular Risk | Dr Rosamund Carey | Catherine Garvey & Barry Taylor |

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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 |
| Ascc. Prof 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 | Apologies |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Carla Strubbia | Non-lay (Intervention Studies) | 03/07/2023 | 02/07/2026 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law)  | 19/03/2019  | 19/03/2022  | Present  |
| Mrs Helen Walker  | Lay (Consumer/Community perspectives)  | 22/12/2020  | 22/12/2024 | Present  |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Associate Professor Nicola Swain (Non-lay (intervention studies)), Ms Dianne Glenn (Lay (consumer/community perspectives)), Ms Neta Tomokino (Lay (consumer/community perspectives)).

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Catherine Garvey, Mrs Helen Walker and Mr Barry Taylor confirmed their eligibility and were co-opted by the Chair as members 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 11 July 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 15182** |
|   | Title:  | Investigating dual-task gait performance using Plantiga insole sensor technology in the management of concussion |
|   | Principal Investigator:  | Dr Nusratnaaz Shaikh |
|   | Sponsor:  | Auckland University |
|   | Clock Start Date:  | 27 July 2023 |

Dr Nusratnaaz Shaikh 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 asked whether, if a concussion was diagnosed, the Researchers would notify the participant’s parents and GP. The Researchers confirmed this to be the case as this is usual practice.
2. The Committee asked if any data will be sent overseas. The Researchers confirmed no data will be sent overseas.
3. The Committee asked about the data produced by the device. The Researchers explained that when the data is inputted, they will use unique identification numbers to identify the device data and, once identified, any identifiers will be removed from the system.

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 the Researcher how competence to provide informed consent would be assessed in participants aged under 16 years. The Researcher explained that they have gone with 12 years to provide more scope of capability and to ensure the children can be fully informed about the study. The Researchers stated they planned to seek advice and consent from the parents. The Committee noted that the nature of the study and the age of the children are such that it is likely that many participating children will be able to provide their own informed consent. The Committee noted that, if a minor can understand the study and providing informed consent, additional parental consent is not required. Please provide information about how capacity to consent will be assessed and outline the process in the protocol.
2. The Committee noted that, where the child participant is not competent to provide independent informed consent, written assent is to be obtained in addition to parental consent. Please provide a simplified information sheet and assent form, suitable for minors lacking capacity to provide informed consent.
3. The Committee asked for clarity in respect of how participants would be assigned to the study groups, and whether participants may be involved in Groups 1 and 2 sequentially. The Committee noted that the protocol currently describes participants completing either Group 1 or Group 2 assessments, but not both. The Researcher explained that all consenting participants would complete Baseline and Group 1 assessments. Participants who suffered a head injury would also complete Group 2 assessments. Please amend the protocol to clearly describe Group assignment during the study.
4. The Committee requested that the research team notifies the participant's GP directly of findings of potential clinical significance; this should not be the responsibility of the participant.
5. The Committee noted that some health data must be retained for at least 10 years after the participant turns 16. Please amend Section 7 of the Data Management Plan (DMP) and the participant information sheet/consent forms (PIS/CFs) accordingly.
6. The Committee noted that the data management plan currently states that data collected prior to withdrawal will continue to be used and analysed (paragraph 10), as does the consent form, however this is contrary to page 2 of the participant information sheet. Please resolve the conflict and amend as necessary.
7. The Committee asked about locality authorisation of the various sites to be used during the study. The Researchers explained that they are in the process of creating a relationship with Auckland Rugby League and this would be the starting point, and that a hui is planned with school managers in South Auckland. Please ensure formal permission is obtained to access study sites, whether schools or sports clubs.
8. The Committee noted that a clubroom is not a particularly private area to conduct an interview and reminded the Researchers to ensure the privacy of participants is respected. Please ensure each location has a suitable private space for study assessments.

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

1. Please make Group allocation during the study clearer to reflect that participants may be involved in Group 1 and Group 2.
2. Please state that, for younger participants, parents will be informed of any head injury as is standard care.
3. Please amend the participant information sheet regarding retention of health information and use of data collected prior to withdrawal from study.
4. Please include HDEC advocacy and Māori cultural support contact details.
5. Other than the CF and additional Assent Form for Adolescent, this PIS is identical to the Adult PIS. Please rephrase throughout to reflect the fact that the parent is consenting to their child participating in the study.

**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 Dominic Fitchett and Dr Devonie Waaka.

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| **2**   | **Ethics ref:**   | **2023 FULL 17880** |
|   | Title:  | Evaluate the impact of noninvasive ventilation (NIV) with expiratory washout on respiratory rate of patients with acute hypercapnicrespiratory failure. A prospective, randomized cross over pilot investigation |
|   | Principal Investigator:  | Dr William Good |
|   | Sponsor:  | Fisher and Paykel Healthcare. |
|   | Clock Start Date:  | 27 July 2023 |

Dr Joanne Lorimer 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 asked who is doing the recruitment on the respiratory ward. The Researcher explained that he will not be involved in clinical ward work during the study period but will be available to consent as they will be recruiting during their research period. There will also be clinical nurse specialists who will be involved in the consent process.
2. The Committee asked about the exclusion of pregnant women and asked for justification. The Researcher explained that historically maintaining safety of all participants is key and they wish to maintain the best possible care for vulnerable participants. Also, the Researcher noted that pregnancy is not common for this group of potential participants. The Committee was happy with the exclusion of pregnant woman from participation because this is not a therapeutic trial and it is the first time this particular mask is being used in this indication.
3. The Committee asked if participants could continue to use the study mask if they wish to after the 2-hour study period. The Researcher explained that participants are free to use the mask after the study period and there will be no extra data collection and monitoring, with the study ending at the 2-hour mark.

**Summary of outstanding ethical issues**

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

1. Please note that the rationale provided for not returning results in Section 11 of the data management plan is incorrect. Please amend to state that the data generated is exploratory and of no clinical utility, as per the application form.
2. Please amend Section 11.1 of the data management plan to state that no clinically significant abnormal findings will be generated in the study, as per the application form.
3. Please remove “Note to researchers” on page 3 of the data management plan.

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

1. On pages 2 and 4 please delete repeated information regarding what personal and health data is collected.
2. On page 3 please state that there may be no benefits to study participation.
3. On page 4, please use the full HDEC-approved commercial compensation statement, noting that reference to "the Industry Guidelines" is not applicable to device trials and should be deleted.
4. Please clarify that if a participant chooses to continue using the investigational mask, no data will be collected after the 2-hour trial period of use, other than the fact that they chose that mask.

**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).*

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| **3**   | **Ethics ref:**   | **2023 FULL 18246** |
|   | Title:  | Evaluating the utility of the BioFire PCR panel in the diagnosis of joint infection |
|   | Principal Investigator:  | Dr Shivani Fox-Lewis |
|   | Sponsor:  | Te Whatu Ora Te Toka Tumai Auckland |
|   | Clock Start Date:  | 27 July 2023 |

Dr Shivani Fox-Lewis 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. A waiver of consent is sought for use of data and tissue. The Committee noted that a well-considered justification has been provided, based on the Tissue Act exemption for quality assurance use and the research use being for the same purpose that the tissue was collected (diagnosis of infection). The Committee noted that existing access to clinical records for standard care should not be used to justify a waiver of consent.
2. The Committee asked if there are plans to undergo formal Māori consultation. The Researcher explained that it is in progress and will be completed before study commencement.
3. The Committee asked for some clarity surrounding the samples and the laboratory numbers associated with the samples. The Researcher explained that samples will be provided to the Researchers labelled with laboratory number only. The sample will then be put into another tube with a study identification number for study purposes. The Researcher further explained there will be password protected spreadsheets that will link the laboratory tube and the study identification number. The Researcher confirmed that data will be provided to the research team in de-identified form.

**Summary of outstanding ethical issues**

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

1. Please collect ethnicity data per National Ethicsl Standard 9.20.
2. Please clarify in the data and tissue management plan who will access identifiable data and the point at which data will be de-identified.
3. Please review the data and tissue management plan and remove template statements and brackets, update the contents page of the data and tissue management plan (multiple instances of “Error! Bookmark not defined.”) and remove the ‘Note to researchers’ on page 3.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee.

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| **4**   | **Ethics ref:**   | **2023 FULL 18325** |
|   | Title:  | A Multicenter, Double-Masked, Randomized, Vehicle-Controlled 12-Month (with a 12-month, Double-Masked Extension) ParallelComparison of the Safety and Efficacy of 0.1% and 0.2% CBT-001 versus Vehicle, Dosed Twice-Daily, in Patients with Pterygium |
|   | Principal Investigator:  | Dr John Rawstron |
|   | Sponsor:  | Cloudbreak Therapeutics, LLC / IQVIA RDS Pty Limited |
|   | Clock Start Date:  | 27 July 2023 |

Dr Adam Watson 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 asked if there will be enrolment of minors in the study. The Researcher confirmed that no minors will be enrolled for this study in New Zealand. The Committee noted that any approval given here is provided on the basis that no minors will be enrolled and that all participants can provide their own independent, informed consent. Furthermore, the assent form will not be approved at this point and, if minors wish to be enrolled in the future, the Researchers will need to come back to HDEC for further approval.
2. The Committee queried the response to B1 of the application form, which states that the trial is non-therapeutic. The researcher confirmed that the response to B1 was incorrect, and that the study is a therapeutic trial.
3. The Committee asked about the source documents the Researchers have provided, and whether they are on-site workbooks or are case report forms that are sent to the sponsor. The Researchers explained that they may use them as source documents at the site but cannot confirm whether all data captured in the forms will be sent to the sponsor. The Committee reminded the Researchers that initials and full date of birth are identifiers and should not be included with any data provided to the Sponsor.
4. The Committee asked for clarification surrounding the potential stand down period after having the treatment, should participants choose to have surgical removal. The Researchers explained there would not be a stand down period as such, but there might be a small delay involved. The Committee requested the Researchers let participants know of any potential delays so surgical treatment can be planned accordingly.

**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 if the study blind would be broken as a result of a participant knowing on-study assessment results (i.e. safety and screening results). The Researchers responded that they do not believe so, as these are clinical assessments. For those assessments that would not result in the study blind being broken, please ensure participants are able to obtain copies of clinical assessments on request.
2. Please ensure ethnicity data relevant to New Zealand is collected at a site level, in addition to protocol-specified CRF fields (C16).
3. The Committee noted that the potential uses of tissue are unclear. The application indicates tissue will be collected for safety monitoring only. The participant information sheet and consent form states that ‘some blood and urine samples may be sent on to another Central Laboratory in Singapore for further analyses, without describing what that analysis may involve, and Section 5 of the data management and tissue plan states that ‘where available and if consented to, additional blood samples from the participant, which were taken for optional genetic testing, will be de-identified and provided to a central laboratory’. Please clarify what is intended and amend the documentation accordingly.
4. The Committee noted that information provided regarding tissue retention is inconsistent. The participant information sheet and consent forms state tissue will be destroyed at the end of the study, while Section 10 of the data management and tissue plan states samples may be retained for 15 years. Please clarify what is intended and amend the documentation accordingly.
5. The Committee noted that notifiable diseases are not being tested for in the current study. Please delete the final bullet point of Section 8.2 of the data management and tissue plan.
6. The Committee noted that Sponsor authorisation of the submitted ERM form is required for HDEC approval. Please ensure this is completed prior to submitting the response to provisional approval.
7. The Committee noted that a practising certificate has been uploaded at E13. Please submit evidence of professional indemnity (MPS Certificate of Membership or similar).

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

PIS/CF Main and Parental:

1. On page 1 please use the lay title as the main title of the PIS/CF.
2. On page 1 please state that this is the first study of the emulsion formulation in humans.
3. On page 1 please change the wording ‘if your child is a woman of childbearing potential’ by replacing the word ‘woman’ with ‘female’.
4. On page 2 please amend the age range of eligible participants, which is 18 years plus in New Zealand but 12 years plus in other jurisdictions.
5. On page 2 please amend the typo on third line of paragraph 2.
6. Please delete teaspoon measurements for blood volumes.
7. Please replace 'subjects' with 'participants' throughout.
8. On pages 5 and 7 the information provided regarding contraception requirements is inconsistent; please state once only.
9. On page 5 participants should not be expected to pay for medications or health care visits to address side effects or symptoms potentially related to the study. Please ensure prompt reimbursement of any such costs and amend the PISCF accordingly.
10. On page 5 please amend the second paragraph to read “…from signing this form until 30 days after…”, as per the following paragraph.
11. On page 7 please delete repetitive information regarding unknown side effects and risks.
12. On pages 5 and 7 the information provided regarding ongoing access to CBT-001 is inconsistent. Please state once only.
13. On page 8 please delete the bullet point regarding local laboratory and radiology access to identifiable data.
14. On page 11 please delete the statement regarding race and ethnicity; this is not considered sensitive information in New Zealand.
15. On page 12 and 13 please delete repeated information regarding access to identifiable health information for audit purposes, access to personal information, and ownership rights.
16. On page 12 please delete the paragraph regarding stigmatisation; it is not applicable to the current study.
17. Please provide clarification about the use of tissue samples and what testing may be done with these tissue samples.

Pregnancy Follow Up PIS/CF:

1. Please submit pregnancy follow-up documents for approval only in the event of a participant or partner pregnancy.

**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 data and tissue management documentation, 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).

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

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| **5**   | **Ethics ref:**   | **2023 FULL 17975** |
|   | Title:  | MK-0616-015: A Phase 3 Randomized, Placebo-Controlled Clinical Study to Evaluate the Efficacy and Safety of MK-0616 in ReducingMajor Adverse Cardiovascular Events in Participants at High Cardiovascular Risk. |
|   | Principal Investigator:  | Dr Rosamund Carey |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Limited (MSD)  |
|   | Clock Start Date:  | 27 July 2023 |

Dr Rusamund Carey, Kim Huljich, Charlene Botha, and Deanna Watson 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 asked for an ethical justification for not providing ongoing access to the study drug on completion of the trial. The Researcher explained that this decision is ultimately up to the sponsor company to make and that the Sponsor would need to provide the ethical reasoning behind the decision. The Committee requested the Researcher ask the Sponsor for further clarification and inform the Committee with an approval non-standard conditions submission once this was received. The Committee referred the Researcher to National Ethical Standards 10.15 - 10.17, regarding access to the intervention after 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. Please ensure registration with clinicaltrials.gov is completed prior to commencing the study in New Zealand.
2. Please note advertisements need to be submitted prior to use.

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

1. Please review the main PIS/CF for repetition.
2. Please amend Section 9 to exclude references to genes and DNA from paragraph one; it appears that the mandatory biomarker testing includes genetic testing.
3. On page 14 please remove vendors and laboratories from the list of those requiring access to identifiable information for audit purposes.
4. On page 15 please state that participants will be informed of any privacy breaches.

**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).*

## General business

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

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| **Meeting date:** | 12 September 2023 |
| **Zoom details:** | Via Zoom: <https://mohnz.zoom.us/j/96507589841> |

 The following members tendered apologies for this meeting.

* Ms Amy Henry
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 1:30pm.